MISSISSIPPI STATE DEPARTMENT OF HEALTH

March 23, 2022

Hart Wood
1030 15th Street NW
Suite B255
Washington, DC 20005
records@americanoversight.org

Re: Public Records Request

Ms. Wood:

With this letter you will find emails and attachments produced by the Mississippi State Department of Health (MSDH) in response to your public records request originally submitted on January 4, 2022. Public records requests at MSDH are governed by Mississippi's Public Records Act (Miss. Code. Ann. § 25-61-1, et seq.) as well as any laws providing exemptions to this Act.

A chart of redactions made in the produced emails and/or their attachments is provided. Note that over 120 emails from the National Biosurveillance Integration Center (NBIC) were completely redacted in alignment with the direction of the U.S. Department of Homeland Security which oversees the NBIC.

Should you have any questions, please reach out to the following agency staff member who helped conduct the review of your documents:

David Trewolla, JD
Director, Data Governance
David.Trewolla@msdh.ms.gov

Sincerely,

DocuSigned by:
Walter, Cassandra 3/23/2022 | 3:05 PM CDT
1D6CE85904314A6...
Cassandra Walter, Esq.
General Counsel
Mississippi State Department of Health

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Envelope Originator:
Trewolla, David
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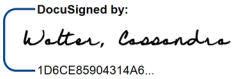
Walter, Cassandra cassandra.walter@msdh.ms.gov Special Assistant Attorney General Mississippi State Department of Health Security Level: Email, Account Authentication (None)	DocuSigned by:  1D6CE85904314A6... Signature Adoption: Pre-selected Style Using IP Address: 75.65.213.119 Signed using mobile	Sent: 3/23/2022 3:01:48 PM Viewed: 3/23/2022 3:05:34 PM Signed: 3/23/2022 3:05:42 PM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/23/2022 3:01:48 PM
Certified Delivered	Security Checked	3/23/2022 3:05:34 PM
Signing Complete	Security Checked	3/23/2022 3:05:42 PM
Completed	Security Checked	3/23/2022 3:05:42 PM

Payment Events	Status	Timestamps

PUBLIC HEALTH AUTHORITY TO PREVENT AND CONTROL THE SPREAD OF COMMUNICABLE AND INFECTIOUS DISEASE

POSITION

The Association of State and Territorial Health Officials (ASTHO) supports the establishment of robust public health legal authorities to facilitate the timely and adequate response to communicable and infectious disease outbreaks. These legal authorities are often exercised without the need of an emergency declaration and may allow, among other things, the abatement of nuisances, investigation of the causes of disease, institution of quarantine measures, ordering individuals or groups to isolate, conducting contact tracing and case investigations, collecting data, temporarily limiting or canceling public events, temporarily restricting or closing venues, and requiring vaccination verification for certain conduct and activities (e.g., school attendance). Beyond their use in the response to the historic pandemic caused by the novel coronavirus, in the past, these powers have been routinely exercised for more commonly experienced disease outbreaks, such as mumps and measles. Additionally, other societal sectors, such as business, education, cultural, and religion often depend on public health to stop the spread of infectious disease, prevent widespread disruptions, and quell public anxiety and fear. Maintaining these state and territorial legal authorities are key to being prepared for communicable and infectious disease outbreaks both now and in the future.

Summary of Recommendations:

- Public health legal authority that facilitates a skillful response to disease outbreaks without undue delay.
- Public health authorities that are guided by data and science.
- Ensure that public health authority balances individual rights with the responsibility to protect the public's well-being.
- Support public health authority that is reasonable and aligned with disease prevention and control activities.
- Public health legal authority that is able and sufficient to respond to future disease

BACKGROUND

Establishing and using legal authority to control the spread of infectious disease dates to before the founding of the country. For example, colonial governments implemented isolation and quarantine precautions for incoming ships to prevent the introduction and spread of smallpox and other contagions.[1] These powers and activities were seen not only as a way of protecting the health of the local communities but also protective of trade and commerce.[2] As the scientific understanding of communicable and infectious disease grew, new tools such as contact tracing, disease investigation, data collection, and vaccines were added to public health's legal authority and practice. During the current pandemic public health authority has been used, with evidenced benefit, to slow the spread of the coronavirus by limiting the size of gatherings, encouraging social distancing, temporarily closing high-risk venues, and requiring the use of face coverings in certain places.[3,4,5,6,7,8,9]

Despite the successes in exercising public health authority, grave questions and negative perceptions about the role and use of public health powers in response to the pandemic and, by implication, future infectious disease outbreaks have arisen. Over the last year, the critical attitude toward the pandemic response has led to the rolling back of public health authority in several jurisdictions.[10] The reductions in public health legal authority will conceivably make it more difficult to respond to future disease outbreaks. As state and territorial policy makers

continue to address the many issues related to the current pandemic, they are encouraged to consider these potential impacts and costs.

RECOMMENDATIONS

With regards to state and territorial public health authority to prevent and control the spread of communicable and infectious disease, ASTHO recommends:

- Maintaining public health's ability to implement non-medical and medical interventions (e.g., social distancing and distribution of vaccines) swiftly and adeptly by resisting the establishment of administrative burdens that delay public health action, endangers the public and leaves our community vulnerable to infectious disease outbreaks.
- Support evidence-based laws and policies related to the identification, prevention, and control of communicable and infectious diseases.
- Ensure that public health legal authority properly and adequately balances the rights of individuals with the responsibility and obligation to protect the public's health and well-being. Law and policy that undermines and encumbers public health decision making or arbitrarily limits the scope of public health authority, can impede the ability to prevent and control the spread of disease.
- Maintain public health legal authority that is reasonable and aligned with the preventing and controlling the spread of infectious disease. For example, individuals subject to isolation or quarantine should be guaranteed the right to due process, allowed to petition a court to review the government's action, and ensured of reducing any economic, social, or emotional harm. Additionally, public health authority should be able to align with disease it is confronted and allowed to be exercised in a way to address the identifiable characteristics of the disease.
- Ensure public health legal authorities that are appropriate and necessary for the prevention and control of future communicable and infectious disease outbreaks. Other airborne, highly contagious illnesses, like measles, can be effectively contained by implementing public health measures similar to those that have been questioned during the pandemic. Furthermore, the next major public health threat may spread in other ways meaning public health authority must be able to respond to novel, unknown diseases.

APPROVAL DATES

Prevention Policy Committee Approval:
Board of Directors Approval:
Policy Expires:

ASTHO membership supported the development of this policy, which was subsequently approved by the ASTHO Board of Directors. Be advised that the statements are approved as a general framework on the issue at a point in time. Any given state or territorial health official must interpret the issue within the current context of his/her jurisdiction and therefore may not adhere to all aspects of this Policy Statement.

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[1] Parmet WE. "Health Care and the Constitution: Public Health and the Role of the State in the Framing Era." *Hastings Const. L.Q.* 1993. 20(2):267-335. Available at https://repository.uchastings.edu/hastings_constitutional_law_quaterly/vol20/iss2/1. Accessed 10-12-2021.

[2] Id.

[3] Castillo R, Staguhn E, Weston-Farber E. "The effect of state-level stay-at-home orders on COVID-19 infection rates." *Am. Journal of Infection Control*. 2020. 48(8):958-960. Available at https://doi.org/10.1016/j.ajic.2020.05.017. Accessed 9-28-2021.

[4] Moreland A, Herlihy C, Tynan MA, et al. “Timing of State and Territorial COVID-19 Stay-at-Home Orders and Changes in Population Movement — United States, March 1–May 31, 2020.” *Morb Mortal Wkly Rep.* 2020. 69:1198–1203. Available at http://dx.doi.org/10.15585/mmwr.mm6935a2. Accessed 9-28-2021.

[5] Lyu W, Wehby G. “Comparison of Estimated Rates of Coronavirus Disease 2019 (COVID-19) in Border Counties in Iowa Without Stay-at-Home Order and Border Counties in Illinois with a Stay-at-Home Order.” *JAMA Netw. Open.* 2020. 3(5):1-7. Available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766229?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=051820. Accessed 9-28-2021.

[6] Cheng V, Wong S, Chaung, V, et al. “The role of community-wide wearing of face masks for control of coronavirus disease 2019 (COVID-19) epidemic due to SARS-CoV-2.” *J. of Infection*. 2020. 81(1):107-114. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7177146/. Accessed 10-25-2021.

[7] Guy GP Jr., Lee FC, Sunshine G, et al. “Association of State-Issued Mask Mandates and Allowing On-Premises Restaurant Dining with County-Level COVID-19 Case and Death Growth Rates — United States, March 1–December 31, 2020.” *Morb Mortal Wkly Rep*. 2021. 70:350–354. Available at http://dx.doi.org/10.15585/mmwr.mm7010e3. Accessed 9-28-2021.

[8] Howard J, Huang A, Li Z, et al. “An evidence review of face masks against COVID-19." *Proc. Natl. Acad. Sci.* 2021. 118 (4):1-12. Available at: https://doi.org/10.1073/pnas.2014564118. Accessed 9-28-2021.

[9] Dasgupta S, Kassem AM, Sunshine G, et al. “Differences in rapid increases in county-level COVID-19 incidence by implementation of statewide closures and mask mandates — United States, June 1–September 30, 2020.” *Ann Epidemiol*. 2021. 57:46-53. Available at https://doi.org/10.1016/j.annepidem.2021.02.006. Accessed 9-28-2021.

[10] Weber L, Barry-Jester AM. “Over Half of States Have Rolled Back Public Health Powers in Pandemic.” *Kaiser Health News*. Sept. 15, 2021. Available at https://khn.org/news/article/over-half-of-states-have-rolled-back-public-health-powers-in-pandemic/. Accessed 11-1-2021.

astho™

From:	state_ph_counsel - Public Health Law Program on behalf of Ferrell, Abigail (CDC/DDPHSIS/CSTLTS/OD)
To:	STATE_PH_COUNSEL@LISTSERV.CDC.GOV
Subject:	Resources from today"s call
Date:	Thursday, July 22, 2021 2:37:59 PM
Attachments:	Klaassen v. Indiana University - Opinion and Order.pdf ASTHO Vaccine Messaging Kit.pdf

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Public Health Emergency Law Training: If you are interested in having PHLP deliver public health emergency law (PHEL) training to your jurisdiction, please email Greg Sunshine at GSunshine@cdc.gov. PHEL training is free and in-person.

Contact for CSTE Legal:
Sunbal Virk svirk@cste.org
CSTE legal mailbox: publichealthlaw@cste.org

Request for IIS law Examples:
Please send the citation to Patricia.Segal.freeman@state.mn.us

Opioid Settlement Information:
State Opioid Settlement Allocation Plans

https://nationalopioidsettlement.com/

Book recommendations:
Deaths of Despair

If you would like to unsubscribe from this ListServ LIST, please send an email to LIST@cdc.gov, enter CDC in the email Subject, and include the following "one" line in the Body of the email: signoff STATE_PH_COUNSEL

Economic Messaging for Policy Discussions with Vaccine Hesitant Legislators

July 2021

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Introduction

The COVID-19 pandemic continues to highlight the necessity of vaccination and the impact vaccine-preventable illnesses can have on communities. But this public health conversation and dilemma over vaccine hesitancy has been ongoing for several decades. Particularly in state legislatures, where vaccine-hesitant lawmakers can cast votes against critical vaccine policies that keep schools, families, and businesses safe.

This messaging kit takes a unique approach to the vaccine-hesitant conversation by focusing on the role of vaccines in protecting personal freedoms and economic well-being. The following guidance was developed following a series of discussions with several states to understand the biggest hurdles facing passage of vaccine legislation.

This kit includes three sections:

Messaging

This section includes a series of talking points to illustrate the role of vaccines in protecting and preserving individual freedoms and economic development. These arguments should be tailored to state-specific data, scenarios, and facts to make them applicable to your legislative audience and policy priorities.

How to Use the Messaging

The guidance in this section demonstrates how to use storytelling tactics to deploy your selected talking points, arguments, and examples. The section is divided into two scenarios: proactively telling your story when meeting with legislators and responding to a lawmaker's request or hearing on short notice.

Example Documents and Tools

This section shows the messaging and sample stories at work, in handouts, infographics, meeting notes, and more. These are intended to serve as examples that can be used to inform the design of your own state-specific messaging and tools.

Audience

The audience for this messaging is any vaccine-hesitant lawmaker holding conservative economic values with an interest in the protection of personal freedoms and liberties.

Messaging Summary

Vaccines Protect People and Businesses

- Vaccines protect individual freedoms.
- Vaccines protect businesses by reducing the spread of viruses and the need for restrictions on public activities.
- Vaccines help ensure your ability to access health care.

Families Pay the Price When Communities Don't Vaccinate

- Working families suffer when vaccine-preventable illnesses close businesses.

Vaccines Protect the Economy, Save Tax Dollars

- Vaccines save taxpayer dollars.
- When people refuse or don't have vaccines, society bears the cost.
- Vaccine-preventable outbreaks of any size can threaten the well-being of rural hospitals.

Messaging and Supporting Facts

Vaccines Protect People and Businesses

Vaccines protect individual freedoms.

Vaccines help protect your freedom to work, attend religious services, send your children to school, and travel as you see fit. An outbreak can lead to local or regional restrictions on these basic freedoms. Without vaccines, freedoms are threatened.

- **Over 110,000 restaurants** closed permanently in 2020 due to COVID-19 restrictions.[1]
- In just five months, over **160,000 businesses** closed their doors, leaving behind thousands of unemployed workers and storefront vacancies within small communities.[2]
- Schools were forced to close or severely limit classroom and extra-curricular activities during the pandemic. In April 2020, over **25 million public school students** were enrolled in schools ordered or recommended to close for in-person education[3] , putting stress on parents who still had to go to work but could not afford to pay for childcare, with those **costs increasing 47%** during the pandemic.[4]
- In response to rising COVID-19 cases, many states implemented curfews and orders to restrict activities, gatherings, and outings deemed "non-essential." [5]
- Several states enforced mandatory quarantines for travelers, required health documentation, or proof of a negative COVID-19 test. If non-compliant, fines were imposed on individuals.[6]

Vaccines protect businesses by reducing the spread of viruses and the need for restrictions on public activities.

Vaccines give employers of all sizes the ability to operate knowing their workers and patrons are protected, thus avoiding harm to the economy.

- Small businesses cannot sustain prolonged outbreaks. Vaccinations limit the impact of infections and provide confidence for merchants and their customers. During COVID-19, only 55% of small businesses projected being able to survive an extended public health crisis.[7]
- Vaccines allow workers to remain on the job. In response to the COVID-19 pandemic, 22% of small businesses considered requiring employees to be vaccinated, for the health of their businesses, workers, and customers.[7]

Vaccines help ensure your ability to access health care.

If an outbreak occurs in a community, medical facilities can become overwhelmed, limiting access to care important to you and your family.

- During the peak of the pandemic, the federal government urged hospitals and other treatment facilities to consider restricting non-emergency surgeries and procedures. [8]
- Delayed procedures likely will lead to higher health care costs for families to bear in the near future. Mortality rates may increase because of delays in important screenings, like those for breast or colorectal cancer. [9]
- Influenza can create an immense strain on health care systems, with **400,000 hospitalizations** in the 2019-2020 flu season. [10] Increased rates of flu vaccinations, coupled with other mitigation measures, resulted in just over **1,500 cases** in the first 40 weeks, reducing the burden of flu cases on communities and hospitals. [11] That's compared to about **38 million** reported symptomatic flu cases documented in the 2019-2020 flu season.

Families Pay the Price When Communities Don't Vaccinate

Working families suffer when vaccine-preventable illnesses close businesses.

If a family member becomes unemployed due to outbreak-related shutdowns, it can bankrupt a household. Families cannot afford to go unvaccinated.

- Vaccines provide job security to working families. In just the first two months of the pandemic, over **22 million** jobs were lost due to shutdowns and restrictions. [12]
- Job losses related to vaccine-preventable illnesses result in the loss of employer-provided health insurance coverage. During the pandemic, almost **15 million workers** and their dependents lost their insurance. [13] COVID-19 hospitalizations can cost between **$17,094 to $45,683**. [14]
- Treatments and hospitalizations for measles can cost a family as much as **$14,000**. [15] This cost includes lab tests and prescription drugs.

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Vaccines Protect the Economy, Save Tax Dollars

Vaccines save taxpayer dollars.

Twenty years of routine childhood immunizations have produced a net savings to taxpayers of nearly $300 billion. [16]

- The 2-Dose-Measles-Mumps-Rubella Vaccination Program alone has saved taxpayers **$3.5 billion.** [17]

When people refuse or don't have vaccines, society bears the cost.

In the first year of the pandemic, with no vaccine yet available, COVID-19 cost American taxpayers $5.9 trillion in federal relief spending [18] [19]**, in addition to $16 trillion lost due to business shutdowns, loss of productivity, declines in consumer spending, and loss of life impacts on families.** [20]

- Even before the pandemic, billions of dollars were lost each year due to vaccine-preventable infections among adults. [21]
- In 2015, unvaccinated adults cost the nation $7 billion in lost productivity, doctor visit expenses, and hospitalizations. [21]

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Vaccine-preventable outbreaks of any size can threaten the well-being of rural hospitals.

Americans depend on the success of their local hospitals. Outbreaks can test hospital finances and force them to limit services, cut staff, or even close.

- Vaccines allow rural hospitals to provide outpatient services, which are a vital source of income for rural hospitals. When these services were restricted due to the pandemic, rural hospitals lost millions of dollars, with 46% now operating in the red. [22]
- Closures of rural hospitals limit a family's health care choices. When a facility closes, an individual must travel thirty minutes or more to receive care at an alternative clinic. [22]
- Rural hospitals are integral to local economies. If one shuts down, unemployment rates can rise 1.6%, and may deter further economic development due to inaccessible health care options for prospective businesses and their employees. [23]
- In the first four months of the pandemic, U.S. hospital providers estimated a loss of $202.6 billion due to increased hospitalizations, canceled surgeries and services, the cost of personal protective equipment (PPE), and front-line worker support in the form of childcare, transportation, and screenings. [24]

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How to Use the Messaging

Why storytelling?

Stories allow you to capture the emotion needed to sway legislative support in favor of your policy proposals. **Vaccination opponents, activists and legislators alike, have successfully leveraged emotional pleas at legislative hearings, in the news media, and on social media channels to dominate the debate and win votes for short-sighted policies.** You must be able to share stories of your own to counter these narratives and promote your public health goals. Pair the messaging points created to address this select group of lawmakers with powerful stories to create a response that addresses the emotional aspects of the argument and delivers your position with impact.

Playing Offense: Telling a Story

Prepare Your Story

Adjust your messaging approach to illustrate your points through effective storytelling. Make everything you say personal.

Know Your Audience

Understand the lawmaker's background and position on vaccines.

Research any previous statements that may have been made in the news or as part of the legislative debate regarding vaccines.

Research voting histories on vaccines or other healthcare-related issues.

Use this information when identifying or choosing the best stories to highlight during your engagements on the vaccine issue.

Know Your Stories

Identify local stories to incorporate into your individual freedoms messaging.

Ask local contacts for help to identify those impacted by local vaccine-preventable outbreaks from local contacts.

Gather stories from people and businesses that align with messaging points, emphasizing those who've suffered personal and financial setbacks.

Match state-specific economic data to your gathered stories and incorporate them into your messaging points.

Customize Your Story

Don't expect a legislator to take your word for it.

Invite the people in your stories to attend your meetings. If they can join you, let them deliver the talking points.

If they cannot attend in person, consider asking your storytellers to make a short video or voice memo recording on their mobile device that you could share in your meeting.

If you want to make a series of points, ask each storyteller to focus on one of the points, that way, when the comments are presented together, each builds on, rather than repeats, the narrative.

Include the details. Explain the specifics of the illness. Talk about the impact of the illness on the family. What are the prospects for the family's recovery? **Where possible, have your storytellers ask lawmakers, in person or on video, to support vaccines.** The specifics of this call to action will depend on the details of the issue or issues in your state or territory.

Deliver Your Story

Once you've gathered your stories/storytellers, here's how to use deploy this messaging in a meeting.

Meetings With Legislators

Tell the story. Allow local examples of economic frustration and harm to demonstrate the impact vaccine hesitancy has on individual freedoms.

Support your messaging with hand-outs featuring quotes and photos of the people and places mentioned in your story.

Provide backup materials, like written statements, previous guest columns, or media statements from the people in your stories. These give your messengers credibility.

Lead your responses to questions with stories, supporting them with relevant facts that point back to your stories whenever possible.

Playing Defense: Responding on Short Notice

Prepare Your Story

The following strategies can help you assemble messaging points when preparation time is limited.

Assess the Messaging Environment

Using the preparation work done for meetings with lawmakers, prioritize the most appropriate stories for your target audience.

Predict the focus of opposing legislators and identify what stories and messaging points would be most convincing given their views on vaccines.

Review lawmakers' previous statements and past witnesses they have recruited, aligning your stories and messages to arguments that likely will be raised during the hearing, meeting, or event.

Assess Your Storytellers

Choose stories and storytellers that best illustrate the message points you believe will counter legislative opponents' arguments.

When the event is scheduled on short notice, ask if you can suggest witnesses. If allowed, offer people who've been damaged personally and economically by a vaccine-preventable outbreak, have experience speaking in public, are familiar to you, and can appear on short notice.

If a witness is unable to attend in person, ask if they could write a short statement or record a statement on a mobile device that could be used as the basis for a written or multimedia submission.

Whether your supporters testify or not, they can provide support through public comment opportunities. These invitations to submit comments, in writing or in person, are useful when responding to legislation or other policy actions. Engage all supporters, individuals and organizations, to respond to these opportunities, being mindful of deadlines associated with comment submissions.

Deliver Your Story

Consider the following strategies for using your messaging during last-minute hearings or meetings.

Prepare Your Testimony

If your messengers cannot attend the hearing or are not invited, find ways to incorporate their personal narratives into your talking points.

Focus your opening statement on as many personal stories as possible to show a direct connection to constituents.

Pair each message point to a story to create a narrative that underscores individual freedom impacts.

Telling Stories During a Hearing

Deliver your story. Use the videos or voice memos from your storytellers if allowed.

When answering questions, begin each response with a person or community hit hard by a vaccine-preventable outbreak, matching opponents' emotional arguments with the emotional impact of the existing or proposed policy.

Submit handouts and videos illustrating your testimony to the committee for inclusion in the record.

"Don't take it from me." Make the offer to connect legislators with the people referenced in your testimony.

Responding to Last-Minute Requests for Information or Meetings from Legislators

When responding to legislator requests for information, pair these documents with any handouts you've created to support your narrative.

Direct all members of your team to continue to use the same storytelling approach to ensure a coordinated and convincing voice on the issue, no matter who is responding to requests.

How to Find Stories/Witnesses

The Best Stories to Tell

Examples: A business owner that saw decreased foot traffic in a store; a family that needed to take off work to care for a sick child; an individual or family that faced high medical bills due to a vaccine-preventable illness.

Using the Media to Find Stories

Comb through media coverage of outbreaks to find quotes or other coverage about families and individuals that have been impacted.

Who Knows People with Stories to Tell?

Contact social service organizations to find people who've been impacted by a vaccine-preventable illness and are willing to share their stories. Start with pro-vaccine organizations for healthcare-related stories. Ask other agencies for help reaching individuals who've been impacted but may be interested in helping prevent future calamities for others.

Work with local public health departments where an outbreak may have taken place. Ask if there are families that would share their experiences regarding the outbreak's impact on their finances and individual freedoms.

How to Prepare and Protect Witnesses

Protecting Contact Information

Do not provide witness contact information to a legislator. Instead, facilitate meetings between legislators and your contacts. Remind witnesses to be careful about sharing contact information with journalists or others who might ask for it.

Explain the Hearing Process

If your witnesses have not previously spoken at a hearing, explain the process and provide them with a list of questions that panelists might ask them to answer. Do what you can to help witnesses feel prepared and confident.

Anticipate Social Media Feedback

Due to the overwhelming tactics of anti-vaccine supporters, prepare your witnesses for the reaction their comments will provoke, particularly on social media. Consider suggesting that they double-check their privacy settings on social media accounts. This will protect them against unwanted messages or comments. ***See the Appendix for instructions on this topic that you can share with your supporters.***

Understand Individual Comfort Level

Identify and respect the comfort level of witnesses. Some may not want to appear in person and would prefer to only submit written testimony. If they ask for help with their remarks, you can suggest areas they may want to address, but be careful not to prompt their statements in any way. The authenticity of their comments is critical to ensuring their voice makes an impact on the debate.

MS-DOH-21-1816-A-000021

Example Documents and Tools

The following documents are examples of tools, resources, and hand-outs that integrate the individual and economic freedom arguments and talking points with local stories, scenarios, and statistics. These documents use fictional data and stories to show examples of storytelling in action to teach you how to apply this approach within your particular setting.

- Graphic Presentation 1: Matching Local Stories to Emphasize Freedom and Economic Talking Points
- Graphic Presentation 2: Matching Talking Points to State-Specific Data
- Meeting Script on a 3x5 Card
- Sample Infographic Handout for Legislators
- Sample Q&A
- Sample Statements
- Examples of Emotion in Anti-Vaccine Stories

MS-DOH-21-1816-A-000022

Graphic Presentation 1: Matching Local Stories to Emphasize Freedom and Economic Talking Points

Identify families and individuals with personal stories that showcase the talking points on a local level, and pair those points with each story.

Note: All stories, names, and scenarios are fictional. Any resemblance to real individuals is coincidental.

Matthew Perez, 48

- Restaurant owner in a college town.
- Responsible for 10 employees.
- Capacity limits reduced ability to serve customers and led to people only wanting to be seated outside, if at all.
- A small town lost a 60-year old gathering place. 10 individuals lost their jobs. Two lost health insurance for themselves and their families.

Matching talking points:

*See **Vaccines Protect Individual Freedoms** on page 5.*

Cheryl Hinks, 55

- Mother of two middle-school-aged children.
- Reduced hours and low staffing at her local hospital delayed her routine mammogram by a year.
- Diagnosed with late-stage breast cancer.
- The cost for treatment exceeded $100,000.
- Husband had to transition from full-time to part-time to help with care.

Matching talking points:

*See **Vaccines Help Ensure Your Ability to Access Health Care** on page 6.*

Alex Hinton, 39

- A former employee of Mr. Perez.
- Lost his job and health insurance for himself and family of four.
- Facing $60,000 worth of medical bills after wife and child fell ill to the vaccine-preventable illness.

Matching talking points:

*See **Working Families Suffer When Vaccine-Preventable Illnesses Close Businesses** on page 7.*

Samantha Long, 39

- Salon owner.
- Responsible for 12 employees. Tips major part of income.
- School closures canceled proms, formals, graduations, dealing a major financial blow.
- Enough cash on hand to survive closures and reduced capacity for 8 weeks. Would have been longer but had to pay for PPE, signage, and other safety precautions.
- Unable to withstand prolonged public health crisis due to decreased revenue and increased operating costs.

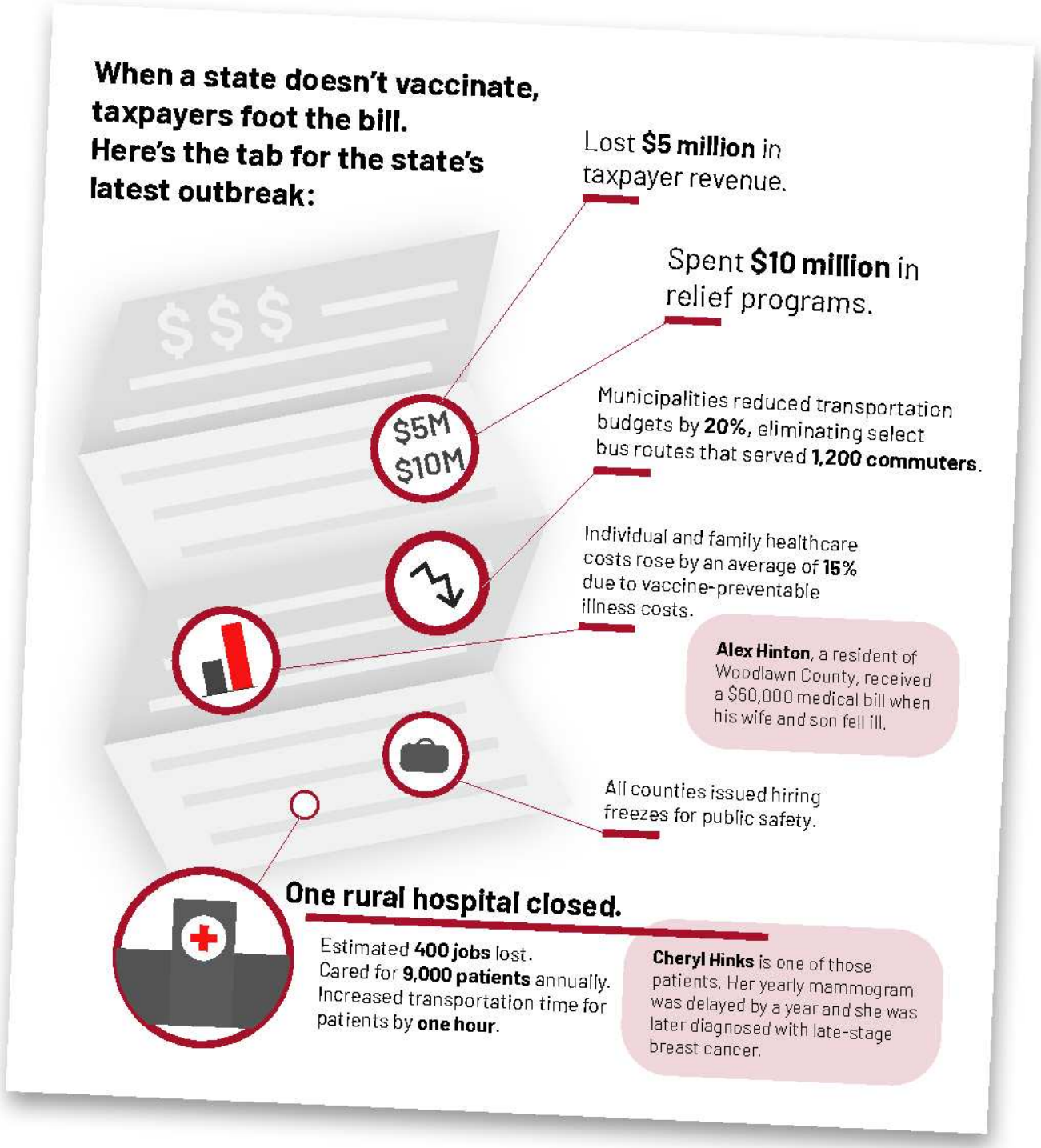
Matching talking points:

*See **Vaccines Protect Businesses by Reducing the Spread of Viruses and the Need for Restrictions on Public Activities** on page 5.*

Graphic Presentation 2: Matching Talking Points to State-Specific Data

Identify state-related facts on economic impact, unemployment, and individual freedoms, and pair this data with stories and talking points to show the state-level impact of an outbreak.

Note: The following scenarios, names, and statistics are fictional and intended to serve as an example of selecting data that supports the talking points.



MS-DOH-21-1816-A-000024

Meeting Script on a 3x5 Card

Vaxx protect individual freedoms.

- Eating and socializing at restaurants (Mr. Perez's business forced to close, 10 employees lost jobs).
- Limiting socialization hurts businesses.
- Restricting travel (out of towners for holidays/sporting events).

Vaxx protect businesses.

- Most businesses don't have the cash to survive long. (Ms. Long's salon only had 8 weeks cash on hand).
- Outbreaks decrease revenue, increase operating costs.
- During COVID only 55% of biz project surviving. Tip-reliant employees hurt the most.

Working families suffer when vaccine-preventable illnesses close businesses.

- Mr. Perez's employees lost their jobs. Ten of the 22 million jobs lost due to COVID.
- Two managers lost health insurance, which their families depended on for coverage and care.
- Employee Alex Hinton has over $60,000 in medical bills after his wife and child fell ill.

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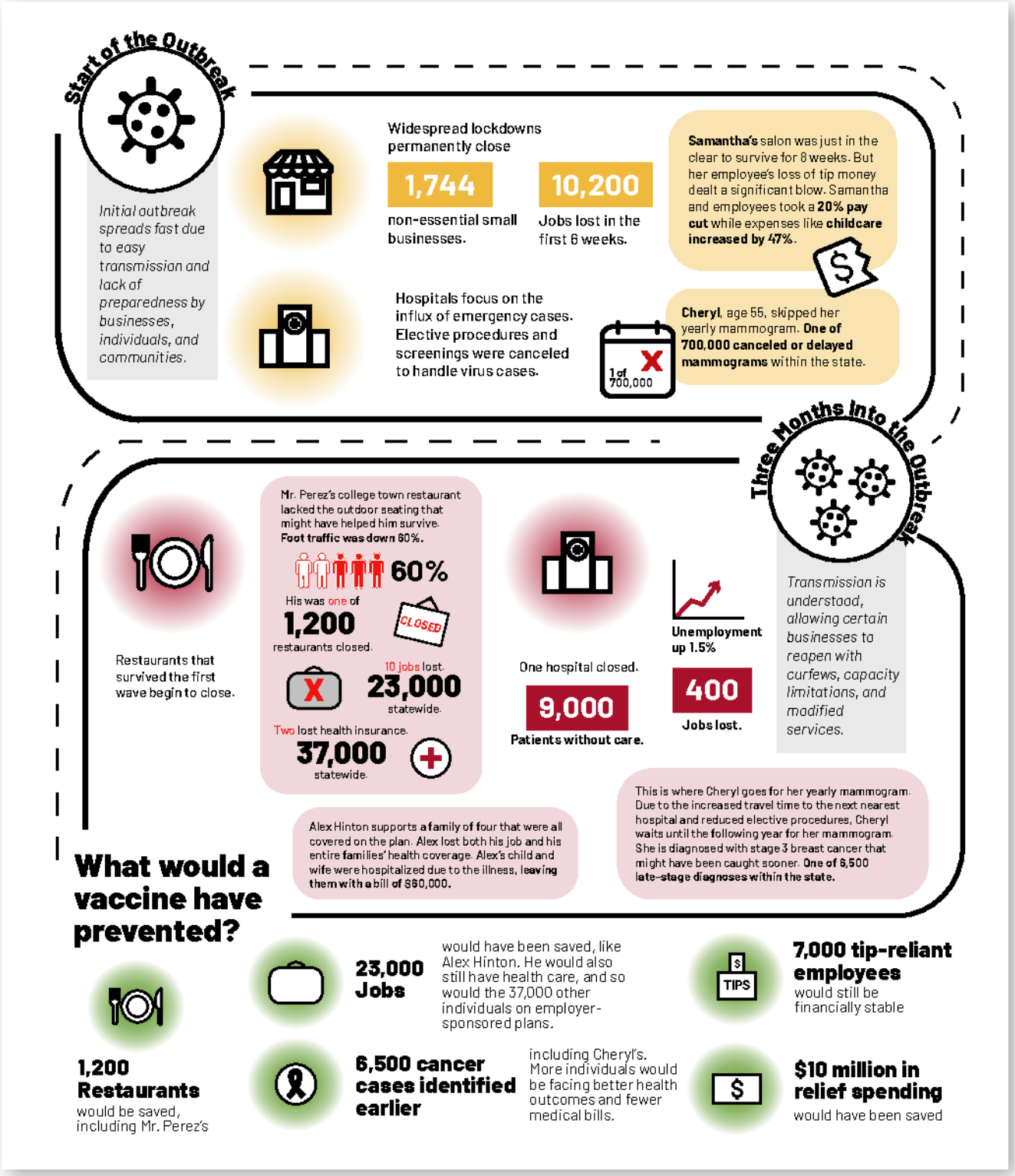
Sample Infographic Handout for Legislators

Organize your story into a graphic handout that visualizes state data, personal stories, and talking points. The following example illustrates this approach using fictional data.



Sample Q&A

Examples of how to combine stories with messaging to answer lawmakers' questions.

Q1. **"The government doesn't have any business in individual health decisions like vaccines. Shouldn't this be a personal choice for families?"**

A1. Vaccines safeguard many of the personal liberties that we value, like going to religious services, working, attending school, or going out for dinner. Mr. Perez's restaurant was thriving when people came together to watch sports and to visit with neighbors and friends. But when the outbreak hit hard, Mr. Perez couldn't keep his doors open and a local establishment shuttered for good. Curfews and capacity limits keep us safe amidst an outbreak, but they can make it difficult to socialize as freely as we'd like. Vaccination allows us to go out and get together safely and eliminates all precautions that could be seen as barriers to individual freedoms.

Q2. **"If there are side effects to vaccines, isn't it irresponsible of the government to encourage the public to get vaccinated? Should we really be prompting families to vaccinate their children and spouses if it could lead to catastrophic side effects?"**

A2. While the medical literature shows that vaccines are rigorously tested to ensure they are safe and effective, I think it's also important to note the indirect health benefits that we usually don't think of. For example, Mr. Hinton lost his job and his employer-sponsored health insurance due to the outbreak. His son and wife contracted the illness and their medical bills totaled over $60,000. His loss of health insurance would not have happened if he was able to keep his job. Unfortunately, that wasn't possible due to the outbreak. We also see that when these outbreaks occur and medical facilities are incredibly busy handling these cases, many patients forgo routine screenings and check-ups that can lead to a later-stage diagnosis.

A2. cont.

That means bigger health care bills and poorer health outcomes just due to delayed visits, as we saw with a local resident, Ms. Hinks, when she delayed her routine mammogram.

There are so many other health and financial factors at play should a vaccine-preventable illness take our state by storm. We're looking at the loss of jobs and health insurance, delayed doctor visits, and late- stage diagnosis of cancer. That's a huge number of health-related illnesses and significant financial stress that we can prevent with vaccines.

Q3. **"The government already spends astronomical amounts of money. These vaccination programs and requiring vaccinations will cost a lot of money, and all of that comes from taxpayers who are paying for far too much already. What's the return on investment for them?"**

A3. Let's talk about the cost of a vaccine-preventable outbreak to taxpayers as individuals and at large. From the individual standpoint, consider Ms. Cheryl Hinks. Her medical bills show the financial benefits and savings to individuals and taxpayers. Because of the recent outbreak, her medical options were limited, and her mammogram was delayed by a year. She was later diagnosed with stage 3 breast cancer. Looking at this financially, her costs for treatments are exceeding $100,000. Now if widespread vaccinations were in place, the hospital would have been able to proceed with screenings and elective procedures as normal, and her chances of catching cancer earlier would have been much higher. It would have saved her, and the thousands of other late-stage diagnosis patients, a significant amount of money in medical bills and protected their access to health care.

That's not even accounting for the medical bill savings for that vaccine-specific illness. If we look at all of the routine childhood immunizations, together they've saved taxpayers nearly $300 billion. That's a huge benefit to American taxpayers that we can't overlook.

MS-DOH-21-1816-A-000028

Q4. "Because of negative side effects and the fact that this is a highly personal, medical decision, shouldn't we leave doctors to have this conversation with patients?"

A4.

Doctors are excellent resources for this, but widespread outbreaks due to vaccine-preventable illnesses can have such a far-reaching impact. Leaving this issue to doctors isn't enough, and if we don't act on this, it can put the economic and financial safety of our state and all families at risk. Ms. Lang's salon was forced to cut back hours because of the outbreak. And since her employees rely on tips, those reduced hours hit them hard. They also had to balance reduced income with other rising costs, like childcare. So, they were going to work for less and paying more for everything else.

In addition, we saw hundreds of businesses and restaurants close. Mr. Perez' business was one of them. He was forced to lay off his 10 employees. All of this shows us that so much is in the balance. People's livelihoods and financial safety are at risk here if we don't take action to ensure families can work, travel, and congregate safely. Vaccines are more than just a medical decision. They can protect our businesses and allow employees to continue working.

MS-DOH-21-1816-A-000029

Sample Statements

Weave together talking points from the message document with the personal narratives you compile from your state.

Mr. Matthew Perez

Sample Statement #1

Mr. Chairman,

As a business owner, the sense of responsibility you have to your customers, community, and employees is enormous. Unfortunately, due to the outbreak and the precautions to stop the spread of the virus, I let a lot of those people down. As a college town restaurant, we need to be open as much as possible to serve our customers. Closing at 10 pm each night with fewer customers than normal just couldn't sustain us. We relied on a lot of out-of-state travel to see the college football games, which was all restricted to help slow the spread. Ultimately, I had to shut the doors permanently, which left my 10 very hardworking, loyal employees without a job, source of income, or health insurance. It left me with a mountain of debt. And now I too am unemployed, searching for a job in an industry that's dying due to the outbreak.

Vaccination would have allowed me to keep the place up and running. If I would have been able to operate knowing that my customers and my employees were safe, we wouldn't have needed to undergo those shutdowns. And our customers would have had the freedom to come in as they please and socialize with their friends and family. The freedom to work and gather as a community was taken away from us because of the virus. I think it's clear that vaccination would have protected my business, my employee's jobs, and a community space that so many have come to enjoy over the past several decades. Small businesses like mine could not sustain themselves throughout this outbreak. And now I'm left to pick up the pieces and try to start over.

MS-DOH-21-1816-A-000030

Ms. Cheryl Hinks

Sample Statement #2

Dear Senator Jones,

I didn't realize the number of routine things I took for granted before the outbreak hit. One of those being the yearly checkups that you do without thinking about them. Because so many people were sick, the hospital where I received my annual mammogram cut back on screenings and elective procedures. So I kept kicking that appointment down the road. Now, this hospital was always struggling, even long before the outbreak, and this outbreak maxed out their resources and forced them to close.

Being from a rural part of the state, the next closest hospital to me was an hour drive. So again, I didn't think much of it as I kept pushing my visit farther down the road given that it was even more inconvenient to get and keep an appointment. One year later, I finally was able to get my screening. And the result? Stage 3 breast cancer.

Now, over $100,000 in medical bills later, I've lost my health and financial stability. I'm one of 6,500 other people who've also received a late-stage diagnosis of cancer. Many others are like me, who were rescheduled time and time again until the inconvenience made it nearly impossible to take care of those routine visits that we had, before the outbreak, taken for granted.

On the surface, my cancer diagnosis doesn't seem to be connected to this vaccine-preventable illness. But it is, and my biggest lingering question is where my physical and financial health could be now if I were able to have that screening on time.

MS-DOH-21-1816-A-000031

Sample Statement #3

Mr. Alex Hinton

Rep. Ochoa,

I always thought about the side effects associated with getting a vaccine. But I never thought of the financial pain it could bring to me and my family until my wife and son became ill. Our income was already cut in half since I had lost my job and the associated health insurance. It was a double whammy to receive the hospital bill on top of everything else. Of course, every penny is worth the lives and health of my family, but the $60,000 bill has wiped out our savings. I worry about the credit score we've been building up over the past two years. I worry about providing for my family and supporting my children through college. I worry about what this means for our financial future in the years ahead.

No one tells you that these illnesses not only make you sick but also deliver crippling financial pain. If you fall ill, the medical bills could drain your bank account. The hospital stays, treatments, and follow-up appointments add up quickly for just one family member, let alone two. And as their health thankfully returns, the debt will linger on with us for years. We never built up our savings and financial stability with a preventable illness in mind. What this horrible experience has shown us is that vaccines are the cheapest insurance policy we have. And for families, it's an investment that cannot be understated.

MS-DOH-21-1816-A-000032

Examples of Emotion in Anti-Vaccine Stories

Roll mouse over headlines for links to stories.

Opinion: I Heard Cries. Then, I Saw The Faces… My Vaccine Story

Assemblyman Jamel Holley: ' I saw the faces of the children, tightly wrapped up in warm winter clothing for long hours into the late night. Some of those children – sadly – were injured from vaccines

Gov't: Girl's Autism-Like Symptoms Linked to Vaccines: Federal Officials Say Vaccines Worsened Condition that Led to Autism Spectrum Disorder in Georgia Girl

Accepting his daughter's diagnosis was difficult, Poling tells WebMD. He says the family was in denial initially that anything was seriously wrong. "After six months of essentially our daughter being a zombie and gone, we knew this wasn't going away," he says. "This was chronic. And we had to come to grips with that."

Mandatory vaccine passports do not belong in the birthplace of freedom | Opinion

"No, these unelected bureaucrats should never be able to coerce anyone in our commonwealth to make such personal medical decisions. There is simply no justification for this overreach. You and you alone should decide."

Defending a parent's right to withhold vaccines when they want to: Mothers and fathers should have the right to refuse stringent CDC guidelines for religious or philosophical reasons

"At the age of 12 months, my son had a very serious reaction to the MMR vaccine," she states. "It was so serious that he had an immediate regression developmentally. He stopped making most sounds and suddenly couldn't even roll over on his own. It was shocking, scary, and a life-changing experience."

I watch her face as she speaks. The emotions are strong. Her sorrow is deep. "I've given thousands of babies vaccines," she continues. "And anyone who reads the label inserts knows that these substances are not without risk. But the risk is very small. I never imagined any child I inoculated would be harmed. I only saw my actions as helpful."

I nod.

"But my son was harmed, badly. It was an undeniable reaction. My son was harmed on my watch and I'm a pediatric nurse. He was harmed by a medical practice I had never questioned and this changed me. It changed our office, too. Now we all approach the topic with added nuance and depth," she explains.

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Appendix – Social Media Privacy Settings

Ensure that your security settings on your social media accounts are secure. This includes enabling privacy settings that allow you to approve who follows you or sends you a friend request, as well as who can comment or interact with your posts. You can even hide posts and account information to make them invisible to those who do not already follow you.

Facebook

Settings > Privacy > Manage your profile

Click through your about tabs including 'Overview,' 'Work and Education,' and more. Each item, such as listed jobs, will allow you to change the visibility from "public" to "friends."

Settings > Profile and Tagging

Under "Viewing and Sharing," change "Who can post on your profile?" and "Allow others to share your post to their stories?" from "public" to "friends."

Settings > Privacy > Your Activity

Change "Who can see your future posts" and "Who can see the people, Pages and lists you follow?" from "public" to "friends."

Settings > Public Posts

Change "Who Can Follow Me?" from "public" to "friends."

Instagram

Profile > Settings > Privacy

Set your account to private.

Twitter

Settings and privacy > Privacy and safety

Enable "Protect your Tweets."

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

RYAN KLAASSEN *et al.*,

Plaintiffs,

v.

THE TRUSTEES OF INDIANA UNIVERSITY,

Defendant.

CAUSE NO. 1:21-CV-238 DRL

OPINION & ORDER

Under guiding principles of federalism, our Constitution preserves the power of the States, within constitutional limits, to adopt laws to provide for public health and safety. Twice the United States Supreme Court has upheld state authority to compel reasonable vaccinations. The States don't have arbitrary power, but they have discretion to act reasonably in protecting the public's health.

Students at Indiana University have a significant liberty protected by the Constitution—refusing unwanted medical treatment based on bodily autonomy. The Fourteenth Amendment says no state may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV § 1. Given this due process protection of liberty, longstanding constitutional law prevents a public university—an arm of the State—from mandating a vaccine for its students unless it has rationally pursued a legitimate interest in public health for its campus community.

This case presents that question: whether Indiana University has acted constitutionally in mandating the COVID-19 vaccine for its students, as announced on

May 21, 2021. Albeit, and this should not be overlooked, this case does so only in the context of a preliminary injunction motion, not for a final decision on the merits.

Indiana University's policy has real implications. Students may be deprived of attending the university without being vaccinated or qualifying for an exemption. Still they have real options—taking the vaccine, applying for a religious exemption, applying for a medical exemption, applying for a medical deferral, taking a semester off, or attending another university or online. The policy applies for the fall 2021 semester only.

Eight students sued Indiana University because of its vaccination mandate and because of the extra requirements of masking, testing, and social distancing that apply to those who receive an exemption. They ask the court to enter a preliminary injunction—an extraordinary remedy that requires a strong showing that they will likely succeed on the merits of their claims, that they will sustain irreparable harm, and that the balance of harms and the public interest favor such a remedy.

The court now denies their motion. The Constitution and longstanding precedent should endure. Recognizing the students' significant liberty to refuse unwanted medical treatment, the Fourteenth Amendment permits Indiana University to pursue a reasonable and due process of vaccination in the legitimate interest of public health for its students, faculty, and staff. Today, on this preliminary record, the university has done so for its campus communities. The students haven't established a likelihood of success on the merits of their Fourteenth Amendment claim or the many requirements that must precede the extraordinary remedy of a preliminary injunction.

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FACTS

A. *Parties*.

Indiana University is a world-renowned public research university, with seven campuses, two regional centers, and three medical centers across the State of Indiana, providing education to over 90,000 undergraduate and graduate students and employment for over 40,000 employees [Ex. 116 ¶ 4]. The university, with its flagship campus in Bloomington, Indiana home to over 40,000 students, continually ranks as one of the top 100 universities in the country, and one of the top 150 universities in the world.

The eight students here have varied backgrounds. Jaime Carini (age 39) is a graduate student pursuing two doctorates in music, with but her examinations and dissertation to complete [Ex. 121 at 10, 19-20, 23]. She has received an exemption from the university's vaccination requirement already [*id.* 57-58].

Ashlee Morris (age 26) is an incoming first year law student at the McKinney School of Law who has worked hard for six years to get there to pursue her J.D. [Ex. 123 at 10, 66-67]. She too has received a religious exemption from the university's vaccination requirement [*id.* 44]. She testifies that she will not attend the law school if she must wear a mask or undergo surveillance testing [*id.* 66-67].

Seth Crowder (age unknown) is pursuing his MBA at the Kelley School of Business [Ex. 124 at 13]. He too has received a religious exemption from the university's vaccination requirement already [*id.* 9, 20-21]. He has not decided if he will return to school if he must wear a mask or undergo surveillance testing this fall semester [*id.* 42].

Macey Policka (age 22) is a senior at Indiana University studying English (medieval studies) [Ex. 125 at 8-9]. She also has received a religious exemption from the university's vaccination requirement [*id.* 22]. She plans to return to Indiana University regardless of the outcome of this case [*id.* 36-37]

Ryan Klaassen (age 19) is an incoming sophomore at Indiana University studying biochemistry [Ex. 120 at 5, 15-17]. He has received a religious exemption to the university's vaccination requirement [*id.* 33]. He says he hasn't decided if he will return to Indiana University if the injunction is not granted. [*id.* 41-43].

Daniel Baumgartner (age 18) is an incoming freshman at Indiana University who plans to study business [Ex. 122 at 8, 12-13]. He has received a religious exemption to the university's vaccination requirement [*id.* 8]. He has not decided if he will go to Indiana University this fall if he must wear a mask or undergo surveillance testing [*id.* 41].

Margaret Roth (age unknown) is an incoming freshman at Indiana University and has already registered for classes [Ex. 126 at 9, 20]. She has a religious objection to the vaccine but has not requested an exemption, though she would qualify, because she prefers not to wear a mask or undergo testing [*id.* 45-47]. She says she will most likely not attend Indiana University if the injunction isn't granted [*id.* 9].

Natalie Sperazza (age unknown) is an incoming sophomore who will be taking five classes this fall [Ex. 127 at 11]. She has not applied for an exemption and believes she wouldn't qualify [*id.* 15-16]. She says she will not attend Indiana University this fall if the policy remains in place [*id.* 42]. She appears to be the only student without an exemption or basis for an exemption.

B. *COVID-19.*

COVID-19 is an infectious disease caused by the novel coronavirus. It primarily spreads through respiratory droplets, viral particles suspended in the air, and touching mucosal membranes with contaminated hands [Ex. 115 ¶ 6].[1] The initial presentation of an infection ranges from no symptoms at all (asymptomatic) to severe illness and death; and even after recovery, various long-term health problems may linger [*id.* ¶ 8].[2]

Individuals with longstanding systemic health inequities or preexisting or immunocompromising conditions, and elderly individuals prove at greater risk of severe illness or hospitalization following an infection [*id.* ¶ 9].[3] Children and young adults are less likely to experience serious illness or death from infection [Ex. 115 ¶ 10; Ex. 117 ¶ 21]. Though data from the Centers for Disease Control and Prevention (CDC) suggest that more young adults are becoming infected with the virus than other age groups [Ex. 115 ¶ 16],[4] these individuals are less likely to require hospitalization or die [*id.* ¶ 10].[5]

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[1] *See also* Ctrs. for Disease Control & Prevention (CDC), *Scientific Brief: SARS-CoV2 Transmission*, https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html.

[2] *See also* CDC, *People with Certain Medical Conditions*, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last visited July 18, 2021); Neal M. Dixit *et al.*, *Post-Acute COVID-19 Syndrome and the Cardiovascular System: What is Known?*, 5 Am. Heart. J. Plus. 100025 (May 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223036/.

[3] *See also* CDC, *People with Certain Medical Conditions*, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last visited July 18, 2021).

[4] Of the total reported cases, those reported from the 18-29 age group account for 22.5 percent of all infections—the highest proportion of any age group—despite accounting for only 16.4 percent of the United States population. *See* CDC, *Demographic Trends of COVID-19 Cases and Deaths in the U.S. Reported to CDC,* https://covid.cdc.gov/covid-data-tracker/#demographics (last visited July 18, 2021).

[5] *See also* CDC, *Risk for COVID-19 Infection, Hospitalization and Death by Age (Updated June 24, 2021)*, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html (last visited July 18, 2021) (individuals aged 30-49 twice as likely to be hospitalized, individuals 50-64 four times as likely to be hospitalized, individuals aged 30-39 four times as likely to die, individuals 40-49 ten times as likely to die, individuals 50-64 thirty-five times as likely to die). The most

Worldwide COVID-19 has infected almost 189 million people and caused 4 million deaths, with these numbers still changing daily.[6] In the United States, the novel coronavirus has infected over 33.5 million citizens, losing to death over 600,000 [Ex. 115 ¶ 15]. Since March 6, 2020, Indiana has had over 750,000 confirmed COVID-19 cases and over 13,000 deaths [*id.* ¶ 14]. The COVID winter of 2020-2021 was particularly rough, until vaccines became options first in December 2020 and then in the early months of 2021.

As vaccination now increases, data gathered by the CDC point toward the waning of new COVID infections across the country—down from a peak of 312,325 new cases reported on January 8, 2021, with a seven-day average positive test rate of 13.85 percent, to 39,719 new cases reported on July 16, 2021, with a seven-day average positive test rate of 5.01 percent.[7] The rate of new cases today is akin, if not greater, to the rate of new cases reported during the peak of the pandemic's first wave in the spring 2020, through the relative rate of positive tests thankfully remains much lower.[8]

Our nation has come a long way since the darker days of 2020 that tested many people, though some uncertainty persists even now in this 2021 summer. The current

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recent CDC figures suggest that only 0.04 percent of cases from this age group result in death, and this group represents only 0.5 percent of all COVID deaths. CDC, *Demographic Trends of COVID-19 Cases and Deaths in the U.S. Reported to CDC*, https://covid.cdc.gov/covid-data-tracker/#demographics (last visited July 18, 2021) (6,174,415 individuals aged 18-29 contracted the virus, and 2,732 individuals died).

[6] *See* CDC, *Global Cumulative Cases of COVID-19 Reported* (July 18, 2021), https://covid.cdc.gov/covid-data-tracker/#global-counts-rates (citing World Health Organization (WHO), *WHO Coronavirus (COVID-19) Dashboard* (July 16, 2021), https://covid19.who.int/).

[7] CDC, *COVID Data Tracker*, https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (last visited July 18, 2021).

[8] *Id.* (35,080 new cases reported on April 9, 2020, with a seven-day average positive test rate of 20.43 percent).

seven-day moving averages of new COVID-19 cases has increased by 69.3 percent in the past week alone; the positive test rate has increased by 40.7 percent; and new hospital admissions have increased by 35.8 percent.[9] Recalling the bell curves we all have become accustomed to seeing, the trend still proves sharply down from the worse days of COVID-19, but virulent and highly transmissible variants of this coronavirus present new challenges [Ex. 115 ¶ 36]. As of July 3, 2021, the CDC estimates that 57.6 percent of new cases come from the Delta variant.[10] New COVID-19 cases often originate in unvaccinated individuals [Ex. 115 ¶ 38-39].

In Indiana, 561 new cases were reported on July 15, 2021; and the most recent data suggest a seven-day average positive test rate of 4.3 percent for unique individuals from July 3, 2021 to July 9, 2021, lower than the national average.[11] Of all positive cases, 18.4 percent, the highest proportion of all age populations, comes from young adults aged 20-29.[11] In Indiana, approximately 67.3 percent of all cases came from the Delta variant.[12] Our country and our state have vastly improved, but challenges remain.

C. *Indiana University Board of Trustees.*

The Indiana General Assembly endows the Indiana University Board of Trustees with the responsibility to fulfill its powers and duties under the law. Ind. Code § 21-27-

[9] CDC, *COVID Data Tracker Weekly Review* (July 16, 2021) https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.

[10] *Id.*; *see also* CDC, *COVID Data Tracker*, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (last visited July 18, 2021).

[11] Indiana State Department of Health, *COVID Dashboard*, https://www.coronavirus.in.gov/2393.htm (last visited July 18, 2021).

[12] Indiana State Department of Health, *COVID Dashboard*, https://www.coronavirus.in.gov/2393.htm (last visited July 18, 2021).

2-1. The Trustees may pass all bylaws necessary to put into effect its powers. Ind. Code. § 21-27-4-3. The Trustees may set conditions and standards for admission that are in the "best interests of the state and the state educational institution." Ind. Code § 21-40-3-1(b).

Among these powers, the Trustees may govern "the conduct of the state educational institution's students, faculty, and employees, wherever the conduct might occur, to prevent unlawful or objectionable acts that . . . violate the reasonable rules and standards of the [university] designed to protect the academic community from . . . a serious threat to person or property of the academic community." Ind. Code § 21-39-2-3(b). The university remains answerable to the legislature, particularly its funding.

D. *State Law on Vaccines*.

Indiana requires all public university students to be vaccinated for diphtheria, tetanus, measles, mumps, rubella, and meningococcal disease before attending school. Ind. Code § 21-40-5-2. All but one of these vaccinations have been required since 1993. Outside these state-mandated vaccines, Indiana University has had a policy for managing infectious and communicable diseases since at least 2015 designed to take "reasonable measures to ensure the safety of members of the university community during global and local infectious disease events" [Ex. 229]. Students must report vaccination status, save for religious and medical exemptions, including any "contraindication to a vaccine" [*id.*]. This reporting occurs according to state law and recommendations from the CDC's Advisory Committee on Immunization Practices. *See* Ind. Code. § 21-40-5-2.

Since this pandemic's advent, many states have considered bills that would prohibit either vaccine "mandates" or vaccine "passports." For instance, just last week

the State of Ohio passed a law banning public vaccine mandates. *See* 2021 Bill Text OH H.B. 244, Sec. 3792.04(B)(1) (signed July 14, 2021). Other states have more reservedly passed laws that would prohibit just having to show proof of COVID-19 vaccination—hence the term COVID-19 passport. Indiana's General Assembly recently enacted law that prohibits a vaccine passport, not a vaccine requirement.[13] Ind. Code § 16-39-11-5.

E. *Vaccine Guidance for Institutions of Higher Education*.

Governmental agencies and collegiate associations have with one chorus promoted vaccination to address the COVID-19 pandemic, though they typically have remained silent on whether universities should mandate a vaccine. Today more than 500 colleges and universities have mandated vaccination, though many are private institutions of higher learning, not public universities.[14]

The CDC recommends that institutions of higher learning (IHEs) "can return to full capacity in-person learning, without requiring or recommending masking or physical distancing" only when "all students, faculty, and staff are fully vaccinated prior to the start of the semester."[15] The Indiana State Department of Health aligns with the CDC.[16]

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[13] This statute applies to "the state or a local unit." Ind. Code § 16-39-11-5(a). The students withdrew their claim under this law because the statute omits a private right of action, leaving enforcement to the Indiana State Department of Health. *See, e.g.*, Ind. Code § 16-19-3-18. For sake of clarity, the court never reaches the point whether this anti-passport law applies to a public university or not.

[14] *See* Andy Thomason & Brian O'Leary, *Here's a List of Colleges That Will Require Students or Employees to Be Vaccinated Against Covid-19*, The Chronicle of Higher Education (July 15, 2021), https://www.chronicle.com/blogs/live-coronavirus-updates/heres-a-list-of-colleges-that-will-require-students-to-be-vaccinated-against-covid-19?cid2=gen_login_refresh ("The Chronicle has so far identified 583 such campuses.").

[15] CDC, *Guidance for Institutions of Higher Education (IHEs)* (June 4, 2021), https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/considerations.html.

[16] ISDH, *Public Resources: Back to School Resources (Universities)* (July 18, 2021), https://www.coronavirus.in.gov/2400.htm.

Likewise citing the CDC, the United States Department of Education has said "IHEs where everyone is fully vaccinated can return to full capacity in-person learning without requiring or recommending masking, physical distancing, or screening testing."[17] The American College Health Association has recommended that institutions require COVID-19 vaccinations for all on-campus students for the fall semester.[18]

F. *Indiana University's Vaccine Mandate.*

Acting under state authority, *see* Ind. Code § 21-38-3-4, and with the vision of promoting public health and restoring the educational and social environment of the university's campuses, President Michael McRobbie created a university restart committee during the spring of 2021 to make recommendations to the Board of Trustees for the fall semester [Ex. 104 at 5; Ex. 116 ¶ 22]. The restart committee's charge was to advise and recommend requirements necessary to resume "normal face-to-face" operations [Ex. 116 ¶ 22].

Indiana University's Executive Vice President for University Clinical Affairs and the School of Medicine's Dean spearheaded the restart committee [*id.* ¶ 23]. It included fifteen members with expertise in public health, epidemiology, virology, data modeling and monitoring, risk mitigation, health equity, health sciences, and law [*id.*; Ex. 300 at 4-

[17] U.S. Dept. of Educ., *ED COVID-19 Handbook, Volume 3: Strategies for Safe Operation and Addressing the Impact of COVID-19 on Higher Education Students, Faculty, and Staff* 9 (June 2021), https://www2.ed.gov/documents/coronavirus/reopening-3.pdf.

[18] Am. College Health Ass'n, *American College Health Association Recommends COVID-19 Vaccination Requirements for All On-Campus College Students in Fall 2021* (April 29, 2021), https://www.acha.org/ACHA/About/ACHA_News/ACHA_Recommends_COVID-19_Vaccination_Requirements_for_Fall_2021.aspx.

5]. The committee consisted of seven MDs, some with additional degrees in public health or other PhDs, and others with graduate degrees in public health, risk mitigation, law, and ethics [Ex. 300 at 5].

The restart committee met regularly to review the university's campus population and experiences from the 2020-2021 year, as well as "guidelines from the CDC, IU Health, the ISDH, the Indiana Governor's Office, and the Central Indiana Corporate Partnership, among others," "scientific literature and data, including COVID-19 case and hospitalization rates for Indiana," and "input from other Indiana and out-of-state IHEs" [Ex. 116 ¶¶ 24-26]. The data considered by the restart committee were vast [Exs. 302-317, PowerPoint presentations from December 8, 2020 to April 6, 2021); *see also* Ex. 301 ¶ 2].

Four MDs from this committee presented near-weekly from December 2020 to June 2021 to Indiana University's Executive Academic Leadership Council, including the President and Executive Vice Presidents as part of the medical response team's ongoing COVID-19 evaluation efforts [Ex. 301 ¶ 4]. The Board of Trustees adopted the restart committee's recommendations for the 2021 fall semester [Ex. 116 ¶ 29].

The aim was short and strategic—vaccinate everyone, subject to certain exemptions [*id.* ¶ 31; Exs. 101, 300]. Initially, the policy required all students, faculty, and staff to submit proof of vaccination before returning to campus, but the university revised this requirement after Indiana passed its anti-passport law [Ex. 101]. The policy today requires all students, faculty, and staff to be fully vaccinated, which the university defines as being two weeks post the second dose of the Pfizer and Moderna vaccines, or two weeks post the single dose of the Johnson & Johnson vaccine, before returning to campus

between August 1 to August 15 for the fall 2021 semester [Ex. 118 at 3, 5; *see also* Exs. 102-104].

The choice of foregoing vaccination is not inconsequential. If not vaccinated, students are not permitted on campus, their emails and university accounts are suspended, and their access cards are deactivated [Ex. 118 at 7]. Although it seems from argument that the university will not create an informant culture, it reserves the right to pursue disciplinary action should a student deceive the process. Faculty and staff who refuse vaccination face termination. The faculty councils from Indiana University—Bloomington and Indiana University-Purdue University Indianapolis and the staff council from Indiana University—Bloomington, have endorsed the policy, as has the graduate and professional student government [Ex. 116 ¶ 45-60].

The university's COVID-19 vaccine policy has exemptions. A student may request an exemption for religious reasons; provide proof from a physician of an allergy to the vaccine or one of its component parts (a medical exemption); provide proof from a physician of active pregnancy or breastfeeding, receiving a hematopoietic or solid organ transplant, receiving treatment with Rituximab within the past 3-6 months, or COVID-specific monoclonal antibodies[19] in the past 90 days (a medical deferral) [Ex. 210 at 3]. Students who are enrolled in an online program, with no on-campus component, don't need to receive the vaccine [*id.*].

[19] Monoclonal antibody therapy involves the injection of laboratory-made proteins that mimic the immune system's ability to fight off various pathogens. FDA, *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab* (April 16, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab.

For those who receive exemption from vaccination, the policy imposes additional safety requirements. These requirements apply to six of the eight students here who have received exemptions and potentially a seventh who qualifies for an exemption. Such students must participate in more frequent mitigation testing, quarantine if exposed to someone who has tested positive for COVID-19, wear a mask in public spaces, and return to their permanent address or quarantine if there is a serious outbreak of COVID-19 [Ex. 118 at 6].

G. *Experts.*

The parties have tendered declarations, supplemental declarations, and testimony from several experts, leaving to the court the task of deciding what weight to give to their opinions. Among the more than 100 exhibits admitted for this preliminary injunction motion, the experts and other materials refer to numerous medical studies and industry guidance on the risks of COVID-19 and the risks of the vaccines—where the parties in part have drawn the battle lines. The court has endeavored to be studious in reviewing at times a daunting record on this emergent timetable.

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The university offers Dr. Cole Beeler, MD,[20] and Dr. Aaron Carroll, MD, MS,[21] and the students tender Dr. Peter McCullough, MD, MPH.[22] All have credentials and opinions that exceed restatement here. Much of that treatment occurs later in this opinion as the court makes additional findings of fact and discusses its legal analysis. Though points of agreement occur at times, these experts largely disagree about the urgency of vaccination, particularly for often younger university students, the effects from natural COVID-19 infection, and the risks of the three emergency use approved vaccinations.

For the students, Dr. McCullough says the risks of COVID-19 to college age students in 2021 proves significantly lower than in 2020 because of the rapidly declining infection rate, increasing likelihood of herd immunity in Indiana, low risk of serious complications or death from COVID-19 in college-aged students, low risk of asymptomatic spread, and other posited COVID-19 treatments [Ex. 117 ¶ 73; *see also* Exs. 221-22, 233-34, 240-41, 246-47, 251]. He views a mandate as unwise and a violation of the medical ethics principle of autonomy translated to the university setting [Ex. 117 ¶ 73]. He opines that the risks associated with the COVID-19 vaccines "are not minor or

[20] Dr. Beeler is an assistant professor of clinical medicine at Indiana University Medical School. He earned his BS and MD from Indiana University and is board certified in infectious disease and internal medicine [Ex. 115 ¶ 1-5; Ex. 128 at 5, 7-11, 13-17, 21-22, 31, 147-150].

[21] Dr. Carroll is the chief health officer for Indiana University and associate dean for research mentoring at Indiana University Medical School who holds various professorial positions. He earned his BA from Amherst College, his MD from the University of Pennsylvania, and his MS from the University of Washington. He is board certified in preventative medicine-clinical informatics, pediatrics, and by the National Board of Medical Examiners [Ex. 116 ¶ 1-6; Ex. 206 at 7-8].

[22] Dr. McCullough is a professor of medicine at Texas A & M University School of Medicine and practices medicine at various Texas hospitals. He received his BA from Baylor University, MD from University of Texas Southwestern Medical School, and his MPH in epidemiology from the University of Michigan. He is board certified in internal medicine and cardiovascular disease [Ex. 117 ¶ 1-12].

unserious and can include hospitalization and death," however "unpredictable" and "impossible to calculate" [*id.*]. His opening declaration largely isn't stated to any reasonable degree of medical certainty [*id.*; *but cf.* Ex. 222 at 11].

For the university, Dr. Beeler says the COVID-19 vaccine mandate facilitates a "safe and reliable way to assure lack of spread of COVID" within the university's campus communities and "prevents morbidity and mortality" [Ex. 115 ¶ 87; *see also* Ex. 319]. He appreciates that, though COVID-19 often will not pose "disproportionate bad outcomes" in the university's constituency, "any bad outcome from COVID is potentially avoidable with the vaccines where the benefit dwarfs the potential rare risks," and risks that "may not be causally linked" [Ex. 115 ¶ 87]. He recalls that "the vaccines used for COVID are based on technology that has been developed over decades and have repeatedly been shown to be safe when given to millions of patients" [*id.*]. He calls the vaccines "known science" applied to a "novel pathogen" with often "uncertain and threatening immediate and long-term consequences to [the university's] students, faculty, staff, and communities at large" [*id.*]. He says the risk of asymptomatic hosts puts others at risk [*id.*]. In support, Dr. Carroll marshals relevant industry, governmental, and university guidance and the relevant scrutiny the restart committee gave to it [Exs. 116, 301]. Dr. Beeler states his opinions to a reasonable degree of medical or professional certainty [Ex. 115 at 25; Ex. 319 at 8].

H. *Emergency Use Authorization of Vaccines.*

COVID-19 caught the world unaware. Initially, there were no vaccines or treatments, and testing was expensive and difficult to secure. Four days after the United

States Department of Health and Human Services (HHS) declared a public health emergency, it issued a second declaration allowing the United States Food and Drug Administration (FDA) to grant emergency use authorizations (EUAs) for medical devices and interventions to combat the pandemic. 85 Fed. Reg. 7316, 7316-7317; 85 Fed. Reg. 18250, 18250-18251.

Despite creating an expedited pathway to distribute new medical products during emergencies, products that receive EUA approval still must adhere to specified safety, efficacy, and manufacturing criteria, and HHS must ensure medical providers and individuals are informed of the product's EUA status, the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown;" and for individuals, of the option to refuse and the consequences of such a decision. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)-(III). An EUA generally allows a manufacturer to apply for EUA approval using interim clinical trial data, and the data need only demonstrate the product "may be effective" and that the known and potential benefits outweigh the known and potential risks.[23] The statute anticipates the FDA will impose additional obligations beyond those enumerated. 21 U.S.C. § 360bbb-3(e)(1)(B).

There have been six significant public health emergencies for which the FDA has authorized EUAs: anthrax, swine flu (H1N1), MERS (Middle East respiratory syndrome

[23] 21 U.S.C. § 360bbb-3(c)(2)(A); FDA, *Emergency Use Authorization for Vaccines Explained*, https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (last visited July 13, 2021).

coronavirus), Ebola, Zika, and now COVID-19.[24] During these events, EUAs were issued for diagnostic tests (swine flu, MERS, Ebola, Zika, and COVID-19), off-label use of previously approved and use of unapproved pharmaceuticals (anthrax, swine flu, and COVID-19), novel vaccines (anthrax and COVID-19), and medical devices (swine flu and COVID-19).[24] FDA authorization for EUA vaccinations began in 2005 during the anthrax scare, particularly for use in the armed forces. *See* 70 Fed. Reg. 5452, 5453 (Feb. 2, 2005).[25] Later in 2009, based on a CDC request, the FDA issued the first EUA that was geared towards civilians, including infants, for Tamiflu, an antiviral otherwise approved for use in adults. 74 Fed. Reg. 56644 (Nov. 2, 2009).[26]

Not all EUAs are created equally. Because of the widespread use of a COVID-19 vaccine, the FDA informed manufacturers that it expected the same level of endpoint efficacy data as required for full approval, enough safety data to justify by clear and compelling evidence the vaccine's safety, and confirmation of the technical procedures and verification steps necessary to support full approval.[27] In short, and as described in more detail below in this opinion's analysis, the FDA promulgated guidance that

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[24] FDA, *Emergency Use Authorization – Archived Information*, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#H1N1 (last visited July 16, 2021).

[25] *See also* Stuart L. Nightingale *et al.*, *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States*, 13(7) Emerging Infectious Diseases 1047 (July 2007), https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article.

[26] CDC, *Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season* (Dec. 7, 2009), available at https://www.cdc.gov/h1n1flu/recommendations.htm#d.

[27] FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (May 2021), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid.

enhanced the basis on which any COVID-19 vaccine would meet EUA approval. In setting these more stringent standards, the FDA invited EUA applications only for vaccines positioned well to receive full approval.[28]

I. *COVID-19 Vaccines*.

In the United States, three vaccines rushed to the front: two using mRNA technology and one using a viral vector [Ex. 115 ¶ 23-26]. Johnson & Johnson's vaccine is a viral vector vaccine (implementing technology since the 1970s) that uses a modified version of a virus to teach the immune system to respond [Ex. 115 ¶ 87].[29] Pfizer and Moderna's vaccines use mRNA, a novel type of vaccine, but one based on decades of research using easily accessible materials found already in many laboratories [*id.*].[30]

[28] The industry guidance has since been superseded twice, once in February 2021 and once in May 2021. FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (May 2021). Pfizer, Moderna, and Johnson & Johnson's applications were submitted in accordance with the October 2020 enhanced guidance, *see* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer-BioNTech)* (2020) https://www.fda.gov/media/144416/download; (application submitted November 20, 2020); FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Moderna)* (2020) https://www.fda.gov/media/144673/download (application submitted November 30, 2020); FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Janssen)* (2021) https://www.fda.gov/media/146338/download (application submitted February 4, 2021).

[29] *See* CDC, *Understanding Viral Vector COVID-19 Vaccines*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html (last visited July 16, 2021).

[30] *See* CDC, *Understanding mRNA COVID-19 Vaccines*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html (last visited July 16, 2021).

Having quickly adapted the existing technology, Moderna started testing the vaccine in humans in March 2020.[31] Pfizer began clinical trials in late April 2020.[32]

By the time Pfizer applied for an EUA on November 20, 2020, their application included safety, immunogenicity, and efficacy data from over 40,000 study participants in ongoing phase I, II, and III, randomized, placebo-controlled, observer-blind, clinical trials conducted in the U.S., Argentina, Brazil, Germany, South Africa, and Turkey.[33] A team of representatives from across the FDA, including experts in clinical review, toxicology, biostatistics, products, production facilities, pharmacovigilance, data integrity, bioresearch monitoring, and labeling reviewed the data submitted by Pfizer, and independently assessed the risks and benefits of the vaccine.[34] The agency granted the EUA on December 11, 2020, noting that Pfizer "met the FDA's expectations as conveyed in [the agency's] June and October guidance documents."[35]

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[31] Nat'l Insts. Health (NIH), *Experimental Coronavirus Vaccine is Safe and Produces Immune Response (Moderna)*, NIH Research Matters (July 21, 2020) https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-safe-produces-immune-response.

[32] NIH, *Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates against COVID-19 in Healthy Individuals*, https://clinicaltrials.gov/ct2/show/NCT04368728 (last visited July 16, 2021).

[33] FDA, *Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum*, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.

[34] *Id.* at 1, 49-54.

[35] FDA, *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020) https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

Moderna applied for an EUA on November 30, 2020.[36] Their application included safety, immunogenicity, and efficacy data from over 30,000 study participants in ongoing phase I, II, and III, randomized, stratified, observer-blind, placebo-controlled clinical trials conducted at 99 locations in the United States.[37] A team of representatives from across the FDA, including experts in clinical review, toxicology, biostatistics, products, production facilities, pharmacovigilance, data integrity, bioresearch monitoring, and labeling, reviewed the data submitted by Moderna, and independently assessed the risks and benefits of the vaccine.[38] The agency granted the EUA on December 18, 2020, noting that "the FDA's expectations described in [the agency's] June and October guidance documents have been met."[39]

Janssen, a Johnson & Johnson company, applied for an EUA on February 4, 2021.[40] Their application included safety, immunogenicity, and efficacy data from five studies, including two randomized, double-blind, placebo-controlled phase III trials, enrolling over 70,000 participants.[41] A team of representatives from across the FDA, including experts in clinical review, toxicology, biostatistics, products, production facilities,

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[36] FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Moderna),* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.

[37] *Id.* at 12-13.

[38] *Id.* at 1, 55-60.

[39] FDA, F*DA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020) https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

[40] FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Janssen),* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.

[41] *Id.* at 13.

pharmacovigilance, data integrity, bioresearch monitoring, and labeling, reviewed the data submitted by Johnson & Johnson, and independently assessed the risks and benefits of the vaccine.[42] The FDA granted the EUA on February 27, 2021, noting that "the vaccine meets the FDA's expectations for safety and effectiveness appropriate for authorization of a vaccine for emergency use."[43]

With these vaccines, an emerging light appeared at the end of the tunnel. As of July 17, 2021, 337,239,448 doses of vaccine have been administered, and 161 million Americans, or 48.5 percent of the total population, is fully vaccinated.[44] Of adults over the age of eighteen, 59.4 percent are fully vaccinated.[44] In Indiana, 5,749,173 doses have been administered, and 2,888,239 Hoosiers, or 49.6 percent of those over the age of twelve, are fully vaccinated.[45] Of ages 18-24, who account for 9.2 percent of the U.S. population, 11,720,847, or 42.2 percent, are fully vaccinated.[46] In Indiana, 164,098 individuals aged 20-24, or 34.7 percent, are fully vaccinated.[47]

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[42] *Id.* at 1, 59-61.

[43] FDA, F*DA Issues Emergency Use Authorization for Third COVID-19 Vaccine* (February 27, 2021) https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[44] CDC, *COVID-19 Vaccinations in the United States*, https://covid.cdc.gov/covid-data-tracker/#vaccinations (last visited July 17, 2021).

[45] *ISDH*, *Indiana COVID-19 Vaccination Dashboard*, https://www.coronavirus.in.gov/vaccine/2680.htm (last visited July 18, 2021).

[46] CDC, *COVID-19 Vaccinations in the United States*, https://covid.cdc.gov/covid-data-tracker/#vaccinations (last visited July 17, 2021).

[47] *ISDH*, *Indiana COVID-19 Vaccination Dashboard*, https://www.coronavirus.in.gov/vaccine/2680.htm (last visited July 18, 2021).

J. *Risks of Vaccines*.

Though the vaccines show remarkable effectiveness against infection and severe cases of COVID-19, and "have undergone and will continue to undergo the most intensive safety monitoring in U.S. history," they are not without risks, heretofore rare for serious risks [Ex. 115 ¶ 33].[48] Many recipients experience mild local and systemic reactions, including fever, headache, muscle pain, chills, and tiredness.[48] In very rare cases, more serious side effects seem to emerge such as allergic reactions or blood clots with low platelets [Ex. 115 ¶ 66; Ex. 117 ¶ 38].[48] For young men specifically, experts are studying a temporal correlation between vaccines and myocarditis, an inflammation of the heart muscle, or pericarditis, inflammation of tissue around the heart [Ex 117 ¶ 37].[49] However, the risk of myocarditis appears to be exceptionally small [Ex. 115 ¶ 67].[50]

The medical community closely tracks adverse events from the vaccine in a national database called VAERS, or the Vaccine Adverse Event Reporting System.[51] This database is used to track adverse events temporally related to all vaccine administration, including for the COVID-19 vaccines, but it is not a definitive or final resource to

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[48] CDC, *Safety of COVID-19 Vaccines*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (last visited July 13, 2021).

[49] *See also* Han W. Kim *et al.*, *Patients with Acute Myocarditis Following mRNA COVID-19 Vaccination*, JAMA Cardiol doi:10.1001/jamacardio.2021.2828 (June 29, 2021) https://jamanetwork.com/journals/jamacardiology/fullarticle/2781602 (finding handful of patients out of 561,197, and all recovered after a few days).

[50] *See, e.g.*, Israeli Ministry of Health, *Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021*, https://www.gov.il/en/departments/news/01062021-03 (last visited July 18, 2021) (121 cases out of a total of 5,049,424 vaccinated individuals).

[51] HHS, *VAERS*, https://vaers.hhs.gov/.

conclusively prove contraindications.[52] "While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness."[53] Nevertheless, the FDA considers VAERS data when assessing whether to make changes to any approval or to apply any additional warnings to vaccines.[54] Based on this surveillance, reports of anaphylaxis appears to be rare, blood clotting concerns are rare but higher in women under the age of 50, myocarditis is rare but more common in young people, and reports of death are rare.[55]

The FDA has issued revisions to the patient and provider fact sheets about the risk of myocarditis and pericarditis acknowledging data about this risk.[56] Furthermore, the FDA and CDC recommended a pause on the use of Johnson & Johnson's vaccine in light of reports of clotting in young women (a pause subsequently lifted).[57] Recent changes last week occurred because of reported neurological impacts of the Johnson & Johnson

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[52] CDC, *Selected Adverse Events Reported after COVID-19 Vaccination*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (last visited July 13, 2021).

[53] CDC, *The Vaccine Adverse Event Reporting System (VAERS) Results* (July 17, 2021), https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=DBF4A737A762F523202A55E30B57.

[54] *See, e.g.*, FDA, *Coronavirus (COVID-19) Update: July 13, 2021* (July 13, 2021) (discussing concerns over VAERS reports of Guillain-Barré Syndrome following vaccination) (available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-july-13-2021).

[55] *Id.*; *see also* CDC, *The Vaccine Adverse Event Reporting System*, https://wonder.cdc.gov/vaers.html (last visited July 14, 2021); CDC, *COVID-19 Vaccination Demographics in the United States, National*, https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Demographics-in-the-United-St/km4m-vcsb (last visited July 18, 2021) (more than 24 million doses of a vaccine have been administered to this age group as of July 14, 2021)

[56] FDA, *Coronavirus (COVID-19) Update: June 25, 2021*, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021 (last visited July 13, 2021).

[57] CDC, *CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html (last visited July 13, 2021).

vaccine, based on VAERS data.[58] These refinements indicate that the ongoing safety of these vaccines are rigorously monitored by agency professionals.

K. *Herd Immunity.*

Much has been said of herd immunity at the national and state levels. The university too wants to achieve herd immunity. Herd immunity occurs when a virus cannot spread because so many of the individuals it encounters are protected against infection [Ex. 117 ¶ 14-17; Ex. 115 ¶ 43-44].[59] The students say we are there [Ex. 117 ¶ 14-17]. The university disagrees [Ex. 116 ¶ 43]. As more infectious variants emerge, some suggest the percent immunized must also increase to reach herd immunity [Ex. 115 ¶ 19-22].[60] Like many aspects of the pandemic, the point at which society is able to conclude enough people have protection from the virus is still undetermined.

The character of immunity is also uncertain. As COVID-19 is a new disease, and the vaccines are even newer, the long-term efficacy of immunity derived from vaccination and infection is not proven [Ex. 117 ¶ 68-72; Ex. 115 ¶ 70].[61] Immune responses appear to exist for at least several months following a COVID-19 infection [Ex. 117 ¶ 68-72; Ex. 319

[58] FDA, *Coronavirus (COVID-19) Update: July 13, 2021* (July 13, 2021) (discussing concerns over VAERS reports of Guillain-Barre syndrome following vaccination) (available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-july-13-2021).

[59] Christie Aschwanden, *The False Promise of Herd Immunity for COVID-19*, Nature, https://www.nature.com/articles/d41586-020-02948-4 (Last visited July 13, 2021).

[60] *See* Kamran Kadknoda, *Herd Immunity to COVID-19*, Am. J. Clin Gypsyamber D'Souza & David Dowdy, *What is Herd Immunity and How Can We Achieve It With COVID-19?*, https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html (last visited July 13, 2021).

[61] *See* Jennifer M. Dan, *Immunological Memory to SARS-CoV-2 Assessed for Up to 8 Months after Infection*, 371(6529) Science eab4063 (Feb. 5, 2021); *See* Chris Baraniuk, *How Long Does Covid-19 Immunity Last?*, 373 BMJ n1605 (June 30, 2021) https://www.bmj.com/content/373/bmj.n1605.short?rss=1.

¶ 1].[61] Dr. Beeler explains a recent study that suggests that vaccination after COVID-19 exposure secures more protection than just antibodies from prior contraction of the virus—in terms of duration and strength against the prevailing variants [Ex. 128 at 82].[62]

The parties disagree over the relative risk of college students spreading the virus to the community, with the students contending the risk is very low [*see* Ex. 117 ¶ 29-31], and the university contending the risk is real [*see* Ex. 115 ¶ 51-52]. There is no consensus on this issue, and some research has not been peer-reviewed.[63] Nevertheless, peer-reviewed research suggests that outbreaks on college campuses pose a risk of spreading to neighboring communities.[64] Data suggest that as of May 26, 2021, 260,000 infections have been linked to universities and colleges in 2021, including 3,062 reported cases across the Indiana University system—though this data appears limited to students, faculty members, staff members, and other college workers, and thus does not provide insight on greater community spread [*see* Ex. 115 ¶ 52].[65] Universities are unique

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[62] *See* Delphine Planas *et al.*, *Reduced Sensitivity of SARS-CoV-2 Variant Delta to Antibody Neutralization*, Nature doi: 10.1038/s41586-021-03777-9, 3 (July 8, 2021) (online ahead of print), https://www.nature.com/articles/s41586-021-03777-9_reference.pdf.

[63] *See* Callum R.K. Arnold *et al.*, *SARS-CoV-2 Seroprevalence in a University Community*: *A Longitudinal Study of the Impact of Student Return to Campus on Infection Risk Among Community Members*, medRxiv Preprint (Feb 19, 2021) https://pubmed.ncbi.nlm.nih.gov/33619497/ (minimum impact on community); *but see* Gabriel T. Bosslet *et al.*, *The Effect of In-Person Primary and Secondary School Instruction on County-Level SARS-CoV-2 Spread in Indiana*, Clinical Infectious Diseases (manuscript accepted) https://doi.org/10.1093/cid/ciab306 (Apr. 13, 2021) (finding that a 10 percent increase in K-12 students attending school in-person corresponded to a daily increase of 0.336 cases per 100,000 residents in the community).

[64] *See* Hannah Lu *et al.*, *Are College Campuses Superspreaders? A Data-Driven Modeling Study*, Computer Methods in Biomechanics & Biomedical Eng'g, https://doi.org/10.1080/10255842.2020.1869221 (Jan. 13, 2021) (Stanford researchers looked at county spikes following outbreaks at 30 universities and concluded that outbreaks at 17 campuses translated directly into respective community spikes).

[65] N.Y. Times, *Tracking Coronavirus Cases at U.S. Colleges and Universities (May 26, 2021)*, https://www.nytimes.com/interactive/2021/us/college-covid-tracker.html (last visited July 13, 2021). The New York Times appears to be the most comprehensive database for tracking COVID-19 cases across U.S. colleges and universities, collecting and compiling data from individual universities, local health

environments, with students, faculty, and staff often in close contact, particularly given the number that call Indiana University home.

L. *The Student's Objections.*

The eight plaintiffs in this case, all students of Indiana University, don't want the vaccine. Six of the eight have received exemptions already. One would qualify if she applied. The other appears not to qualify for an exemption.

Ryan Klaassen is concerned that the vaccine is too new to be safe [Ex. 120 at 18]. He objects to the masking and testing requirements because of their unreasonableness and the potential for discrimination [*id.* 36]. He complied with the university's mask policy during his freshman year, including wearing a mask in most places, and has undergone many COVID-19 tests [*id.* 27].

Jaime Carini has up to seven more years to finish her joint dissertation after she finishes her exams [Ex. 121 at 23]. Her physician provided a letter saying she should not take the vaccine, though the letter has not been presented to the university or to the court [Ex. 121 at 52-53]. She applied for a religious exemption and received one [*id.* 57]. She did not apply for a medical exemption [Ex. 100 ¶ 187 (never applied for one); Ex. 121 at 60]. Despite wearing a mask in public spaces when required and previously taking several COVID-19 tests, she objects to the mask policy because it makes it difficult for her to breathe, she gets bad acne from the mask, and she struggles deadlifting with a mask [Ex.

departments, counties, states, and through open record requests at universities who would not otherwise provide data.

121 at 44, 47-51]. She also doesn't like surrendering her biological information for testing [*id.* 55]. In total, she views the university's policy as a cultural harm [*id.* 55-56].

Daniel Baumgartner says he has a deeply held religious objection to wearing a mask and being tested. He wore a mask while attending religious services, in school, and at stores in the past [Ex. 122 at 8, 18-20]. He previously contracted COVID-19 and says he has "natural" COVID antibodies, though for how long he doesn't know [*id.* 21-22].

Ashlee Morris believes she previously contracted COVID-19 [Ex. 123 at 27-28]. She has been tested before and acknowledges that she did not suffer any lasting harm from the test [*id.* 35]. She wore a mask to work, on a plane, and when she went to a casino, but not to stores even if signs were posted [*id.* 35-37]. She testifies she has a religious objection to wearing a mask and being tested [*id.* 45-48]. She admits that she has never experienced discrimination because she did not wear a mask [*id.* 56].

Seth Crowder has a deeply held religious objection to wearing a mask and being tested [Ex. 124 at 29-30]. He has worn a mask once or twice a week since March 2020, including to stores and restaurants [*id.* 22].

Macey Policka objects generally to the extra requirements of masks and tests because of the minimal risk to those in her age group, also stating that vegans and pescatarians are less likely to experience serious illness [Ex. 125 at 28]. She lived on the Bloomington campus for the 2020 school year, complied with the university's masking policy, and underwent weekly mitigation testing from which she states she did not suffer any harm [*id.* 14-18]. She has never experienced judgment or alienation due to wearing a

mask at the university but is concerned about having to wear a mask while pursuing her theatre degree [*id.* 25, 42].

Margaret Roth objects to the mask and testing requirements because she thinks masks are silly and she claims nasal swabs cause cancer [Ex. 126 at 12, 29, 35-36]. She has worn a mask while at school, shopping, and working [*id.* 31-33]. She has a religious objection to the vaccine but did not file for an exemption because she doesn't want to be subject to testing or wear a mask [*id.* 45-47].

Natalie Sperazza complied with the university testing and masking requirement during the 2020 school year [Ex. 127 at 30-32]. She has been tested for COVID-19 many times, including while working at Amazon, where she would occasionally go to get tested just to have a break [*id.* 25-26, 30].

M. *Procedure.*

The students filed a preliminary injunction motion. The court expedited briefing and discovery. The court held oral argument on July 13, 2021, after receiving the record the day before. The parties stipulated to the admissibility of all exhibits. The parties stipulated not to present additional testimony at the preliminary injunction hearing because it would duplicate what they had presented already.

Further evidentiary hearing is generally required for a preliminary injunction motion when there are "genuine issues of material fact" and either side "intends to introduce evidence [at the hearing] that if believed will so weaken [the other's] case as to affect the judge's decision on whether to issue the injunction." *Ty, Inc. v. GMA Accessories, Inc.*, 132 F.3d 1167, 1171 (7th Cir. 1997). That said, such a hearing isn't necessary when the

evidence would essentially duplicate the declarations, depositions, and other documents the parties have already submitted. *See Goodman v. Ill. Dep't of Fin. & Pro. Regul.*, 430 F.3d 432, 439 (7th Cir. 2005) (summarizing *Ty, Inc.*, 132 F.3d at 1171); *Ty, Inc.*, 132 F.3d at 1171. No additional hearing was necessary here. The court has considered over a hundred written exhibits, including sworn depositions and declarations, and heard three hours of argument. This motion is ripe for immediate ruling.

STANDING

Before considering the preliminary injunction motion, the court must ensure its jurisdiction. *See Common Cause Ind. v. Lawson*, 937 F.3d 944, 949 (7th Cir. 2019); *Simic v. City of Chicago*, 851 F.3d 734, 738 (7th Cir. 2017). The United States Constitution confines the federal judiciary's power to "Cases" and "Controversies." U.S. Const. Art. III § 2. For a case or controversy to exist, a plaintiff must have standing—an injury, fairly traceable to the defendant's conduct, that the court's decision will likely redress. *Uzuegbunam v. Preczewski*, 141 S. Ct. 792, 797 (2021); *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

Indiana University raises the issue of standing. Of the eight students here, six have received an exemption under the university's policy and one (Margaret Roth) qualifies so long as she pursues it. This leaves one student (Natalie Sperazza) who yet faces an unexemptible choice this semester: either she gets vaccinated or she cannot attend Indiana University this fall. She doesn't qualify for an exemption. At minimum, she has standing—an injury fairly traced to Indiana University's decision to mandate the vaccine and one the court can redress. *See Uzuegbunam*, 141 S. Ct. at 797; *Taylor v. McCament*, 875 F.3d 849, 853 (7th Cir. 2017).

The court has subject matter jurisdiction under Article III so long as one plaintiff has standing. *See Horne v. Flores*, 557 U.S. 433, 446 (2009); *Massachusetts v. E.P.A.*, 549 U.S. 497, 518 (2007). Even when the standing of others may prove doubtful, *see*, *e.g.*, *Chi. Joe's Tea Room, LLC v. Vill. of Broadview*, 894 F.3d 807, 813 (7th Cir. 2018), the court's jurisdiction remains intact so long as one plaintiff has demonstrated standing to assert her rights, *Horne*, 557 U.S. at 446. The court thus may proceed to this preliminary injunction motion without addressing the standing of the other students. *See id.*

That said, the court remains mindful (and the reader should too) that it cannot issue a mere advisory opinion. Article III's "case or controversy" requirement prohibits "advisory opinions that do not affect the rights of the parties before the court." *Matlin v. Spin Master Corp.*, 979 F.3d 1177, 1181 (7th Cir. 2020) (citation omitted). The court isn't a law office established for legal advice—the federal judiciary decides cases, not hypothetical outcomes. If the court's decision doesn't affect a litigant's rights, "the aggrieved party [is] unable to illustrate the redressability component of standing, rendering any judicial decision in the case an impermissible advisory opinion." *United States v. Brixen*, 908 F.3d 276, 280 (7th Cir. 2018). In short, the court won't decide today issues that would not redress the injuries these particular students allege.

PRELIMINARY INJUNCTION STANDARD

A preliminary injunction is a "very far-reaching power, never to be indulged [] except in a case clearly demanding it." *Cassell v. Snyders*, 990 F.3d 539, 544 (7th Cir. 2021) (quoting *Orr v. Shicker*, 953 F.3d 490, 501 (7th Cir. 2020)). To obtain an injunction, the students "must make a threshold showing that: (1) absent preliminary injunctive relief,

[they] will suffer irreparable harm in the interim prior to a final resolution; (2) there is no adequate remedy at law; and (3) [they have] a reasonable likelihood of success on the merits." *Tully v. Okeson*, 977 F.3d 608, 612-13 (7th Cir. 2020) (quoting *Turnell v. CentiMark Corp.*, 796 F.3d 656, 662 (7th Cir. 2015)); *see also Winter v. Nat. Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). If they make these threshold showings, the court "consider[s] the balance of harms between the parties and the effect of granting or denying a preliminary injunction on the public interest." *Tully*, 977 F.3d at 613 (quotation omitted).

ANALYSIS

A. *These Students Aren't Likely to Succeed on the Merits.*

No case to date has decided the constitutionality of whether a public university, such as Indiana University, may mandate that its students receive a COVID-19 vaccine.[66] Given the unique constitutional nature of this case, the court assesses the students' likelihood of success first, ever mindful that this determination proves preliminary only.

The students must show a likelihood of success on the merits. This is their burden. This showing must be "strong," which "normally includes a demonstration of how the applicant proposes to prove the key elements of [the] case." *Tully*, 977 F.3d at 613 (quoting *Ill. Republican Party v. Pritzker*, 973 F.3d 760, 762-63 (7th Cir. 2020)). Though an "applicant need not show that [she] definitely will win the case," a "mere possibility of success is not enough." *Pritzker*, 973 F.3d at 762-63.

[66] A district court recently upheld a COVID-19 vaccine mandate, albeit by a private employer (hospital). *See Bridges v. Houston Methodist Hosp.*, 2021 U.S. Dist. LEXIS 110382, 7-8 (S.D. Tex. June 12, 2021).

1. *The Fourteenth Amendment.*

The students pursue a Fourteenth Amendment claim. The Bill of Rights—the first ten amendments to the United States Constitution—originally applied only to the federal government. *See McDonald v. City of Chicago*, 561 U.S. 742, 754 (2010). Individual states weren't obligated to respect its protections against citizens. *See Livingston's Lessee v. Moore*, 32 U.S. 469, 551-52 (1833); *see also McDonald*, 561 U.S. at 754 (citing *Moore*, 32 U.S. at 551-52). This changed with the Fourteenth Amendment in 1868.

The Fourteenth Amendment "furnishe[d] an additional guaranty against any encroachment by the States upon the fundamental rights [that] belong to every citizen as a member of society." *United States v. Cruikshank*, 92 U.S. 542, 554 (1875); *accord United States v. Morrison*, 529 U.S. 598, 622 (2000); *see also* 42 U.S.C. § 1983; *Albright v. Oliver*, 510 U.S. 266, 271 (1994); *Power v. Summers*, 226 F.3d 815, 819 (7th Cir. 2000). For today's dispute, the Fourteenth Amendment says no "State [may] deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV § 1. This due process clause applies to the States and protects, absent a deprivation with due process, certain rights to life, liberty, and property. Indiana University is a state actor, *Medlock v. Trustees of Ind. Univ.*, 738 F.3d 867, 871 (7th Cir. 2013), so the Fourteenth Amendment also applies to it.

As interpreted, the Fourteenth Amendment has both substantive and procedural dimensions. *See Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985). This case concerns substantive due process—"a substantive limitation on the power of government to legislate." *Durigan v. Sanitary Dist. No. 4*, 5 F. Appx. 492, 494 (7th Cir. 2001); *see Campos*

v. Cook Cnty., 932 F.3d 972, 975 (7th Cir. 2019). The Fourteenth Amendment protects a person's substantive rights in life, liberty, and property. U.S. Const. amend. XIV § 1. Certain rights or liberties have been deemed "fundamental," so they receive greater protection. *See Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997).

Bearing that in mind, the court initially approaches this case in a two-fold manner. First, the law requires a "careful description" of the asserted right or liberty. *See id.* at 721; *see*, *e.g.*, *Doe v. City of Lafayette*, 377 F.3d 757, 768 (7th Cir. 2004). Second, the court must determine whether the so-defined right or liberty is fundamental under the Constitution. *See Glucksberg*, 521 U.S. at 721; *Doe*, 377 F.3d at 768. The Fourteenth Amendment's due process clause specially protects fundamental rights and liberties—those that objectively are "deeply rooted in this Nation's history and tradition" and so "implicit in the concept of ordered liberty" that "neither liberty nor justice would exist if they were sacrificed." *Glucksberg*, 521 U.S. at 721 (citations omitted); *accord Khan v. Bland*, 630 F.3d 519, 535 (7th Cir. 2010). These guideposts direct and restrain due process decisionmaking. *Glucksberg*, 521 U.S. at 721.

Many rights explicitly secured in the Bill of Rights are considered fundamental, having been gradually incorporated as substantive guarantees under the Fourteenth Amendment. These fundamental rights include, as examples, freedom of speech, *Gitlow v. New York*, 268 U.S. 652 (1925); freedom of the press, *Near v. Minnesota*, 283 U.S. 697 (1931); the right against cruel and unusual punishment, *Robinson v. California*, 370 U.S. 660 (1962); and the right to keep and bear arms, *McDonald*, 561 U.S. at 742. There are others.

Fundamental rights aren't limited to those specifically enumerated in the Bill of Rights. Beginning with *Griswold v. Connecticut*, 381 U.S. 479, 483 (1965), the Supreme Court recognized a right to privacy within the "penumbra" of other constitutional protections and called it fundamental. This right to privacy has included the right for both married and unmarried couples to purchase contraceptives, *see Griswold*, 381 U.S. at 484-86; *Eisenstadt v. Baird*, 405 U.S. 438, 454-55 (1972), to abortion, *see Roe v. Wade*, 410 U.S. 113, 153 (1973), to sexual privacy, *Lawrence v. Texas*, 539 U.S. 558, 578 (2003), and to marital privacy, *Obergefell v. Hodges*, 576 U.S. 644, 664-65 (2015). As these cases illustrate, privacy rights largely have been confined to "to sexual and reproductive rights, such as the right to use contraceptives or have an abortion or engage in homosexual acts." *Wolfe v. Schaefer*, 619 F.3d 782, 784 (7th Cir. 2010).

The students and university disagree on the constitutional analysis. Declaring a right or liberty fundamental has important implications. Modern constitutional jurisprudence employs a different analysis when a person's fundamental right is at stake. If the government infringes on a fundamental right, the court often applies strict scrutiny. *Glucksberg*, 521 U.S. at 721. In such circumstances, the Fourteenth Amendment "forbids the government to infringe . . . fundamental liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Id.* (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993)); *see*, *e.g.*, *Siefert v. Alexander*, 608 F.3d 974, 981 (7th Cir. 2010); *Ent. Software Ass'n v. Blagojevich*, 469 F.3d 641, 646 (7th Cir. 2006). This is the most rigorous form of constitutional scrutiny of government action.

Whereas infringements on other rights or liberties, though still constitutionally scrutinized, must meet what courts call rational basis review. *Glucksberg*, 521 U.S. at 722, *Sweeney v. Pence*, 767 F.3d 654, 668 (7th Cir. 2014). The law normally applies this standard to Fourteenth Amendment challenges to infringed liberties, if not fundamental or based on a suspect classification. *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring); *see, e.g.*, *Glucksberg*, 521 U.S. at 721. It is less stringent than strict scrutiny. Under rational basis review, "legislation is presumed to be valid and will be sustained if the classification drawn by the statute is rationally related to a legitimate state interest." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985). The students argue for strict scrutiny, and the university argues for rational basis review.

2. *The Constitution in a Public Health Crisis.*

We live in the era of the COVID-19 virus—worldwide seeing to nearly 189 million cases and 4 million deaths, with these numbers changing daily. The United States hasn't been immune. Our citizens have recovered or struggled to recover from over 33 million cases of this novel coronavirus when over 606,000 tragically have passed.[67] A public health crisis of this magnitude begs the question: how should the law respond to state action that infringes on the People's liberties during such times?

To be sure, the Constitution isn't put on the shelf. Indeed, in times of crisis, perhaps constitutional adherence proves the very anchor we all need against irrational and overweening government intrusion that would otherwise scuttle the ship. As the

[67] CDC, *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory* (July 16, 2021), https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases.

arbiters of the Constitution's checks and balances, *see Marbury v. Madison*, 5 U.S. 137, 176-78 (1803); *accord Morrison*, 529 U.S. at 616, the courts play an important role in ensuring that the government doesn't simply declare a never-ending public emergency and expand its powers *ad libitum* to the People's detriment.

Under our country's federalist system, state and federal governments share regulatory authority over public health matters. States traditionally exercise most authority under their inherent police power—and reasonably so when public health may flux and evolve by locale. States thus have the power, within constitutional limits, to pass laws that "provide for the public health, safety, and morals[.]" *Barnes v. Glen Theatre*, 501 U.S. 560, 569 (1991); *accord Glucksberg*, 521 U.S. at 729-31; *Zucht v. King*, 260 U.S. 174, 176-77 (1922), *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 24-25 (1905).

To answer the question today, the court travels back in time to 1905: a time before the modern tiers of constitutional analysis (strict scrutiny and rational basis) and one rampaged by the smallpox epidemic. In that year, the United States Supreme Court issued a leading decision in answer to this question.

In *Jacobson*, 197 U.S. at 12, Massachusetts passed a law that allowed a city, if "necessary for the public health or safety," to enforce vaccination of its citizens. If a person refused, he could be fined $5.00 (about $140.00 today). *Id.*; *Cuomo*, 141 S. Ct. at 70 (Gorsuch, J., concurring). The law allowed an exception for children who had physician-signed certificates saying they weren't fit for vaccination, but no such exemption existed for adults. *Jacobson*, 197 U.S. at 12.

The City of Cambridge, relying on this statute and acting through its board of health, ordered its citizens vaccinated for smallpox. *Id.* at 12-13. Smallpox was devastating, claiming almost 300 million lives in the 20th century before being eradicated.[68] In the early 1900s, and closer to the time that Massachusetts wrestled with the disease, there were 1,596 cases of smallpox in Boston, with 270 deaths, in a city with a population close to 561,000.[69] Massachusetts, particularly Boston, was an epicenter of one of two major smallpox outbreaks. Opponents of vaccination questioned its safety and efficacy; though generally safe, it could cause ulceration, lobar pneumonia, cellulitis, parotitis, sepsis, and tetanus, to name a few conditions.[70] Side effects ostensibly posed a greater problem than mild smallpox.[71] The smallpox vaccine wasn't risk-free in the early 1900s. That said, vaccinations had been used for some considerable time—begun by state-supported facilities in England in 1808 and mandated by many other countries throughout the 1800s before the Massachusetts mandate in 1902. *Id.* at 31, n.1. This all transpired before the FDA came into being.

Henning Jacobson refused the vaccine in Massachusetts. After a trial, a jury found him guilty of refusing the vaccine. The court sentenced him to jail until he paid the $5.00

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[68] *See D L Heymann et al., Successful Smallpox Eradication: What Can We Learn to Control COVID-19?*, 27 J. Travel Med. 1 (2020).

[69] Michael R. Albert *et al.*, *The Last Smallpox Epidemic in Boston and the Vaccination Controversy, 1901-1903*, 344 New Eng. J. Med. 375 (2001).

[70] *Id*. at 375-76.

[71] Bernard Brabin, *An Analysis of the United States and United Kingdom Epidemics (1901-5) – The Special Relationship that Tested Public Health Strategies for Disease Control*, 64 Med. Hist. 1, 26 (2020).

criminal fine. On appeal, he argued that the Massachusetts law authorizing the vaccine mandate violated his Fourteenth Amendment rights. *Id.* at 13.

The United States Supreme Court rejected his challenge. A state's police power "must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety." *Id.* at 25. This power included the "authority of a state to enact quarantine laws and health laws of every description;" and such power extended to "all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states." *Id.* The Constitution gave Massachusetts broad deference: a court should only intervene "if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is beyond all question, a plain, palpable invasion of rights secured by the fundamental law." *Id.* at 31.

Of note, *Jacobson* upheld only the constitutionality of the state statute, *id.* at 39 ("We now decide only that the statute covers the present case, and that nothing clearly appears that would justify this court in holding it to be unconstitutional and inoperative in its application to the plaintiff in error."); and phrased its holding in terms of a reasonable regulation established "directly by legislative enactment," *id.* at 25, but the case contemplated the action of local state bodies when vested legislatively with the power to act to safeguard public health and safety, *see*, *e.g.*, *id.* at 25, 38. A State's power, "whether exercised directly by the legislature, or by a local body acting under its authority, may be exerted in such circumstances," and only "regulations so arbitrary and oppressive in

particular cases [would] justify the interference of the courts to prevent wrong and oppression." *Id.* at 38.

The students want *Jacobson* confined to its time, whereas the university believes it applies with full force. In the years since, the high court has leaned on *Jacobson* to uphold government measures intended for the public welfare under effectively rational basis review, finding the measures reasonably advancing a legitimate state interest. For example, *Zucht*, 260 U.S. at 175-77, relied on *Jacobson* to uphold a city ordinance excluding from its public schools children not having a certificate of vaccination, holding that it was within the state's police powers reasonably to so act. According to *Zucht*, *Jacobson* settled the state's power "to provide for compulsory vaccination" and, "consistently with the federal Constitution, delegate to a municipality authority to determine under what conditions health regulations shall become operative." *Id.* at 176. This was not authorization of "arbitrary power," but only that broad discretion required for the protection of the public health." *Id.* at 177. In doing so, "state and federal legislatures [enjoy] wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007) (citing *Jacobson*, 197 U.S. at 30-31).

Based on this power, states and their authorized arms have historically adopted vaccination mandates. For instance, all fifty states and the District of Columbia have laws

requiring students to receive certain vaccines before they may attend school.[72] Many align their vaccine requirements with CDC's immunization recommendations, and all laws provide exemptions for medical reasons and nearly all religious exemptions.[72] Adult vaccination mandates often have been limited to the private employment sector,[73] though not always. For instance, the State of Indiana requires all public university students to receive vaccinations for diphtheria, tetanus, measles, mumps, rubella, and meningococcal disease, save for religious and medical exemptions. *See* Ind. Code § 21-40-5-2.

Similarly, but outside the vaccination context, *Hamilton v. Regents of the University of California*, 293 U.S. 245, 264 (1934), relied on *Jacobson* to uphold a state university's decision to compel military training for its students (five years before World War II). Certain minors (not adults) were required to take a course in military science and tactics, part of training prescribed by the country's war department at the time. The students objected on religious grounds through the Fourteenth Amendment—"no more than an assertion that the due process clause of the Fourteenth Amendment as a safeguard of 'liberty' confers the right to be students in the State University free from obligation to take military training as one of the conditions of attendance." *Id.* at 262. *Hamilton* held this view "untenable," recognizing the government's duty to the people to maintain

[72] Nat'l Conf. of State Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements* (April 30, 2021), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx.

[73] Michael J. Vernick, Molly E. Whitman & McKenzie F. Miller, *The Mandate Maze*, Inside Higher Ed (May 25, 2021), https://www.insidehighered.com/views/2021/05/25/advice-legal-issues-related-vaccine-mandates-opinion.

peace and order and every citizen's "reciprocal duty, according to his capacity, to support and defend government against all enemies." *Id.* at 262-63. Justice Cardozo eloquently concurred: "The right of private judgment has never yet been so exalted above the powers and the compulsion of the agencies of government. One who is a martyr to a principle—which may turn out in the end to be a delusion or an error—does not prove by his martyrdom that he has kept within the law." *Id.* at 268.

Repose the thought whether we face just such a common enemy today in COVID-19. In this century, other than the Supreme Court's reliance on *Jacobson* in 2007, *see Gonzales*, 550 U.S. at 163, courts have returned again to its guidance during the COVID-19 pandemic. Just last year, this circuit endorsed *Jacobson*. *See Pritzker*, 973 F.3d at 763 ("The district court appropriately looked to *Jacobson* for guidance, and so do we."). The circuit held that "*Jacobson* t[ook] off the table any general challenge" to an executive order that subjected religious gatherings to recommended limits on gatherings, rather than mandatory ones. *Id.* at 763-64. The Illinois governor implemented "an order designed to address a serious public-health crisis," and *Jacobson* afforded broad deference "[a]t least at this stage of the pandemic." *Id.*

That decision was almost ten months ago—in terms of the law very recent, but in terms of this ever-evolving health crisis before the proverbial rinderpest. We are no longer at the same stage of the COVID-19 pandemic; indeed, some—like the students—argue that the pandemic is effectively over. And since this circuit's *Pritzker* decision, more cases bearing on the subject of public health in the COVID-19 pandemic have arrived.

One such decision—and one heavily briefed by the parties—is *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63 (2020). In *Cuomo*, the State of New York adopted capacity restrictions on religious institutions that treated them less favorably than so-called "essential" businesses, *id.* at 66, including liquor and hardware stores, *id.* at 69 (Gorsuch, J., concurring). *Cuomo* applied strict scrutiny because the law targeted religious practice contrary to the First Amendment, as incorporated against the states by the Fourteenth Amendment, and enjoined the limitations, saying they were not narrowly tailored to fulfill the state's compelling interest in controlling the spread of COVID-19. *Id.* at 67 (majority opinion).

Cuomo enhanced the law's focus under the First Amendment. *See Cassell*, 990 F.3d at 543 (citing *Cuomo* for the proposition that "[i]ntervening authority from the Supreme Court offers plaintiffs a greater prospect for success on the merits of their First Amendment claim than either the district court or we had expected"). So this begs another question: to what extent has *Cuomo*—if any—impacted the broad deference the court would seemingly afford a state during a pandemic under *Jacobson* to act in the interest of public health? *Cuomo*'s majority opinion never referenced *Jacobson*.

The students read *Cuomo* as implicitly overruling *Jacobson*, or at least as abrogating it. Though the Supreme Court may overrule a case without explicitly saying so, *see Levine v. Heffernan*, 864 F.2d 457, 461 (7th Cir. 1988), this is a tall task. Before a federal court concludes that the Supreme Court has implicitly overruled a prior decision, it must be "certain or almost certain that the decision or doctrine would be rejected by the higher court if a case presenting the issue came before it." *Olson v. Paine, Webber, Jackson & Curtis,*

Inc., 806 F.2d 731, 741 (7th Cir. 1986). This high bar is rarely met. *Id.* It isn't met here. *Cuomo* and *Jacobson* involved entirely different modes of analysis, entirely different rights, and entirely different kinds of restriction. *See Cuomo*, 141 S. Ct. at 70 (Gorusch, J., concurring) (saying the same). "*Jacobson* applied what would become the traditional legal test associated with the right at issue"—exactly what *Cuomo* did. *Id.* The cases walk hand-in-hand.

This history isn't all rosy. Unsuccessful thus far, the students turn to *Buck v. Bell*, 274 U.S. 200 (1927). In a rather infamous case, an eight-member majority, save for one dissenting justice, upheld the involuntary sterilization of a woman based on a Virginia law that rested on faulty science and public support for "eugenics"—the repulsive notion that the human race could be improved by controlling reproduction from those with developmental challenges, mental illness, or criminal histories. Citing *Jacobson* for the principle that "compulsory vaccination is broad enough to cover cutting the Fallopian tubes," and offering the chilling justification that "[t]hree generations of imbeciles are enough," the majority upheld the law against a Fourteenth Amendment challenge. *Id.* at 207. This case isn't *Buck*; and one over-extension of *Jacobson* merely counsels once more that the Constitution cannot be cut loose even now, in a pandemic's seeming twilight. *Cuomo*, 141 S. Ct. at 68.

Jacobson was written before the modern tiers of constitutional scrutiny, so a legitimate question is the extent to which *Jacobson* applies with full force today. This is a topic of some debate. *See, e.g.*, *id.* at 70 (Gorsuch, J., concurring) ("*Jacobson* didn't seek to depart from normal legal rules during a pandemic, and it supplies no precedent for doing

so."); *Calvary Chapel Dayton Valley v. Sisolak*, 140 S. Ct. 2603, 2608 (2020) (Alito, J., dissenting) ("it is a mistake to take language in *Jacobson* as the last word on what the constitution allows public officials to do during the COVID-19 pandemic"); *Big Tyme Inv., LLC v. Edwards*, 985 F.3d 456, 470-71 and n.3 (5th Cir. 2021) (Willett, J., concurring) ("I am not the first to express doubts about *Jacobson*"); *S. Bay United Pentecostal Church v. Newsom*, 959 F.3d 938, 943 n.2 (9th Cir. 2020) (Collins, J., dissenting) ("I am unable to agree with the Fifth Circuit's conclusion that *Jacobson* instructs that all constitutional rights may be reasonably restricted to combat a public health emergency.") (quotations omitted), *cert. denied*, 140 S. Ct. 1613 (2020). No Supreme Court opinion has overruled or abrogated *Jacobson*.

Considering the modern tiers of constitutional scrutiny, the court reads *Jacobson* and *Cuomo* harmoniously, appreciating their respective spheres. Though *Jacobson* was decided before tiers of scrutiny, it effectively endorsed—as a considered precursor—rational basis review of a government's mandate during a health crisis. *See Jacobson*, 197 U.S. at 31; *see also Cuomo*, 141 S. Ct. at 70 (Gorusch, J., concurring). In its words, if a law purporting to be enacted to protect public health "has no real or substantial relation to [that legitimate aim]" or if the law proves "a plain, palpable invasion of rights secured by the fundamental law," the court's job is to give effect to the Constitution. *Jacobson*, 197 U.S. at 31. Should the court have this melding of history and modernity wrong in faithfully adhering to the Fourteenth Amendment's plain original meaning of "life" and "liberty," comfort should come in knowing that *Jacobson*, whether rational basis review by any other name, leads to the same result today.

This view remains consistent with the right at stake in *Jacobson*: though a true "liberty" proved at stake—the right to refuse a vaccine during a smallpox epidemic—this interest in bodily autonomy, though protected by the Constitution, wasn't fundamental under the Constitution to require greater scrutiny than rational basis review. *See Sweeney*, 767 F.3d at 668 (rational basis review for infringements on non-fundamental rights). At the same time, *Jacobson* didn't hold that the government's authority in a pandemic balloons for it do whatever it wants in the name of public safety.

Jacobson instead counseled that federal courts should require a rational relation to a legitimate interest in public health. *See Jacobson*, 197 U.S. at 31; *Cuomo*, 141 S. Ct. at 70 (Gorsuch, J., concurring). That *Cuomo* imposed heightened scrutiny of the government's interference with the free exercise of religion—a fundamental right under the First Amendment—was presciently contemplated a century beforehand by *Jacobson*: a court should intervene if a state imposes a regulation that is "beyond all question, a plain, palpable invasion of rights secured by the *fundamental* law." *Jacobson*, 197 U.S. at 31 (emphasis added). Because *Cuomo* involved a fundamental right, a "right[] secured by the fundamental law" under today's jurisprudence, the court intervened. *See Cuomo*, 141 S. Ct. at 67; *see also Glucksberg*, 521 U.S. at 721 (Fourteenth Amendment forbids the government to infringe "fundamental" liberty interests at all, unless it has narrowly tailored its law to serve a compelling state interest). The Constitution's original meaning should be so enduring.

The university seems to argue that *Jacobson* gave even more deference than rational basis review during a public health crisis, but not fairly so; and, even then, *Jacobson* cannot

be taken once more too far. *See, e.g.*, *Big Tyme*, 985 F.3d at 467; *ARJN #3 v. Cooper*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 22286, 19 (M.D. Tenn. Feb. 5, 2021); *Let Them Play MN v. Walz*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 23485, 15 (D. Minn. Feb. 8, 2021); *Culinary Studios, Inc. v. Newsom*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 23775, 38-39 (E.D. Cal. Feb. 8, 2021); *Oakes v. Collier Cnty.*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 15174, 4 n.4 (M.D. Fla. Jan. 27, 2021); *M. Rae, Inc. v. Wolf*, __ F. Supp.3d __, 2020 U.S Dist. LEXIS 241961, 16 n.25 (M.D. Pa. Dec. 23, 2020); *Denver Bible Church v. Azar*, 494 F. Supp.3d 816, 829 (D. Colo. 2020); *AJE Enterprise LLC v. Justice*, 2020 U.S. Dist. LEXIS 222186, 12 (N.D. W. Va. Oct. 7, 2020).

Jacobson doesn't justify blind deference to the government when it acts in the name of public health or in a pandemic. For instance, the decision left the door open for people with legitimate medical concerns to challenge the vaccine mandate. *See Jacobson*, 197 U.S. at 38-39. And the deference owed to the States during a pandemic or public health crisis under *Jacobson* doesn't extend indefinitely. *See Pritzker*, 973 F.3d at 763.

> [A]t the outset of an emergency, it may be appropriate for courts to tolerate very blunt rules. . . . [B]ut a public health emergency does not give . . . public officials *carte blanche* to disregard the Constitution for as long as the medical problem persists. As more medical and scientific evidence becomes available, and as States have time to craft policies in light of that evidence, courts should expect policies that more carefully account for constitutional rights.

Calvary Chapel, 140 S. Ct. at 2605 (Alito, J., dissenting); *accord Cassell*, 458 F. Supp.3d at 993-94 ("courts must remain vigilant, mindful that government claims of emergency have served in the past as excuses to curtail constitutional freedoms.").

In short, the Constitution doesn't permit the government to declare a never-ending public emergency and expand its powers arbitrarily. *See Belcher v. Norton*, 497 F.3d 742, 753 (7th Cir. 2007) ("substantive due process . . . affords protection of the individual against arbitrary action of government"). Instead, as our country and communities progress through a pandemic, the government must continually update its practices in light of the most recent medical and scientific developments. And a law or policy should be written with a mindset that medicine and science, and the circumstances that they create, will evolve, and so must the law or policy evolve or be revisited in amendment.

In sum, the law today recognizes *Jacobson* as a precursor to rational basis review. This is consistent with statements of many justices who continue to acknowledge *Jacobson* as good law, albeit with constitutional restraint.[74] Government action that infringes on the liberty interest here, as in *Jacobson*, is subject to rational basis review. *See Sweeney*, 767 F.3d at 668.

[74] *See, e.g., Democratic Nat'l Comm. v. Wisconsin State Legislature*, 141 S. Ct. 28, 43 (2020) (Kagan, J., dissenting). ("To be sure, deference is usually due to a legislature's decisions about how best to manage the COVID pandemic.") (citing *South Bay*, 140 S. Ct. at 1613-14) (Roberts, C.J., concurring in denial of an injunction seeking to prevent a COVID-19 executive order); *South Bay*, 140 S. Ct. at 1613 (Roberts, C.J., concurring); *Calvary Chapel*, 140 S. Ct. at 2608 (Alito, J., dissenting) ("Language in *Jacobson* must be read in context"); *id.* at 2614 (Kavanaugh, J., dissenting); *Cuomo*, 141 S. Ct. at 71 (Gorsuch, J., concurring); *Cuomo*, 141 S. Ct. at 79 (Sotomayor, J., dissenting) (courts "play a deadly game in second guessing the expert judgment of health officials about the environments in which a contagious virus, now infecting a million Americans each week, spreads most easily"); *Glucksberg*, 521 U.S. at 742 (Stevens, J., concurring) ("As Justice Brennan pointed out in his *Cruzan* dissent, we have upheld legislation imposing punishment on persons refusing to be vaccinated . . . . In most cases, the individual's constitutionally protected interest in his or her own physical autonomy, including the right to refuse unwanted medical treatment, will give way to the State's interest in preserving human life.").

3. *Defining the Right & Constitutional Analysis.*

The students assert a right to refuse the vaccine, saying the mandate infringes on their bodily autonomy and medical privacy. Indiana University throws a challenge flag here. To it, these students are merely saying they have a right to refuse a vaccine *so that* they may attend college. The university says the right being infringed then isn't the right to refuse a vaccine, but the right to attend college. Indeed, if they choose to forego college at Indiana University, there is no vaccine requirement. To the university, the students aren't being forced to take the vaccination against their will; they can go to college elsewhere or forego college altogether. If this case were merely that, merely the right to attend university, this state action wouldn't trample on their rights. There is no fundamental or constitutional right to a college education, *see, e.g.*, *Charleston v. Bd. of Trustees*, 741 F.3d 769, 774 (7th Cir. 2013); *Bissessur v. Ind. Univ. Bd. of Trustees*, 581 F.3d 599, 601 (7th Cir. 2009); *Williams v. Wendler*, 530 F.3d 584, 589 (7th Cir. 2008), much less one at a particular institution.

But that's not what this case concerns, and that's not the liberty at stake. The "unconstitutional conditions doctrine" forbids the university from pulling the rug out from under the students in a roundabout way. Under this doctrine, argued by the students as "coercion," "the government may not deny a benefit to a person because he exercises a constitutional right." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (citations omitted); *Regan v. Taxation with Representation of Wash.*, 461 U.S. 540, 545 (1983). This doctrine protects constitutional rights "by preventing the government from coercing people into giving them up." *Koontz*, 570 U.S. at 604. It "aims to prevent

the government from achieving indirectly what the Constitution prevents it from achieving directly." *Planned Parenthood of Ind. v. Comm'r*, 699 F.3d 962, 986 (7th Cir. 2012). The students say this state actor is denying a benefit—a public university education—because they are exercising a constitutional right to refuse a vaccine.

The first step in an unconstitutional condition claim "is to identify the nature and scope of the constitutional right arguably imperiled by the denial of a public benefit." *Id.* Here, the Fourteenth Amendment "liberty" at stake is a college student's right to refuse a vaccine, today at this stage of the pandemic [Tr. 26, 30-31]. The Supreme Court has assumed (using its word) and strongly suggested that individuals have a constitutional right to refuse unwanted medical treatment, *see, e.g., Cruzan v. Director, Missouri Dept. of Health* 497 U.S. 261, 279 (1990); *Glucksberg*, 521 U.S. at 720. *Cruzan* held that a competent individual had a constitutional right to refuse unwanted lifesaving hydration and nutrition; and *Glucksberg* recognized that an individual had a liberty interest in refusing unwanted lifesaving medical treatment, though not any fundamental right to assisted suicide. *See Cruzan*, 497 U.S. at 279; *Glucksberg*, 521 U.S. at 728.

But in these, and in other cases, this liberty interest has remained confined either by duly enacted and constitutional state laws or the state's legitimate interests that it had rationally pursued in regulation. *See also Washington v. Harper*, 494 U.S. 210, 221-22 (1990) (prisoner has a "significant liberty interest in avoiding the unwanted administration of antipsychotics drugs under the Due Process Clause . . . [but] no greater right than that recognized under state law"); *Vitek v. Jones*, 445 U.S. 480, 492 (1980) ("Compelled treatment in the form of mandatory behavior modification programs . . . was a proper

factor to be weighed by the District Court. . . . Were an ordinary citizen to be subjected involuntarily to these consequences, it is undeniable that protected liberty interests would be unconstitutionally infringed absent compliance with the procedures required by the Due Process Clause."); *Ingraham v. Wright*, 430 U.S. 651, 673, 683 (1977) ("Among the historic liberties so protected was a right to be free from, and to obtain judicial relief for, unjustified intrusions on personal security. . . . The Eighth Amendment's prohibition against cruel and unusual punishment is inapplicable to school paddlings, and the Fourteenth Amendment's requirement of procedural due process is satisfied by Florida's preservation of common-law constraints and remedies.")

The rights recognized (or assumed) in these cases weren't "simply deduced from abstract concepts of personal autonomy." *Glucksberg*, 521 U.S. at 725. They were rooted in longstanding common law rules or legal traditions consistent with this Nation's history. *See id.* The students, quite skillfully represented in this emergency setting, offer no preliminary record of such historic rules, laws, or traditions that would facilitate the court's announcement, now in mere days from receiving this case, that a right to refuse a vaccine is anything more than a significant liberty under the Fourteenth Amendment.

The dearth of this record isn't a passing point. Indeed, both *Cruzan* and *Glucksberg* were limited to an individual's choice related to the refusal of lifesaving subsistence or medical treatment—with no ramifications to the physical health of others. Vaccines address a collective enemy, not just an individual one. Indeed, "the elimination of communicable diseases through vaccination [is] one of the greatest achievements of public health in the 20th century," *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 226 (2011) (Scalia,

J.) (citation and quotations omitted), and it continues to be so now in this century. A vaccine is implemented as a matter of public health, and historically hasn't been constitutionally deterred from state mandate. *See, e.g.*, *Zucht*, 260 U.S. at 176-77; *Jacobson*, 197 U.S. at 30-31.

In the backdrop of the Fourteenth Amendment's ratification in 1868, for instance, England had already passed its first compulsory vaccination act for smallpox in 1853 (and so had many countries). *See Jacobson*, 197 U.S. at 31, n.1. Science wasn't absolute or infallible at that time—nor is it today. But the "possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases." *Id.* at 35. Appreciating the relative risks of vaccines, they nonetheless "are effective in preventing outbreaks of disease only if a large percentage of the population is vaccinated." *Wyeth*, 562 U.S. at 227.

Added comfort comes from the consistent use of rational basis review to assess mandatory vaccination measures. *See, e.g.*, *Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944) (parent "cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds" and "[t]he right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death"); *Zucht*, 260 U.S. at 176-77; *Jacobson*, 197 U.S. at 30-31; *Phillips v. City of New York*, 775 F.3d 538, 542-43 (2d Cir. 2015); *Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. Appx. 348, 355-56 (4th Cir. 2011); *W.D. v. Rockland Cnty.*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 33515, 74 (S.D.N.Y. Feb. 22, 2021); *Doe v. Zucker*, __ F. Supp.3d __, 2021 U.S.

Dist. LEXIS 28937, 111 (N.D.N.Y. Feb. 17, 2021); *Connecticut Citizens Defense League, Inc. v. Lamont*, 465 F. Supp.3d 56, 72 (D. Conn. 2020); *Middleton v. Pan*, 2016 U.S. Dist. LEXIS 197627, 20 (C.D. Cal. Dec. 15, 2016); *George v. Kankakee Cmty. Coll.*, 2014 U.S. Dist. LEXIS 161379, 8-9 (C.D. Ill. Oct. 27, 2014), *recommendation adopted*, 2014 U.S. Dist. LEXIS 160737, 1-2; *Boone v. Boozman*, 217 F. Supp.2d 938, 954 (E.D. Ark. 2002).

Given over a century's worth of rulings saying there is no greater right to refuse a vaccination than what the Constitution recognizes as a significant liberty, the court declines the students' invitation to extend substantive due process to recognize more than what already and historically exists. *See Glucksberg*, 521 U.S. at 721; *Harper*, 494 U.S. at 221-22; *Prince*, 321 U.S. at 166-67; *Zucht*, 260 U.S. at 176-77; *Jacobson*, 197 U.S. at 30-31.

Quite separately from this, the Constitution never provides a fundamental right to a collegiate education. Nor does it secure as a fundamental liberty a student's right to attend a public university no matter his or her vaccinated status. The court isn't saying a student doesn't have the right to choose. Of course every individual does—subject to the state's reasonable measures designed to pursue legitimate ends of disease control or eradication.

The students argue that the university's vaccine mandate doesn't provide for informed consent. "The notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Cruzan*, 497 U.S. at 269. Informed consent "entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each." *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972). The students acknowledge that, for medical products under an EUA like the

three COVID-19 vaccines, HHS must establish conditions to facilitate informed consent. *See* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). HHS must ensure that individuals taking the vaccine are informed "that the Secretary has authorized the emergency use of the product," "of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown," and "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." *Id.*

The students admit that the informed consent requirement under the EUA statute only applies to medical providers. The university isn't directly administering the vaccine to its students; instead, it is requiring students to obtain the vaccine from a medical provider and to attest that they have been vaccinated, save for certain exemptions. The students will be informed of the risks and benefits of the vaccine and of the option to accept or refuse the vaccine by their medical providers. *See id.* The university isn't forcing the students to undergo injections. The situation here is a far cry from past blunders in medical ethics like the Tuskegee Study.[75]

The university is presenting the students with a difficult choice—get the vaccine or else apply for an exemption or deferral, transfer to a different school, or forego school for the semester or altogether. But this hard choice doesn't amount to coercion. The

[75] *See* CDC, *The U.S. Public Health Service Syphilis Study at Tuskegee* (as part of a study on the history of untreated syphilis, "researchers did not collect informed consent from participants and they did not offer treatment, even after it was widely available"), https://www.cdc.gov/tuskegee/index.html (last visited July 16, 2021).

students taking the vaccine are choosing it among other options, and before the shot reaches their arms, they are made aware of the risks and the option to refuse.

One last point before moving on. As a final push, the students argue that the vaccination requirement violates their free exercise of religion. The First Amendment says "Congress shall make no law . . . prohibiting the free exercise" of religion. U.S. Const. amend. I. The Supreme Court has declared this right to exercise religion as fundamental and subject to strict scrutiny. *See Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940). But the Constitution also permits general regulations that incidentally burden religious practices: the "right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)." *Employment Division v. Smith*, 494 U.S. 872, 879 (1992) (quotations omitted). Neutral and generally applicable regulations need only be supported by a rational basis. *Ill. Bible Colleges Ass'n v. Anderson*, 870 F.3d 631, 639 (7th Cir. 2017).

The vaccine mandate is a neutral rule of general applicability. It applies to all students, whether religious or not. It doesn't discriminate among religions. Indeed, the university has chosen to *enable* the practice of religion by providing a religious exemption to this vaccination requirement—one that the university, on this record, has freely granted to students if they request it, no questions asked. This is consistent with the Constitution. *See Nikolao v. Lyon*, 875 F.3d 310, 316 (6th Cir. 2017) (religious plaintiff had no constitutional right to an exemption from mandatory vaccination law for public school students, though state provided one); *Phillips*, 775 F.3d at 543 (state "could

constitutionally require that all children be vaccinated in order to attend public school. . . . [but the State went] beyond what the Constitution requires by allowing an exemption for parents with genuine and sincere religious beliefs"); *see also Workman*, 419 F. Appx. at 356; *Whitlow v. California*, 203 F. Supp.3d 1079, 1084 (S.D. Cal. 2016); *Boone*, 217 F. Supp.2d at 954. Indiana University adopted a religious exemption, despite a religious-neutral vaccine mandate, which the law views as a matter of grace. Indeed, six of the eight students here applied for just such a religious exemption and obtained one.

In short, based on this analysis, all roads effectively lead to rational basis review: *Jacobson* as a precursor to or stand-alone iteration of it, the modern tiers of constitutional scrutiny, the unconstitutional conditions doctrine, and the First Amendment as applied through the Fourteenth Amendment to this state actor. And to this road once traveled the court now turns.

4. *On This Preliminary Record, Non-Exempt Students Haven't Shown a Likelihood of Success on their Claim that Indiana University Lacks a Rational Basis for Its Vaccine Mandate.*

Determining that the students have a liberty interest under the Fourteenth Amendment's due process clause doesn't end the analysis. *See Cruzan*, 497 U.S. at 278. To decide whether the students' constitutional rights have been violated, or more appropriately whether they are likely to succeed on such a claim, the court must balance their liberty against the relevant state interests in accord with the Constitution. *See id.* Two students aren't exempt from the COVID-19 vaccine mandate: Natalie Sperazza and Margaret Roth. They assert a right to refuse the vaccine, saying the mandate infringes on their bodily autonomy and medical privacy.

"Stemming the spread of COVID-19 is unquestionably a compelling interest." *Cuomo*, 141 S. Ct. at 67 (majority opinion). According to the federal government and the State of Indiana, a state of emergency persists related to COVID-19, all the while restrictions are being scaled back gradually. Recognizing today's status of this pandemic, neither health professionals, government representatives, nor this court may say public health *vis-à-vis* COVID-19 has waned from being a legitimate state interest. Improved it undoubtedly has—today seems a world altogether different from last year—but public health remains a legitimate interest of the state to pursue. Indiana University too has a legitimate interest in promoting the health of its campus communities—students, and not least the faculty and staff who come daily in contact with them.

The students argue that the pandemic is basically over, but this goes against current proclamations from the Secretary of Health and Human Services, the Indiana State Department of Health, Governor Eric Holcomb, and the CDC, all then supported for institutions of higher learning by the U.S. Department of Education and the American College Health Association.[76] In Indiana (and nationally), the trend line remains sharply down (since winter) in terms of both new cases and deaths, though the recent snapshot of seven-day lookbacks proves nearly triple what it was just when this case commenced.

[76] *See, e.g.*, U.S. Dep't of Educ., *ED COVID-19 Handbook, Volume 3: Strategies for Safe Operation and Addressing the Impact of COVID-19 on Higher Education Students, Faculty, and Staff* 9 (June 2021), available at [Ex. 116 at 7], https://www2.ed.gov/documents/coronavirus/reopening-3.pdf ("COVID-19 vaccination is the leading prevention strategy [institutions of higher learning] can use to return to normal operations."); Am. College Health Ass'n, *ACHA Guidelines: American College Health Association Recommends COVID-19 Vaccination Requirements for All On-Campus College Students in Fall 2021* (Apr. 29, 2021), https://www.acha.org/ACHA/About/ACHA_News/ACHA_Recommends_COVID-19_Vaccination_Requirements_for_Fall_2021.aspx. Though it appears many public universities, including those in the State of Indiana, are ACHA members, Indiana University is not. The guidance is nonetheless pertinent here.

It isn't unreasonable to believe that, absent concerted vaccination, the fall and winter months will prove more arduous than these summer months for the university [Ex. 129 at 32]. Vastly improved, yes; out of the woods we aren't, not on this preliminary record.

The students argue that the bell curve that depicts ongoing cases and deaths from this pandemic's outset mirrors the CDC's continuum of pandemic phases that directs more conservative measures, not more draconian ones [*see*, *e.g.*, Exs. 212, 222, 230-231]. The students call this pandemic in the "deceleration" or "preparation" intervals—terms of art that define its waning stages. Deceleration occurs when state or local health officials rescind community mitigation measures because no new cases are occurring or are occurring infrequently; and preparation occurs when the pandemic is declared ended because evidence indicates that the disease is transitioning to seasonal patterns of transmission [Ex. 231]. The overall trend line may well support a seeming deceleration [*cf.* Exs. 222, 319]; but Indiana University insisting on vaccinations for its campus communities is rationally related to ensuring the public health of students, faculty, and staff this fall. Even under the university's pandemic and infectious disease action levels [Ex. 212], the university must continue to consult CDC and Indiana State Department of Health standards; and those today favor vaccination.

Let's not forget why we are here at this more promising stage of the pandemic, July 18, 2021. Antibody resistance developed naturally from prior cases has been a contributor to be sure; but, materially, improvement has come because of vaccinations—nationally over 161 million complete (over 337 million doses) and statewide nearly 3 million complete (and over 5.7 million doses). The vaccination campaign has markedly

curbed the pandemic. In fact, certain age-stratified, agent-based modeling of COVID-19 has concluded that another 279,000 deaths and nearly 1.25 million more hospitalizations would have occurred by the end of June 2021 but for the vaccines.[77] Stemming illness, hospitalizations, or deaths at the university level hardly proves irrational.

It isn't a foregone conclusion that this is overkill. This pandemic continues to evolve, and medicine and science with it. Science is a process in search of fact. One such moving target is the Delta variant (B.1.617.2). A mere four days ago Indiana reported 612 COVID cases—the highest count in more than six weeks (since May 27, 2021)—that health officials attributed largely to the Delta variant and the unvaccinated population. Though this daily case count is much lower than at the pandemic's height, the CDC, Indiana's State Department of Health, and epidemiologists have identified the Delta variant of particular lingering concern.[78] The CDC labeled Delta a "variant of concern" in mid-June.[79] Current science shows it more virulent and transmissible. A peer-reviewed study from scientists (issued July 8, 2021) found that the Delta variant has mutations that allow it to evade certain natural antibodies, with vaccination proving the best protection [Ex.

[77] *See* Alison Galvani *et al.*, *Deaths and Hospitalizations Averted by Rapid U.S. Vaccination Rollout* (Commonwealth Fund, July 2021), https://doi.org/10.26099/wm2j-mz32.

[78] *See* Shari Rudavsky, *Delta Variant on the Rise in Indiana, State Health Officials Say*, IndyStar (July 9, 2021, 12:58 PM), https://www.indystar.com/story/news/health/2021/07/09/covid-delta-variant-rise-indiana-state-health-officials-say/7908502002/ ("Not only is the Delta variant more readily transmitted from person to person, there's some indication it may cause more severe disease, said Indiana State Health Commissioner Dr. Kris Box.").

[79] *See See* CDC, *SARS-CoV-2 Variant Classifications and Definitions* (July 13, 2021), https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html.

319].[80] Reports of surges of Delta cases among the 12-29 age group have occurred.[81] For now, Indiana University has reasonably concluded that the safety and public health of its campus communities can be augmented by the vaccines [*id.*]. *See Gonzales*, 550 U.S. at 163 (citing *Jacobson*, 197 U.S. at 30-31) (the law gives "wide discretion to pass legislation in areas where there is medical and scientific uncertainty").

Indiana University reasonably believes the vaccine promotes the safety of not only its students, but that of its entire community. This wasn't (and still isn't) a decision taken lightly. It wasn't a decision reached overnight. It wasn't a decision taken by some fly-by-night committee undetached from the current science, the current progress of the fight

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[80] *See* Delphine Planas *et al.*, *Reduced Sensitivity of SARS-CoV-2 Variant Delta to Antibody Neutralization*, Nature doi: 10.1038/s41586-021-03777-9, 3 (July 8, 2021) (online ahead of print), https://www.nature.com/articles/s41586-021-03777-9_reference.pdf ("[A] single dose of Pfizer or AstraZeneca was either poorly or not at all efficient against Beta and Delta variants. Both vaccines generated a neutralizing response that efficiently targeted variant Delta only after the second dose.") According to Dr. Beeler, the data show that 50 percent of individuals had antibodies to the Beta variant and 47 percent had antibodies to the Delta variant one year after natural infection, whereas those who had vaccination after natural infection maintained 100 percent antibodies to both variants a year later [Ex. 319 ¶ 1]. According to Yale Medicine, the Delta variant is 50 percent more transmissible. *See also* Venkata-Viswanadh Edara *et al.*, *Infection and Vaccine-Induced Neutralizing-Antibody Responses to the SARS-CoV-2 B.1.617 Variants*, N. Eng. J. Med. DOI: 10.1056/NEJMc2107799 (July 7, 2021) https://www.nejm.org/doi/full/10.1056/NEJMc2107799; Kathy Katella, Yale Med., *5 Things to Know About the Delta Variant* (July 15, 2021), https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid.

[81] *See See* Ian Mount *et al.*, *The Kids are (not) Alright: Europe Sounds the Alarm as Delta Variant Soars Among Teens and 20-Somethings*, Fortune (July 8, 2021, 11:58 AM), https://fortune.com/2021/07/08/kids-vulnerable-covid-delta-variant-vaccinated-europe/ (seeing surge of Delta cases among the 12-29 age group); *see also* Public Health England, *SARS-CoV-2 Variants of Concern and Variants under Investigation in England: Technical Briefing 17*, 15 (June 25, 2021), https://www.nature.com/articles/s41586-021-03777-9_reference.pdf. A recent United Kingdom study, albeit still abstracted, concluded that most Delta infections in a younger group (age 5-49) occurred in the unvaccinated population. *See* Steven Riley *et al.*, *REACT-1 Round 12 Report: Resurgence of SARS-CoV-2 Infections in England Associated with Increased Frequency of the Delta Variant*, medRxiv (June 21, 2021) (not peer-reviewed pre-print), https://www.medrxiv.org/content/10.1101/2021.06.17.21259103v1.

against the pandemic, or experience and training in relevant fields of study. The restart committee was led by Indiana University's Executive Vice President for University Clinical Affairs and the School of Medicine's Dean. The committee consisted of seven MDs, some with additional degrees in public health or other PhDs, and others with graduate degrees in public health, risk mitigation, law, and ethics [Ex. 300 at 5]. Of its 15 members, two were deans of public health and others were experts in public health, epidemiology, virology, and other relevant areas of the health sciences, including health equity [Ex. 116 ¶ 23]. The committee met regularly and considered a wide variety of sources and information [*id.* ¶ 24].

A mere sampling of presentations from committee meetings from December 8, 2020 to April 6, 2021 [Exs. 302-317] shows the committee focused on COVID-19 evolution; EUA data; reactogenicity data; communications with the Indiana State Department of Health; CDC guidelines and updates; university-wide surveillance testing and data; data trends based on vaccinated and unvaccinated individuals; on-campus and off-campus transmission events; morbidity and mortality figures; efficacy of mitigation efforts on and off campus; international, national, state, county, and school vaccine uptake data; vaccine efficacy against variants; vaccine risk data; vaccine hesitancy surveys and campus opinion polling; and policies and requirements of other universities across the country [*see also* Ex. 301 ¶ 2]. In addition, four MDs from this committee presented near-weekly from December 2020 to June 2021 to Indiana University's Executive Academic Leadership Council, including the President and Executive Vice Presidents as part of the medical response team's ongoing COVID-19 evaluation efforts [*Id.* ¶ 5]. The process ultimately

filtered through the judgment of the Board of Trustees. This was a deliberative decision based on a wealth of scientific, medical, empirical, and industry-wide data.

For the impact of this vaccine mandate, the students focus only on the student body; and that is certainly an important part of the analysis here. The students argue that the fatality rate for healthy individuals age 20-49 is far less than older individuals [*see*, *e.g.*, Ex. 117 at 21-24; Ex. 243]. Dr. McCullough calls the mortality rate 0.15 percent [Ex. 241 ¶ 3]. He testifies that 16 deaths of young adults (aged 18-29) occurred in 2020, but none thus far in 2021 [Ex. 117 ¶ 34]. The students point out that the university's student body had one death last year [*id.* ¶ 25]. Indiana University reasonably views a 0.15 percent death rate as unacceptable for its communities, particularly given the safe preventative measure of a vaccine [Ex. 319 ¶ 4]. At approximately 90,000 students, that rate would risk 135 student lives, not accounting for other mitigation efforts to the better or those with immunocompromising conditions to the worse. The university's student population is not a homogenous group of just young healthy adults [*id.*].

In addition, the student's position overlooks the larger Indiana University community. Dr. McCullough, in fairness, takes a wider snapshot yet, pointing to a longitudinal serosurvey (blood sampling) of community residents near Pennsylvania State University suggesting that students' return in August 2020 had limited transmissible effect on the local community [Ex. 117 ¶ 29-30].[82] But Indiana University's perspective was more intimate. The university analyzed the number of individuals

[82] *See* Callum R. K. Arnold *et al.*, *SARS-CoV-2 Seroprevalence in a University Community: A Longitudinal Study of the Impact of Student Return to Campus on Infection Risk Among Community Members*, medRxiv (Feb. 14, 2021) (non-peer reviewed pre-print), https://pubmed.ncbi.nlm.nih.gov/33619497/.

within its campus population known to have increased risk factors for COVID-19 and determined that over 8,500 faculty and staff remained at increased risk of complications if they contracted the disease [Ex. 116 ¶ 26], with the ongoing risk of asymptomatic spread that vaccines help address [Ex. 129 at 53-54]. Faculty and staff at Indiana University who have daily contact with students represent an even broader demographic than just the student body, and this policy was intended to protect them too. The court credits Dr. Carroll and Dr. Beeler over Dr. McCullough on this point given their firsthand knowledge of Indiana University's specific circumstances.

The university's policy has broad support within its community. As of June 25, 2021, over 42,000 students had received the vaccine; and that number has no doubt grown [Ex. 116 ¶ 46]. Two university faculty councils—elected representative bodies interested in the quality of learning and student life—issued statements in support [*id.* ¶ 47]. The staff council at Indiana University's main campus in Bloomington likewise endorsed the policy [*id.* ¶ 49]. The graduate and professional student government also issued a resolution supporting the policy [*id.* ¶ 50]. Eight students have filed this lawsuit, and perhaps others await this ruling to decide. Under the circumstances, on this preliminary record, the law respects the right of this university community to self-govern reasonably.

To that point, no one has argued that Indiana University's policy is *ultra vires*. Indiana's General Assembly endowed the university's Board of Trustees to act in the "best interests of the state and the state educational institution," Ind. Code § 21-40-3-1(b), including the power "to prevent unlawful or objectionable acts that . . . violate the reasonable rules and standards of the [university] designed to protect the academic

community from . . . conduct presenting a serious threat to person or property of the academic community," Ind. Code § 21-39-2-3(b). The university remains answerable to the legislature, particularly its coffers.

The Indiana General Assembly has prohibited a vaccine passport in this state, but not a vaccine requirement. *See* Ind. Code § 16-39-11-5. Still, in assessing the reasonableness of vaccination mandates, the law considers underlying legislative authority. *See Zucht*, 260 U.S. at 175; *Jacobson*, 197 U.S. at 12-13; *see also Washington*, 494 U.S. at 221-22 (recognizing liberty interest under both state's policy and due process clause, but "no greater right than that recognized under state law"). On this preliminary record, Indiana University faces still an "objectionable" and "serious threat" to the "academic community" that its vaccination policy seeks reasonably to address for campus health. *See Zimmerman v. Bd. of Trustees of Ball State Univ.*, 940 F. Supp.2d 875, 890-91 (S.D. Ind. 2013) (defining "objectionable"). This is consistent with the Fourteenth Amendment.

Focusing on just mortality risk from COVID-19 leaves out much of the debate. Dr. McCullough and Dr. Beeler (with Dr. Carroll), for instance, offer competing views on the risks of the novel coronavirus and the risks of the vaccines [Exs. 115-117, 222, 319].[83] This is precisely the debate of medical professionals that state policymakers, including

[83] The experts at times debate relatively modest side effects from vaccines after natural infection (*e.g.*, fever or fatigue), but these are self-limited and not dangerous [Ex. 319 ¶ 6], so the court addresses them no more here. Even Dr. McCullough admits that other longstanding vaccines, including those mandated by state law, have common side effects, such as a risk of a fever [Ex. 117 ¶ 56].

authorized arms of the state, are best suited to resolve in setting policy for constituents, including here for the students at Indiana University.

Without vaccination, college-aged students remain at risk for serious long-term complication from COVID-19, including prolonged debilitating symptoms that interfere with normal life such as myocarditis, reduced aerobic capacity, and brain damage [Ex. 319 ¶ 5].[84] Long COVID remains a studied phenomenon. With Indiana reporting that individuals aged 20-29 have had more positive cases than any other age demographic [Ex. 115 ¶ 14], and with more than 260,000 cases linked to American college and universities since January 1, 2021 [*id.* ¶ 17], this proves still a legitimate risk.[85] Focusing only on mortality disregards the serious compromise to the quality of life that face some students who contract the virus [*see also id.* ¶ 10-11].

The students say the risks of the vaccine, especially at this stage and to their age group, outweigh any benefits a vaccine might confer. These argued risks include

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[84] *See* Mark W. Tenforde *et al.*, *Symptom Duration and Risk Factors for Delayed Return to Usual Health Among Outpatients with COVID-19 in a Multistate Health Care Systems Network — United States, March–June 2020*, 69:30 Morbidity and Mortality Weekly Report 993, 997-98 (July 24, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6930e1.htm?s_cid=mm6930e1_w ("Nonhospitalized COVID-19 illness can result in prolonged illness and persistent symptoms, even in young adults and persons with no or few chronic underlying medical conditions."); Giovanni Andrea Gerardo Crameri *et al.*, *Reduced Maximal Aerobic Capacity after COVID-19 in Young Adult Recruits, Switzerland, May 2020*, 25(36) Euro. Surveillance 1, 2 (Sept. 10, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7502899/pdf/eurosurv-25-36-2.pdf ("We observed a statistically significant decrease in VO_2 max among COVID-19 convalescents compared with naive and asymptomatically infected recruits"); Gwenaelle Douaud *et al.*, *Brain Imaging Before and After COVID-19 in UK Biobank*, medRxiv (Jun. 20, 2021) (not peer-reviewed pre-print), https://www.medrxiv.org/content/10.1101/2021.06.11.21258690v2 ("In both cases we identified significant (corrected-P<0.05) effects of COVID-19, primarily relating to loss of grey matter in cortical areas directly connected to primary olfactory and gustatory cortex.")

[85] The New York Times has tracked coronavirus cases at American college and universities, though its numbers have not been seemingly updated since May 26, 2021. *See* The New York Times, *Tracking Coronavirus Cases at U.S. Colleges and Universities*, https://www.nytimes.com/interactive/2021/us/college-covid-tracker.html (last visited July 18, 2021).

myocarditis, clotting, death, and others [Ex. 117 ¶ 48-49]. Some of these concerns are easier to assuage based on current science than others—and the court isn't the final arbiter of an evolving science, only of the law. The court must base today's decision on the snapshot of this preliminary record alone. It answers the question only whether the students have made a strong showing that Indiana University failed to act reasonably in achieving campus health to warrant the extraordinary remedy of a preliminary injunction.

That said, Dr. Beeler concludes that with millions of people getting the vaccine, experts "have [a] much tighter lens than we normally would for any other vaccine in history to identify some of those extremely rare concerns" [Ex. 128 at 80], and that younger people have a "higher probability" of facing issues with COVID-19 infection than after vaccination [*id.* 78]. All vaccine manufacturers conducted Phase 3 trials for EUA that never revealed the risks the students have presented [*id.* 79].

Since then, reports have shown the risk of myocarditis (heart inflammation), while present and something worthy of continued investigation, to be seemingly rare—one study suggesting the risk is about eight in one million and the other study suggesting the risk is about twenty in one million.[86] This issue has garnered increasing attention. The FDA reported CDC data (through May 31, 2021) of 475 cases of myocarditis (heart inflammation) and pericarditis (inflammation of membrane around heart) in vaccinated

[86] *See* Han W. Kim *et al.*, *Patients with Acute Myocarditis Following mRNA COVID-19 Vaccination*, JAMA Cardiol (June 29, 2021), https://jamanetwork.com/journals/jamacardiology/fullarticle/2781602; Israeli Ministry of Health, *Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021* (Feb. 6, 2021), https://www.gov.il/en/departments/news/01062021-03.

individuals age 30 and younger [Ex. 117 ¶ 49].[87] This data came from the Vaccine Adverse Event Reporting System (VAERS)—anecdotal data that, while important to analyze, requires further investigation before drawing conclusions. *See*, *e.g.*, *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) ("case reports alone ordinarily cannot prove causation"); *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989-90 (8th Cir. 2001) ("causal attribution based on case studies must be regarded with caution").[88] Still, on June 24, 2021, a CDC safety panel reported a "likely association" in young adults from mRNA COVID-19 vaccines and myocarditis and pericarditis, though it emphasized that it remained rare and typically mild, with the benefits of the vaccine still outweighing the risks [Ex. 117 ¶ 51].[89] This assessment of heart inflammation's rarity and the overarching benefits of the vaccines has a bench of current medical support on this record,[90] again

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[87] *See* FDA, *Vaccines and Related Biological Products Advisory Committee June 10, 2021 Meeting Presentation*, https://www.fda.gov/media/150054/download#page=17 (last visited July 16, 2021).

[88] *See also* CDC, *The Vaccine Adverse Event Reporting System (VAERS) Results* (July 17, 2021), https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=DBF4A737A762F523202A55E30B57 ("While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness.").

[89] *See* Advisory Board, *CDC Panel Reports 'Likely Association' of Heart Inflammation and mRNA COVID-19 Vaccines in Young People* (June 24, 2021), https://www.advisory.com/daily-briefing/2021/06/24/heart-inflammation.

[90] *See also* Saif A. Mouch *et al.*, *Myocarditis Following COVID-19 mRNA Vaccination*, 39 Vaccine 3790, 3793 (May 28, 2021), https://pubmed.ncbi.nlm.nih.gov/34092429/ (noting "mild" myocarditis and only "possible"—not probable—connection to vaccination, and concluding that the "individual and public benefit from COVID-19 vaccination outweighs these rare findings"); *accord* Carolyn M. Rosner *et al.*, *Myocarditis Temporally Associated with COVID-19 Vaccination*, Circulation (June 16, 2021) (manuscript only), https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.055891 ("[N]o data are available specific to vaccine-associated myocarditis. The clinical course of vaccine-associated myocarditis-like illness appears favorable, with resolution of symptoms in all patients. Given the potential morbidity of COVID-19 infection even in younger adults, the risk-benefit decision for vaccination remains highly favorable."); Mayme Marshall *et al.*, *Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination*, 148(1) Pediatrics (July 2021) (peer-reviewed case report) https://pediatrics.aappublications.org/content/early/2021/06/04/peds.2021-052478 ("This report summarizes a series of US cases of myocarditis and myopericarditis following the Pfizer-BioNTech COVID-19 mRNA vaccine in adolescent males . . . . At present, there is no definite causal relationship between these

giving Indiana University a rational connection between its mandate and its aim of campus health. This proves no less true when contracting COVID-19 (without the vaccine) already presents a risk of myocarditis [Ex. 319 ¶ 5]. No one should blithely dismiss the call for further investigation, but the students' case isn't strong today.

The students argue the temporal association of these risks, but just because the rooster crows doesn't mean he caused the sun to rise. A close review of Dr. McCullough's testimony reveals a true failing. Even he, the students' own tendered expert, a credentialed and board-certified physician in internal medicine and cardiovascular disease, stops short of declaring a causative link between any vaccine and myocarditis. He uses soft and inconsequential language, calling his suspicion "possible" and "unpredictable" [Ex. 117 ¶ 48, 73], not probable or causative to a reasonable degree of medical certainty. *See Harris v. Owens-Corning Fiberglas Corp.*, 102 F.3d 1429, 1433 (7th Cir. 1996) ("mere possibility of . . . causation is not enough"). He says he has examined college-age patients with myocarditis after a vaccine injection [Ex. 117 ¶ 59], but once again never testifies that one was caused by the other. *See Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904–05 (7th Cir. 2007) ("mere existence of a temporal relationship between taking a medication and the onset of symptoms does not show a sufficient causal relationship").

cases and vaccine administration. . . . The benefits of vaccination significantly exceed possible risks."); Elisabeth Albert *et al.*, *Myocarditis Following COVID-19 Vaccination*, 16(8) Radiology Case Reports 2142, 2144 (May 2021) (case report) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8130498/ (University of Massachusetts researchers found "small risk" of myocarditis, and concluded that "there is a significantly higher risk of cardiac involvement from COVID-19 infection compared to COVID-19 vaccination" such that "vaccination should remain the cornerstone for population immunity").

With ever evolving COVID-19 science, more will be known tomorrow, next month, and next year; but a courtroom is no place for guesswork today, even if well-inspired. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *Constructora Mi Casita v. NIBCO, Inc.*, 448 F. Supp.3d 965, 970-71 (N.D. Ind. 2020). Dr. Beeler testifies that "there is no proof of causation between the vaccination and myocarditis" [Ex. 115 ¶ 69]. The court gives Dr. McCullough's testimony little weight on this record.[91] These statements are made with considered humility. The court isn't deciding causation today to be sure. At the same time, the students haven't marshaled strong evidence that would call into legitimate question the reasonableness of the university's actions, or to meet their burden of an extraordinary remedy of a preliminary injunction.

The students return to VAERS to discuss the risk of death from the vaccines. Dr. McCullough says VAERS reported 6,136 deaths after vaccines as of June 18, 2021 [Ex. 117 ¶ 45]. He says VAERS received more adult death reports from COVID-19 vaccines than all other vaccines combined [*id.*]. The students offer an interim abstract from clinically

[91] For additional examples, Dr. McCullough cites one article that "*speculate[s]* that adverse reaction against the COVID-19 vaccine was responsible for the development of myocarditis *due to its temporal relationship*." Tommaso D'Angelo *et al.*, *Myocarditis after SARS-CoV-2 Vaccination: A Vaccine-induced Reaction?*, Can. J. Cardio. (June 9, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8187737/ (last visited July 17, 2021) (emphases added). Even then, the authors say "substantial evidences other than temporal aspects still need to be provided to demonstrate the causality[.]" *Id.* Dr. McCullough also cites a Reuters article concerning an Israeli study, rather than the study itself, when the Reuters article appears to overstate the study. For instance, the article refers to 275 cases, but those cases included both COVID-19 exposures and vaccinations. Only 148 cases occurred after vaccination. Even so, the study's authors conclude merely that there is "*some probability for a possible link* between the second vaccine dose and the onset of myocarditis among young men aged 16 to 30," not a probable link. Israeli Ministry of Health, *Surveillance of Myocarditis (Inflammation of the Heart Muscle) Cases Between December 2020 and May 2021* (Feb. 6, 2021), https://www.gov.il/en/departments/news/01062021-03 (emphasis added).

trained reviewers that considered the VAERS data as of April 2021, who grouped the reports as those where the vaccine was most likely not a factor, where it may have been, and where it was the most likely factor [Ex. 254].[92] Of the 250 deaths reported at the time, the reviewers concluded that 13 deaths were most likely caused by vaccines, noting that these individuals had strong reactions soon after vaccination and died the same day or during the next couple days [*id.*], though again temporal anecdotes like these aren't as telling. *See Ervin*, 492 F.3d at 904–05. They warrant further investigation to be sure; but in close review this interim abstract offers no scientific or medical basis for drawing its conclusion. Indeed, when the court asked counsel at oral argument what the basis was for it, he too could offer no explanation [Tr. 34-37]. And more to the point, Dr. McCullough again stops short of testifying that any one reported death in VAERS was caused by a vaccine, despite this interim abstract [Ex. 117 at 21-26]. The students thus haven't presented evidence today demonstrating Indiana University's decision was irrational in pursuing its goal of campus health.

The CDC has explored this issue as well and seems to have marshaled data, at this time, that any risk of death is rarer than the risk of death from a young adult COVID-19 infection. According to the CDC, 25,038,458 individuals aged 18-29 have been given their first dose of the vaccine as of July 18, 2021, with VAERS reporting a total of 68 deaths, or

[92] *See* Scott McLachlan *et al.*, *Analysis of COVID-19 Vaccine Death Reports from the Vaccine Adverse Events Reporting System (VAERS) Database* (June 2021) (not peer-reviewed pre-print), https://www.researchgate.net/publication/352837543_Analysis_of_COVID-19_vaccine_death_reports_from_the_Vaccine_Adverse_Events_Reporting_System_VAERS_Database_Interim_Results_and_Analysis. Dr. Beeler calls this a "reliable study looking at an unreliable system" based on passive reports unvalidated by studies and unconfirmed data [Ex. 128 at 124-25].

approximately 0.00027 percent, if in fact any are related.[93] Alternatively, of the 6,174,415 cases of COVID-19 in this age group, 2,732 died, or approximately a 0.04 percent.[94] In balancing the risks,[95] Indiana University wasn't irrational in favoring the route that promoted greater safety for its students.

The experts disagree over the relative risk of asymptomatic transmission (and indeed over many scientific conclusions), with the students contending that transmission from asymptomatic infections is "trivial and inconsequential" [Ex. 117 ¶ 26-27],[96] and the university pointing to its own experience and national trends indicating that asymptomatic transmission is "certainly still very possible" [Ex. 115 ¶ 52].[97] As with any

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[93] *See* CDC, *The Vaccine Adverse Event Reporting System*, https://wonder.cdc.gov/vaers.html (data contains reports processed as of July 9, 2021); CDC, *COVID-19 Vaccination Demographics in the United States, National*, https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Demographics-in-the-United-St/km4m-vcsb (last visited July 14, 2021).

[94] CDC, *Demographic Trends of COVID-19 Cases and Deaths in the U.S. Reported to CDC*, https://covid.cdc.gov/covid-data-tracker/#demographics (last visited July 18, 2021).

[95] The rate of community spread of COVID-19 in the counties in which the university's campuses are based is classified as "moderate" to "high" by the CDC. CDC, *COVID Data Tracker: COVID-19 Integrated County View*, https://covid.cdc.gov/covid-data-tracker/#county-view (last visited July 18, 2021).

[96] Zachary Madewell *et al.*, *Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis*, 3(12) JAMA Network Open e2031756 (Dec. 14, 2020) (Universities of Florida and Washington researchers conclude the rate of transmission from asymptomatic and presymptomatic carriers in a household is 0.7 percent, but acknowledge finding was based on a small sample size, did not differentiate between asymptomatic and presymptomatic carries, and that significant questions remain about infectiousness) https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102.

[97] *See* Michael A. Johansson *et al.*, *SARS-CoV-2 Transmission from People Without COVID-19 Symptoms*, 4(1) JAMA Network Open e2035057 (Jan. 7, 2021) (CDC Office of Deputy Directory for Infectious Disease researchers' disease model suggests that transmission from asymptomatic individuals account for 24% of all transmissions) https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707; Jennifer K. Bender *et al.*, *Analysis of Asymptomatic and Presymptomatic Transmission in SARS-CoV-2 Outbreak, Germany, 2020*, 27(4) Emerg. Infect. Dis. 1159 (April 2021) (European Centre for Disease Prevention & Control and Robert Koch Institute reviewed seven asymptomatic and 46 symptomatic cases and concluded little to no transmission from asymptomatic cases and 75 percent from presymptomatic cases) https://wwwnc.cdc.gov/eid/article/27/4/20-4576_article; *see also See* Sten H. Vermund & Virginia E. Pitzer, *Asymptomatic Transmission and the Infection Fatality Risk for COVID-19: Implications for School Reopening*, 72(9) Clin. Infect. Dis. 1493-96 (May 1, 2021) (Yale researchers conclude that asymptomatic transmission "likely represents a substantial proportion of total new infections")

new pathogen, scientific understandings of the character and risks of transmission are ever evolving, but a review of the balance of the current peer-reviewed research and other literature presented by the parties suggest that asymptomatic transmission, while less prevalent than symptomatic transmission, routinely occurs. Naturally, this conclusion may change as scientists continue to study the virus and population transmission events.

Other risks exist or may become known. For instance, the FDA warns of the potential for blood clots, reported the most in females ages 18-49, but calls this risk "remote."[32] Just four days ago, the FDA added a warning to its fact sheet for the Janssen COVID-19 vaccine that Guillain-Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells and causes muscle weakness and sometimes paralysis) has occurred in some people who have received the vaccine. The FDA calls this risk "very low."[98] In contrast, Dr. Beeler testifies that brain damage proves a risk from COVID-19 without a vaccine [Ex. 319 ¶ 5], as do several neurological diagnoses, particularly for those hospitalized by a COVID-19 infection.[99] The risks aren't all one-

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https://pubmed.ncbi.nlm.nih.gov/32584967/; Diana Buitrago-Garcia *et al.*, *Occurrence and Transmission Potential of Asymptomatic and Presymptomatic SARS-CoV-2 Infections: A Living Systematic Review and Meta-analysis*, 17(9) PLoS Med e1003346 (Sept. 22, 2020) (University of Bern and World Health Organization researchers conclude risk of infection from an asymptomatic individuals exists but is decreased 65 percent compared to symptomatic) https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003346.

[98] See FDA, *Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older* (July 18, 2021), https://www.fda.gov/media/146305/download.

[99] *See, e.g.*, Maxime Taquet *et al.*, *6-Month Neurological and Psychiatric Outcomes in 236,379 Survivors of COVID-19: A Retrospective Cohort Study Using Electronic Health Records*, 8 Lancet Psychiatry 416-27 (published online April 6, 2021), https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(21)00084-5/fulltext (though calling for more data, concluding that the "severity of COVID-19 had a clear effect on subsequent neurological diagnoses"). In fairness, this same study said whether COVID-19 was associated with Guillain-Barré syndrome "remains unclear."

sided, but the wealth of data and studies on which Indiana University has relied makes the likelihood that the students will prevail on their claim here quite low.

Don't forget that vaccines generally aren't without medical risks. In 1993, the Indiana General Assembly required that all public university students receive vaccinations for five conditions, *see* Ind. Code § 20-12-71-11, which it later amended in 2007 to add one more, *see* Ind. Code § 21-40-5-2. Today that required list covers diphtheria, tetanus, measles, mumps, rubella, and meningococcal disease. Early diphtheria vaccines began in the 1920s, with more recent vaccines being developed in the 2000s. Tetanus vaccines were introduced in the late 1940s. The first measles vaccine was developed in 1963, with the MMR vaccine licensed for use in 1971. The MMRV vaccine (which protects against measles, mumps, rubella, and varicella) was licensed in 2005 per the CDC. The first meningitis vaccine was licensed in 1974 in the United States, but more modern vaccines were licensed in 2005, 2012, and then 2015. Risks of these vaccines are varied, including more minor issues of fever or headache to more serious concerns of seizure or death, though frequently low risks.

To be sure, EUA of the COVID-19 vaccines occurred on a tighter timetable and has existed only since December 2020 and February 2021. The students thus voice concerns about the experimental nature of the vaccines, though their counsel assures that their suit will persist even if the FDA grants the vaccine manufacturers full approval. Not all EUAs are equal, and the one required for COVID-19 vaccines was more robust than usual.

For an EUA to issue, the U.S. Department of Health and Human Services (HHS) must first conclude that the biological threat identified in the emergency declaration "can

cause a serious or life-threatening disease or condition[.]" 21 U.S.C. § 360bbb-3(c)(1). Additionally HHS must conclude, "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe" the new product is effective in diagnosing, treating, or preventing the disease and "the known and potential benefits of the product . . . outweigh the known and potential risks of the product, taking into consideration the material threat posed" by the public health emergency. 21 U.S.C. § 360bbb-3(c)(2). Further, there must be "no adequate, approved, and available alternative to the product" and the product must comport with "other criteria as the Secretary may by regulation prescribe." 21 U.S.C. § 360bbb-3(c)(3)-(4).

In addition to these criteria, HHS must ensure medical providers are informed of the product's EUA status, the "significant known and potential benefits and risks of the . . . product, and of the extent to which such benefits and risks are unknown," and the availability, risks, and benefits of alternative products. 21 U.S.C. § 360bbb-3(e)(1)(A)(i)(I)-(III). HHS must ensure that individuals who receive the product are informed of the product's EUA status, the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown," and "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)-(III). For these reasons, those who go to get these vaccines receive fact sheets from the FDA.

The impetus behind issuing an EUA, as opposed to going through the process for full FDA approval, comes from the urgency required. The standard process for vaccine approval requires a manufacturer to demonstrate compliance with statutory, regulatory, and agency standards. *See* 42 U.S.C. § 262(j); 21 U.S.C. § 355(b)(1)(A); 21 C.F.R. §§ 601.2(a), 600.3(n), (p). Among other things, a manufacturer must conduct various studies, including clinical trials, to prove that the vaccine is safe for use and is effective. 21 U.S.C. § 355(b)(1)(A)(i); 21 C.F.R. § 600.3(s). These trials must be complete before an application can be submitted; indeed for COVID-19, the FDA requires manufacturers to collect and include any data from severe adverse events for six months after the trials conclude.[100] Though this process is designed to ensure safe vaccines for public use, it can take an average of ten years to go from a mere idea to an approved vaccine.[101] This can occur more quickly too; indeed, just two days ago, the FDA granted priority review of one vaccine, reportedly meaning that full approval from the FDA could come as soon as early next year.[102]

On the other hand, as opposed to waiting until clinical trials conclude, an EUA allows a manufacturer to apply using interim clinical trial data, and the data need only

[100] 21 U.S.C. § 355(b)(1)(A)(i); 21 C.F.R. § 601.2(a), (e); § 601.20(a); *see also* FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* (June 2020); FDA, *Vaccine Development 101*, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (last visited July 13, 2021).

[101] *See* Mark M. Struck, *Vaccine R&D Success Rates and Development Times*, 14 Nature Biotech. 591, 592 (1996), https://www.nature.com/articles/nbt0596-591.pdf?origin=ppub.

[102] *See* BioNTech, *U.S. FDA Grants Priority Review for the Biologics License Application for Pfizer-BioNTech COVID-19 Vaccine* (July 16, 2021), https://investors.biontech.de/news-releases/news-release-details/us-fda-grants-priority-review-biologics-license-application.

demonstrate the product "may be effective" and the known and potential benefits outweigh the known and potential risks.[103] Additionally, distribution and testing can occur simultaneously.[104] Although at first blush, the efficiency of an EUA may seem to risk the greater surety of safety and efficacy, the statute anticipates the FDA will impose additional obligations beyond those enumerated. *See* 21 U.S.C. § 360bbb-3(e)(1)(B).

In October 2020, the FDA released industry guidance detailing the benchmark criteria for a COVID-19 vaccine to receive an EUA.[105] Though not legally binding,[106] the industry guidance acknowledged that a COVID-19 vaccine was a "complex biological product[] . . . intended to be administered to millions of individuals, including healthy people, to prevent disease . . . [and has] the potential for broad use under an EUA."[107] Because the virus would only be overcome through the sweeping immunity of the American public, the FDA informed manufacturers that approval would be given to

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[103] 21 U.S.C. § 360bbb-3(c)(2)(A); FDA, *Emergency Use Authorization for Vaccines Explained*, https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (last visited July 12, 2021).

[104] *Compare* 21 C.F.R. § 601.21 (products under development cannot be shipped for the purpose of introduction into commerce), *with* 21 U.S.C. § 360bbb-3(e)(1)(B)(i) (allowing discretion for the agency to work with manufactures on distribution issues); *see also* FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#preparedness (last visited July 12, 2021).

[105] FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (October 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19.

[106] An industry guidance does not have the force of law, as it does not go through the rulemaking process. However, an industry guidance informs a manufacturer of the criteria the FDA would consider sufficient to receive approval pursuant to their statutory authority. *See, e.g.*, FDA, *Rules, Regulations and Guidance*, https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance (last visited July 18, 2021) (describing industry guidance as informing the tobacco industry of "pathways to legally market new tobacco products").

[107] FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* at 2.

those EUA applications that went beyond the safety and efficacy requirements prescribed by statute, and also expected manufacturers to consult with the FDA on the various non-clinical components of vaccine development and distribution as the clinical trial progressed.[108] The FDA wanted the same level of efficacy data as for full approval, enough safety data to justify providing the vaccine to healthy individuals, and confirmation of the technical procedures and verification steps necessary to support full approval.[109]

Thus, manufacturers were expected to submit "adequate manufacturing information to ensure its quality and consistency" as well as "data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner"—a heightened bar from the "may be effective" standard prescribed by statute—while still allowing the manufacturers to complete their trials for full authorization.[43] The FDA "strongly encourage[d]" manufacturers to provide interim data and analyses before applications were submitted, and noted that requirements described were "essential to ensure that clinical development of a COVID-19 vaccine has progressed far enough that issuance of an EUA for the vaccine would not interfere with the ability of an ongoing Phase 3 trial to demonstrate effectiveness of the vaccine to support licensure and to continue safety assessments[.]"[43]

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[108] *See* FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 6-7, 9 (October 2020); 21 U.S.C. § 360bbb-3(c).

[109] FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 4, 9 (October 2020).

Although the FDA directs manufacturers to present evidence of efficacy that meet the standards necessary to receive full approval,[43] a key distinction between EUA and full approval remains. To receive full approval for a COVID-19 vaccine, a manufacturer must monitor and submit evidence of "serious and other medically attended adverse events in all study participants for at least 6 months after completion of all study vaccinations."[110] However, for an EUA, the manufacturer may submit its safety data based on a median two-months follow-up for every individual who completed the vaccine regimen.[111] The FDA concluded that a "2-month median follow-up (meaning that at least half of vaccine recipients in clinical trials have at least 2 months of follow-up) after completion of the full vaccination regimen will allow identification of potential adverse events that were not apparent in the immediate postvaccination period and will also provide greater confidence in their absence, if none are observed."[112] Based on its experience with vaccine studies and approvals, the FDA concluded that "adverse events considered plausibly linked to vaccination generally start within 6 weeks after vaccine receipt," regardless of the type of vaccine received, and thus the median two-month follow-up was justified "by extensive historical experience with adverse events after vaccination, the need for a vaccine to address the current pandemic, and the magnitude of vaccine effectiveness that will be required to support a favorable benefit–risk profile

[110] FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 15 (June 2020).

[111] *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 10 (October 2020).

[112] Philip R. Krause & Marion Gruber, *Emergency Use Authorization of Covid Vaccines – Safety and Efficacy Follow-up Considerations*, 383 N. Engl. J. Med. e107(2) (Nov. 5, 2020). Dr. Marion Gruber is the director and Dr. Phillip Krause is the deputy director of the Office of Vaccines Research and Review at the FDA.

for use of a Covid-19 vaccine under an EUA."[111] Thus, in setting these stringent expectations, the FDA invited EUA applications only for vaccines positioned well to receive full approval.[113]

The statute grants the agency flexibility to impose additional requirements necessary to meet the safety and efficacy concerns despite the urgency of a public health emergency. The agency understood that a vaccine designed to be given to hundreds of millions of Americans, healthy and otherwise, required significant safety and efficacy data for approval. The consequences of skimping on these steps, or even adhering to the statutory-minimum requirement of potential effectiveness, was too great; so the FDA directed manufacturers to present evidence of efficacy that led to standards necessary to receive full approval. And true, though the safety follow-up necessary to receive an EUA is much shorter than would otherwise be required, the FDA made this conclusion based on its expert assessment and experience that significant latent negative outcomes associated with vaccinations traditionally occur within six weeks of receipt.[114]

Indiana University closely considered the FDA's EUA requirements when adopting its policy. The specialists on the university restart committee appreciated that

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[113] The industry guidance has since been superseded twice, once in February 2021 and once in May 2021. FDA, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (May 2021). Pfizer, Moderna, and Johnson & Johnson's applications were submitted in accordance with the October 2020 guidance, *see* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer-BioNTech)* (2020) (application submitted November 20, 2020); FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Moderna)* (2020) (application submitted November 30, 2020); FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Janssen)* (2021) (application submitted February 4, 2021).

[114] Philip R. Krause & Marion Gruber, *Emergency Use Authorization of Covid Vaccines – Safety and Efficacy Follow-up Considerations*, 383 N. Engl. J. Med. e107 (Nov. 5, 2020).

all three COVID-19 vaccines had been "studied in robust multi-centered, international, randomized-controlled trials and proven both effective and safe in millions of people" [Ex. 115 ¶ 60; *see also* Ex. 115 ¶ 24, 61-69]. These specialists explained that the EUA vaccines had been based on technology that has been studied for decades [*id.* ¶ 87]. Though even "small differences in chemical structure can sometimes make very large differences in the type of toxic response that is produced," *McClain v. Metabolife Intern, Inc.*, 401 F.3d 1233, 1246 (11th Cir. 2005); *accord Glastetter*, 252 F.3d at 990, much like the FDA, the university concluded that campus safety reasonably outweighed any lingering risks with the vaccines. This wasn't just any ordinary EUA process, but EUA on proverbial steroids. The university reasonably concluded that the "benefit dwarfs the potential rare risks" [Ex. 115 ¶ 87].

Progress has been made because of the vaccine, not despite it. To the extent that lingering medical and scientific debate remain on this record, the court remains resolved that Indiana University has acted reasonably here in pursuing public health and safety for its campus communities [*cf.* Exs. 115, 116].[115] *See Gonzales*, 550 U.S. at 163 (state

[115] For instance, Dr. McCullough says the vaccine manufacturers "skipped testing" for genotoxity, mutagenicity, teratogen[i]city, and oncogenicity" [Ex. 117 ¶ 36]. Dr. Beeler explains that this claim, including the suspicion about mutagenesis, takes a "backwards view of how RNA works in the cell and [is] not currently supported by consensus opinion" [Ex. 115 ¶ 64]. Concerns about the impact of a vaccine on fertility are largely addressed by the policy because Indiana University allows exemptions for pregnant women [Ex. 115 ¶ 86]. Naturally, truly measuring the impact of any intervention, or disease for that matter, on overall fertility to any degree of certainty requires longitudinal and perhaps even generational studies. Even under the FDA's full approval requirements for a COVID-19 vaccine, a manufacturer is not required to submit data on the long-term impact on overall fertility in the population to receive approval. FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 7 (June 2020). Instead, the agency recommends conditioning the enrollment of pregnant women and "women of childbearing potential who are not avoiding pregnancy" in a clinical trial on the completion of Developmental and Reproductive Toxicology (DART) studies. FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 7, 11 (June 2020). A similar recommendation appears in the EUA guidance. *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 9 (October 2020). Though DART

legislatures have "wide discretion to pass legislation in areas where there is medical and scientific uncertainty"); *Zucht*, 260 U.S. at 176 ("municipality may vest in its officials broad discretion in matters affecting the application and enforcement of a health law").

Today, Indiana University has a rational basis to conclude that the COVID-19 vaccine is safe and efficacious for its students. The vaccine has been used on about 157 million Americans; and data now about eight months later, though it will grow more robust in years to come, is considerable and shows major side effects are rare. Much like over 500 universities and colleges in the United States that have done the same,[116] Indiana

studies review many components of fertility and pregnancy in animal models, FDA, *S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals Guidance for Industry* (May 2021), the application of these studies to the approval or a COVID-19 vaccine relate to the testing, marketing, and use of vaccines in pregnant women and in women who could imminently become pregnant, *see* FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 7, 11 (June 2020); *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* 9 (October 2020). And though DART studies in animals certainly shed light on greater concerns about fertility and are important, full vaccine approval is not conditioned on fertility studies in women or men. *See id.* Instead, the impact of a vaccine on pregnancy and pregnancy outcomes in women is a vital post-approval safety assessment. *see* FDA, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* 17 (June 2020). Moderna and Johnson & Johnson submitted DART studies as part of their EUA applications. Both manufacturers identified no fertility or development concerns based on these studies. FDA, *Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation – Emergency Use Authorization (EUA) Application for mRNA-1273* (Dec. 17, 2020); Janssen Biotech, Inc, *Vaccines and Related Biological Products Advisory Committee Meeting February 26, 2021* (Feb. 26, 2021). Pfizer submitted DART results after its EUA was granted. The studies showed the vaccine did not impact female fertility or development, albeit in rats. Christopher J. Bowman *et al.*, *Lack of Effects on Female Fertility and Prenatal and Postnatal Offspring Development in Rats with BNT162b2, a mRNA-based COVID-19 Vaccine*, 103 Reproductive Toxicology 28 (Aug. 2021).

[116] Andy Thomason and Brian O'Leary, *Here's a List of Colleges That Will Require Students or Employees to Be Vaccinated Against Covid-19*, The Chronicle of Higher Education (July 15, 2021), https://www.chronicle.com/blogs/live-coronavirus-updates/heres-a-list-of-colleges-that-will-require-students-to-be-vaccinated-against-covid-19?cid2=gen_login_refresh ("*The Chronicle* has so far identified 583 such campuses."). Generally, courts "should not invade the domain of local authority except when it is necessary to do so" to enforce fundamental rights. *Jacobson*, 197 U.S. at 38. In addition to the Fourteenth Amendment's protections, a wide variety of states have enacted legislation relating to vaccine mandates or vaccine documentation, including Ohio just this last week. *See* 2021 Bill Text OH H.B. 244, Sec. 3792.04(B)(1) (signed into law on July 14, 2021); *cf., e.g.,* Ark. Code Ann. § 20-7-142 (prohibiting vaccine mandate); Fla. Stat. § 381.00316 (prohibiting governmental entities from requiring COVID-19 vaccination documentation and prohibiting educational institutions from requiring that students provide COVID-19 vaccination documentation); 2021 Bill Text CA A.B. 327 (proposed) (bill that would prohibit entities from requiring

University reasonably relies on the vaccine as a measure to return to normal school functioning. The students say the mandate is unreasonable because no other Indiana government agency mandates the vaccine. But just because it has gone above what others have done doesn't make it unreasonable. Indeed, universities are unique places, with lots of people gathered and living together in close quarters for months at a time. That Indiana University's mandate goes beyond what other public universities in Indiana have done doesn't compel a finding that this policy is unreasonable; indeed, other universities in the state have mandated the vaccine, and many others around the country have too.

Indiana University is following the recommendations of other well-established agencies, including the Centers for Disease Control, U.S. Department of Education, and the Indiana State Department of Health. These are reliable sources to assess the reasonableness of measures implemented, though the court must be cautious not to expand the guidance beyond what it says. *See United States v. Newton*, 996 F.3d 485, 489 (7th Cir. 2021); *Mays v. Dart*, 974 F.3d 810, 823 (7th Cir. 2020), *cert. filed*. To be sure, the CDC doesn't recommend that schools "mandate" the vaccine—a point the students make—but such a recommendation isn't consistent with the CDC's purview, which is to act as an informative agency. At the same time, the university's policy isn't inconsistent with the CDC's recommendations. The CDC says institutions of higher learning "can return to full capacity in-person learning, without requiring or recommending masking or physical distancing for people who are fully vaccinated" [Ex. 116 ¶ 12]. The CDC's

COVID-19 vaccination documentation). The court will not overstep into the legislative sphere when the state's or state arm's conduct has complied with the Constitution.

guidance to universities is that "[v]accination is the leading prevention strategy to protect individual from COVID-19 disease and end the COVID-19 pandemic."[117] This will enhance the student body's opportunities, allowing them to have a more fulfilling college experience.

Vaccination helps the university get to herd immunity. As its expert, Dr. Beeler, has said, COVID-19 vaccination is an important tool to help stop the pandemic because widespread vaccination will help achieve "herd immunity," which is when enough people in a community are sufficiently protected from COVID-19 to stem its spread [Ex. 115 ¶ 19-20].[118] To be sure, experts debate whether herd immunity is achievable for COVID-19 [Ex. 115 ¶ 21], but Indiana University rationally believes vaccination is the leading prevention strategy to protect individuals from COVID-19 disease. According to Dr. Beeler, "Indiana has not reached herd immunity" [Ex. 115 ¶ 43; *see also* Exs. 128 at 60, 129 at 23]. As Dr. Beeler explains, "immunity is not static with this virus, and things do change specifically as it relates to variants of concern. . . . The longer that the coronavirus remains in the population, each vulnerable individual that gets infected is the opportunity for further mutations in the virus. And eventually, just by evolutionary theory, the virus will develop ways to bypass the current immune stress" [Ex. 128 at 61]. The mutability of COVID-19 remains higher than other conditions addressed by a single

[117] CDC, *Guidance for Institutions of Higher Education (IHEs)* (last updated June 4, 2021), https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/considerations.html.
[118] *See* CDC, *COVID-19 Vaccines Are Free to the Public* (last visited June 27, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/no-cost.html; CDC, *Key Things to Know about COVID-19 Vaccines* (last visited June 27, 2021) ("CDC Key Things"), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html.

vaccine, like measles, mumps, and rubella [*id.* at 151-52]. With the variants of concern affecting recent numbers, and based on Dr. Beeler's well-reasoned explanation, the court tends not to credit Dr. McCullough's viewpoint that herd immunity has already been achieved.

Overall, the students' arguments amount to disputes over the most reliable science. But when reasonable minds can differ as to the best course of action—for instance, addressing symptomatic versus asymptomatic virus spread or any number of issues here—the court doesn't intervene so long as the university's process is rational in trying to achieve public health. *See, e.g.*, *Phillips*, 775 F.3d at 542 ("plaintiffs argue that a growing body of scientific evidence demonstrates that vaccines cause more harm to society than good, but as *Jacobson* made clear, that is a determination for the [policymaker], not the individual objectors"). There is a rational basis for making distinctions here. No student, including those not yet exempt, have shown that Indiana University's vaccine mandate as applied to them violates rational basis review. The court thus denies their request to enjoin it preliminarily.

5. *On This Preliminary Record, Exempt Students Haven't Shown a Likelihood of Success on their Claim that Indiana University Lacks a Rational Basis for Its Vaccine Policy, Including Additional Requirements.*

Six students are exempt from the vaccination mandate but challenge the additional measures of mask wearing, testing, and social distancing: Ryan Klaassen (Ex. 100 ¶ 180-81), Jaime Carini (¶ 182-95), Macey Policka (¶ 207-08), Daniel Baumgartner (¶ 196-200), Ashlee Morris (¶ 201-04), and Seth Crowder (¶ 205-06). Collectively, they argue that these requirements, oft-used over the last year, infringe on their bodily autonomy, medical

privacy, religious beliefs, and essentially become a "scarlet letter" targeting them for bullying and scorn from their peers for their medical conditions or religious beliefs.[119]

Indiana University first challenges this argument on a procedural ground. It says these students failed to challenge its masking or testing policies in their complaint. They cite to the well-known legal principle that "a plaintiff is the master of her own complaint," and that courts shouldn't read unalleged assertions into a complaint. *Thornley v. Clearview AI, Inc.*, 984 F.3d 1241, 1246 (7th Cir. 2021); *see also Caterpillar, Inc. v. Williams*, 482 U.S. 386, 398-99 (1987). The complaint isn't so narrowly pleaded. It gives fair notice that the students are challenging the vaccine mandate and the policy's additional requirements. *See* Fed. R. Civ. P. 8(a)(2); *Bell Atl. Corp. v Twombly*, 550 U.S. 544, 555 (2007).

Indiana University's vaccine mandate is multifaceted. It requires all students, faculty, and staff to receive a COVID-19 vaccine and report their vaccination status, or to obtain an exemption and comply with the additional requirements. The university lumps the various parts of this mandate under a general "COVID-19 vaccine requirement" umbrella. For instance, on Indiana University's "frequently asked questions" page about its COVID-19 vaccination requirement, the section provides that vaccinations are required, the deadlines for such vaccinations, the need for students to report vaccination status, the exempted categories, and the additional requirements imposed on exempted students, along with the consequences for failing to get a vaccine [Ex. 118 at 3-6].

[119] The scarlet letter is a literary reference to a mark that identifies one as belonging to a certain group in a scornful or ostracizing way. *See* Nathaniel Hawthorne, *The Scarlet Letter* (1850).

Because the students challenge the additional requirements under substantive due process, the court again begins by first examining the specific right they assert. *See Doe*, 377 F.3d at 768. These students argue that they have rights to refrain from wearing a mask and to refuse nasal testing. But there is no fundamental constitutional right to not wear a mask. *Kelly v. ImagineIF Library Entity*, 2021 U.S. Dist. LEXIS 111958, 8 (D. Mont. June 15, 2021); *Whitfield v. Cuyahoga Cnty. Pub. Library Found.*, 2021 U.S. Dist. LEXIS 92944, 4 (N.D. Ohio May 17, 2021); *Denis v. Ige*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 91037, 14 (D. Haw. May 12, 2021); *W.S. by Sonderman v. Ragsdale*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 98185, 5 (N.D. Ga. May 12, 2021); *Forbes v. City of San Diego*, 2021 U.S. Dist. LEXIS 41687, 11 (S.D. Cal. Mar. 4, 2021); *Stewart v. Justice*, __ F. Supp.3d __, 2021 U.S. Dist. LEXIS 24664, 20 (S.D. W. Va. Feb. 9, 2021); *Oakes v. Collier Cnty.*, 2021 U.S. Dist. LEXIS 15174, 4 (M.D. Fla. Jan. 27, 2021); *Shelton v. City of Springfield*, 497 F. Supp.3d 408, 414 (W.D. Miss. 2020); *see also Ryan v. Cnty. of DuPage*, 45 F.3d 1090, 1092 (7th Cir. 1995) (no constitutional right to *wear* a mask); *United States v. Berglund*, 2021 U.S. Dist. LEXIS 78476, 2 (D. Minn. Apr. 23, 2021) ("Courts have repeatedly found that requiring participants at trial to wear face masks due to the COVID-19 pandemic does not violate a criminal defendant's constitutional rights.").[120] Nor is there a fundamental constitutional right to not be tested for a virus before entering a place of public accommodation. *Aviles v. De Blasio*, 2021 U.S. Dist. LEXIS 38930, 50 (S.D.N.Y. Mar. 2, 2021); *see also Webb v. Johnson*, 2021 U.S. Dist. LEXIS

[120] Plaintiffs cite to a recent Florida state court decision which held, based on its state constitution, that the right to privacy applies to a mask-wearing mandate, triggering strict scrutiny. *See Green v. Alachua Cnty.*, 2021 Fla. App. LEXIS 8634 (Fla. Dist. Ct. App. June 11, 2021). But as this case makes clear, it is based on Florida's state constitution, not the federal constitution. It is thus inapposite here.

95392, 13 (D. Neb. Mar. 2, 2021) (D. Neb. May 19, 2021) (prisoner had no fundamental right to refuse having his temperature taken); *Wilcox v. Lancour*, 2021 U.S. Dist. LEXIS 11968, 23-24 (W.D. Mich. Jan. 22, 2021) (prisoner had no fundamental right to refuse a nasal passage test for COVID-19); *Little Rock Family Planning Servs. v. Rutledge*, 458 F. Supp.3d 1065, 1074 (E.D. Ark. 2020) (applying *Jacobson* to uphold requirement that women obtain negative COVID-19 test before medical procedure).

The court declines the students' invitation to expand substantive due process rights to include the rights not to wear a mask or to be tested for a virus. These aren't rights so "deeply rooted in this Nation's history and tradition" and so "implicit in the concept of ordered liberty" such that "neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997) (quotation omitted); *Khan v. Bland*, 630 F.3d 519, 535 (7th Cir. 2010). These aren't issues of fundamental constitution import, but often transient and trivial inconveniences.

But wait, certain students say: mask wearing and testing violates their religion. The First Amendment says "Congress shall make no law . . . prohibiting the free exercise" of religion. U.S. Const. amend. I. The right to exercise religion is fundamental. *See Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940). As a fundamental right, it would trigger strict scrutiny, but the Supreme Court has held that general regulations that have the effect of incidentally burdening religious practices in general and neutral ways need only be rationally supported by the state. "[T]he right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his

religion prescribes (or proscribes)." *Smith*, 494 U.S. at 879 (quotation omitted); *accord Ill. Bible Colleges Ass'n v. Anderson*, 870 F.3d 631, 639 (7th Cir. 2017).

Indiana University's extra requirements fit within the neutral and generally applicable laws protected by *Smith*. The vaccine mandate contains an early reference to religion by way of exemption; but this isn't used to *burden* religion, but instead gives those of religious conviction the *benefit* of freely practicing their religious conviction to refuse the vaccine. *See Listecki v. Official Comm. of Unsecured Creditors*, 780 F.3d 731, 744 (7th Cir. 2015) ("A benefit to religion does not disfavor religion in violation of the Free Exercise Clause."); *see also Smith*, 494 U.S. at 888 (Scalia, J.) (no exemption required). The students who received the religious exemption are subject to the same extra requirements as those who receive the medical exemption.

One may well applaud the university for going beyond what the constitution requires: courts have consistently held that schools that provided a religious exemption from mandatory vaccination requirements did so *above and beyond* that mandated by the Constitution. *See Nikolao*, 875 F.3d at 316; *Phillips*, 775 F.3d at 543; *Workman*, 419 F. Appx. at 356; *Whitlow*, 203 F. Supp.3d at 1084; *Boone*, 217 F. Supp.2d at 954. What the students request now is a religious exemption from the religious exemption, but Indiana University has no obligation to provide this. *See Smith*, 494 U.S. at 879.

On this record, the court finds no merit in the students' contention that wearing masks essentially labels them with a "scarlet letter" that targets them for religious bullying. Indiana University has both medical and religious exemptions, and the same requirements are imposed on both groups. There is no evidence that any exempted

person must reveal publicly which exemption they obtained. Wearing masks thus doesn't signify to others that the individual religiously objects to the vaccination; they could fall within either exempted category, or they could be a vaccinated individual who chooses to take the extra (and unrequired) precaution to wear a mask. A student wearing a mask may well just be precautious in light of COVID-19 variants or because of immunosuppressing conditions. This record is devoid of any evidence of bullying or discrimination.

To be sure, there are some unique circumstances when wearing a mask could negatively impact the student's educational experience. For example, Jaime Carini is pursuing doctorates in organ performance and literature and musicology and, to complete her graduate program, she must perform at organ recitals [Ex. 121 at 22, 27]. She believes performing these recitals while masked will have an impact on her performance as an organist, who use their whole bodies to perform [*id.* 90]. Similarly, Macey Policka is pursuing a degree in theater with an emphasis on acting, and she says the mask requirement is "devastating" to her education [Ex. 125 at 41]. She says wearing a mask has a huge impact on how she can interact with other actors and will put her at a distinct disadvantage to other student actors who don't have to wear masks [*id.*]. Though the court sympathizes with these concerns, these are matters for the university reasonably to address, not matters of constitutional import.

The students once more assert another alleged right—this time the right to the confidentiality of their medical information—to obtain strict scrutiny. But this circuit has never recognized one's constitutional right to privacy to medical information. *Franklin v.*

McCaughtry, 110 F. Appx. 715, 719 (7th Cir. 2004); *Rowe v. Wexford of Ind.*, 2021 U.S. Dist. LEXIS 31766, 3-4 (N.D. Ind. Feb. 22, 2021). This right may exist by statute, but isn't found in the Constitution. And this circuit recognized that such a right, if any, is minimized when in the public context. *See Franklin*, 110 F. Appx. at 719 (describing hospital emergency rooms, doctor's offices, and school infirmaries). The court declines finding such a fundamental right in the context here.

That said, the court applies rational basis review for the extra requirements of masks and testing for the exempted students. Indiana University has a legitimate interest in promoting the health and safety of its students. And the masks and testing are rationally related to achieving those measures. This is true for several reasons.

First, both vaccinated and unvaccinated people can still get the virus. Though health experts differ on the efficacy of masks in preventing the spread of COVID-19, such a dispute is left to the resolution of the policymakers, particularly when studies have shown universal mask wearing resulted in decreases in COVID rates than populations that forewent masks [Ex. 128 at 108]. And social distancing continues to be recommended by the CDC and health experts as effective at eliminating the spread of the disease.[121] The students offer no sound evidence that social distancing isn't effective.

Second, the CDC says schools should account for students, faculty, and staff who aren't vaccinated.[122] And it has continued to recommend masks and social distancing for

[121] CDC, *How to Protect Yourself & Others*, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html (updated June 11, 2021).

[122] CDC, *Guidance for Institutions of Higher Education (IHEs)*, https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/considerations.html#section1 (updated June 4, 2021).

these individuals.[122] This is consistent with what Indiana University has already done for a semester as well.

Third, even students who feel fine and don't have a fever may still have the virus as an asymptomatic individual, so the heightened precautions as to them continue to be rational.[123] Despite the low mortality rates, young adults can still transmit the virus to others [Ex. 115 ¶ 10-11]. For those with milder or even asymptomatic cases, as is more prevalent in this age group, the risk of inadvertent transmission grows [Ex. 115 ¶ 53-55].

Fourth, these measures are reasonable in scope. The testing methods are reasonable for the circumstances: they plan to use a rather non-intrusive saliva test. *See Banks v. United States*, 490 F.3d 1178, 1189 (10th Cir. 2007) ("saliva tests impose minimal intrusions"); *Padgett v. Ferrero*, 294 F. Supp.2d 1338, 1342 (N.D. Ga. 2003) ("bodily intrusion of taking . . . saliva sample is minimal"); *see also Wilson v. Collins*, 517 F.3d 421, 428 (6th Cir. 2008) (saliva sample is less intrusive than blood drawing). Though this form of testing may be less reliable than nasal testing, it is significantly less intrusive—and given that the students' assert their right to bodily autonomy, this is a good thing. Though it may present some inconvenience for the students by taking time away from their studies, this impact is minimal and within the sound discretion of the school.

Fifth, students have lived with mask mandates for over a year now, so it is nothing that is unreasonable, at least not when the risk still exists. These students have worn

[123] *See, e.g.*, Sten H. Vermund & Virginia E. Pitzer, *Asymptomatic Transmission and the Infection Fatality Risk for COVID-19: Implications for School Reopening*, 72(9) Clin. Infect. Dis. 1493-96 (May 1, 2021) (Yale researchers conclude that asymptomatic transmission "likely represents a substantial proportion of total new infections").

masks at school, stores, work, church, and even at a casino. In other contexts, the government has lawfully mandated wearing protective gear, like a mask, when it also provides benefits to the public—like mandated bicycle helmets, hair nets, ear plugs, and any number of personal protective equipment. *See, e.g.*, *Burr v. Atty. Gen. Delaware*, 641 F. Appx. 194, 196 (3d Cir. 2016) (*per curiam*) (seatbelt mandate held constitutional); *Picou v. Gillum*, 874 F.2d 1519, 1519 (11th Cir. 1989) (Powell, J.) (state statute requiring motorcycle riders to wear protective headgear was constitutional). It is no less reasonable here.

B. *Irreparable Harm & Adequate Remedy at Law.*

Irreparable harm is "harm that cannot be repaired and for which money compensation is inadequate." *Orr*, 953 F.3d at 502 (quoting *Graham v. Med. Mut. of Ohio*, 130 F.3d 293, 296 (7th Cir. 1997)) (quotations omitted). To the extent that the students establish a constitutional harm, the law presumes irreparable harm. *See, e.g.*, *Cuomo*, 141 S. Ct. at 67-68 (First Amendment free exercise of religion); *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (First Amendment political association); *Christian Legal Society v. Walker*, 453 F.3d 853, 859 (7th Cir. 2006) ("loss of First Amendment freedoms is presumed to constitute an irreparable injury"); *Ezell v. City of Chicago*, 651 F.3d 684, 699 (7th Cir. 2011) (Second Amendment); *Preston v. Thompson*, 589 F.2d 300, 303 n.3 (7th Cir. 1978) ("The existence of a continuing constitutional violation constitutes proof of an irreparable harm."); *Doe v. Mundy*, 514 F.2d 1179, 1183 (7th Cir. 1975) (right to privacy); *Democratic Nat. Committee v. Bostelmann*, 447 F. Supp.3d 757, 769 (W.D. Wis. 2020); *Planned Parenthood of Ind. v. Commissioner*, 194 F. Supp.3d 818, 835 (S.D. Ind. 2016) (presuming equal protection and substantive due process harms irreparable); 11A Wright & Miller, Federal Practice &

Procedure § 2948.1 (2d ed. 1995) ("When an alleged deprivation of a constitutional right is involved . . . most courts hold that no further showing of irreparable injury is necessary."). That remains true only with the vaccine mandate.

That doesn't mean every alleged harm in this case is irreparable. A delay in collegiate or graduate education isn't typically irreparable harm. *See, e.g.*, *Phillips v. Marsh*, 687 F.2d 620, 622 (2d Cir. 1982); *Hodges v. Bd. of Supervisors*, 2020 U.S. Dist. LEXIS 153949, 7 (E.D. La. Aug. 25, 2020); *Pierre v. University of Dayton*, 143 F. Supp.3d 703, 714 (S.D. Ohio 2015) ("[C]ourts have also held that a suspension is not irreparable."); *Baer v. Nat'l Bd. of Med. Examiners*, 392 F. Supp.2d 42, 49 (D. Mass. 2005) (inability to continue as medical student without interruption is not a harm that is irreparable to potential medical career).

Each exempted student testified that he or she wore masks on many occasions during the pandemic.[124] Any concerns about the hypothetical segregation or discrimination are only speculative and don't constitute irreparable harm. *See Duthie v. Matria Healthcare, Inc.*, 543 F. Supp.2d 958, 960 (N.D. Ill. 2008). Several students have been tested for COVID-19 multiple times with no irreparable harm. And though a few students cite concerns about the safety of nasal testing swabs, Indiana University's testing uses saliva. Though some students say the extra requirements are unnecessary or inconvenient, neither concern rises to the level of irreparable harm. *See, e.g.*, *Students v. United States Dep't of Education*, 2016 U.S. Dist. LEXIS 150011, 125 (N.D. Ill. Oct. 18, 2016); *Right Field Rooftops, LLC v. Chicago Baseball Holdings, LLC*, 87 F. Supp.3d 874, 895 (N.D. Ill.

[124] *See* Ex. 120 at 27 (Ryan Klaassen); Ex. 121 at 44 (Jaime Carini); Ex. 122 at 19-20 (Danial Baumgartner); Ex. 123 at 35-36 (Ashlee Morris); Ex. 124 at 22 (Seth Crowder); Ex. 125 at 17 (Macey Policka); Ex. 126 at 31 (Margaret Roth); Ex. 127 at 29-32 (Natalie Sperazza).

2015) ("inconvenience does not show that harm would be irreparable); *Lewis v. Silverman*, 2005 U.S. Dist. LEXIS 20347, 6-7 (N.D. Ind. Sept. 16, 2005).

Wearing masks, undergoing surveillance testing, and social distancing also aren't indicative of irreparable harm, but consistent with CDC guidelines [Ex. 129 at 28]. *See Orr*, 953 F.3d at 502 (defining irreparable harm). For these particular circumstances, the students also have an adequate remedy at law—money damages. The presumption that money is never an adequate remedy for constitutional violation is wrong. *See Campbell v. Miller*, 373 F.3d 834, 835 (7th Cir. 2004). Such damages would be normal and adequate to address what, even in the most severe light, to be no more than a personal injury. *See id.*

To be inadequate, a remedy needn't be "wholly ineffectual," but it must be "seriously deficient as compared to the harm suffered." *Foodcomm Intern. v. Barry*, 328 F.3d 300, 304 (7th Cir. 2003). If there were to be a constitutional injury here, the court could see that there is no adequate remedy at law if it didn't issue the preliminary injunction. That is less potent when the likelihood of success is so low. *See Adams v. City of Chicago*, 135 F.3d 1150, 1154 (7th Cir. 1998) (if court finds neither irreparable harm nor a likelihood of success, the "analysis ends and the preliminary injunction should not be issued"); *Dish Network LLC v. Cox Media Grp., LLC*, 2020 U.S. Dist. LEXIS 126850, 20 (N.D. Ill. July 20, 2020) (plaintiff's "failure to demonstrate a reasonable likelihood of success on the merits alone is enough to deny its motion"); *Geneva Intern. Corp. v. Petrof, SPOL, S.R.O.*, 529 F. Supp.2d 932, 940 (N.D. Ill. 2007) ("Because [plaintiff] fails to demonstrate irreparable harm, we need not continue to analyze the remaining factors.").

In short, the court presumes the students could establish irreparable harm and the absence of an adequate remedy at law, except as noted here.

C. *The Balance of the Harms and Public Interest Favor Indiana University.*

The balance of harms against the parties and the public interest favor denying the preliminary injunction. This is a sliding scale analysis. The court "weighs the balance of potential harms" against "the movant's likelihood of success." *Turnell*, 796 F.3d at 662. The more likely the plaintiff is to win, the less the balance of harms needs to favor them; the less likely, the more it must weigh in their favor. *Id.* The court has already said the students' likelihood of success is low, and the odds favor the university.

To be sure, the students have a significant liberty interest in refusing unwanted medical treatment. Telling them they must take unwanted medical treatment is a significant intrusion on their liberty. And under the harm principle, "the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others." John Stuart Mill, *On Liberty* 9 (1859); *see Cassell*, 990 F.3d at 550. If the students' decision to refuse the vaccine affected themselves alone, the balance of harms would almost certainly weigh in favor of granting a preliminary injunction.

But the evidence reasonably shows that they aren't the only ones harmed by refusing to get vaccinated: refusing while also not complying with heightened safety precautions could "sicken and even kill many others who did not consent to that trade-off." *Cassell*, 990 F.3d at 550. This certainly impacts the public interest: the students "are not asking to be allowed to make a self-contained choice to risk only their own health" in

making this decision—their decision necessarily bears on the health of other students, faculty, and staff. *Id.* The balance of harms doesn't weigh in the students' favor here.

And because the students aren't being forced to take the vaccine against their will, the harm is demonstrably less. Though the students may have to forego a semester of school or transfer somewhere else—certainly a difficult and inconvenient choice, and not one lightly tossed aside—they have options. Other colleges in Indiana and around the nation haven't mandated vaccines. Indiana University says it will reassess the mandate after this semester. This mandate will also enhance the academic environment for all students, faculty, and staff by fostering in-person education and a more traditional college experience, educationally and socially. Today, based on this record, the balance of harms tilts heavily in favor of the university.

The public interest also favors denying a preliminary injunction. The court isn't a policymaker: that role is left to the States. On multiple occasions, the Supreme Court has "recognized the role of the States as laboratories for devising solutions to difficult legal problems." *Arizona State Legislature v. Arizona Independent Redistricting Commission*, 576 U.S. 787, 817 (2015) (quoting *Oregon v. Ice*, 555 U.S. 160, 171 (2009)); *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring) ("States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear"); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."). Enabling the this state

university to work through these problems reasonably fosters public health and safety in areas of scientific uncertainty. *See Gonzales*, 550 U.S. at 163 (citing *Jacobson*, 197 U.S. at 30-31) (the law gives "wide discretion to pass legislation in areas where there is medical and scientific uncertainty"); *Cassell*, 990 F.3d at 549 ("scientific uncertainty surrounding the pandemic further cautions against enjoining state coronavirus responses unless absolutely necessary"); *see also Cuomo*, 141 S. Ct. at 68 ("Members of this Court are not public health experts").

To be sure, if the students had shown a likelihood that the university was unreasonably infringing on their constitutional rights, enjoining that violation would be in the public interest. *See Joelner v. Village of Washington Park*, 378 F.3d 613, 620 (7th Cir. 2004) ("upholding constitutional rights serves the public interest") (quoting *Newsom v. Albermarle Cnty. Sch. Bd.*, 354 F.3d 249, 261 (4th Cir. 2003)); *Ind. Fine Wine & Spirits, LLC v. Cook*, 459 F. Supp.3d 1157, 1171 (S.D. Ind. 2020) (same). But this concern doesn't apply here because the students have a low likelihood of success.

In short, the balance of harms and the public interest favor Indiana University and the determination that it has reasonably determined the best course of action for the health of its academic community this upcoming fall semester. And in doing so, Indiana University plans to return sooner to normal operations—thus serving much more than just its academic community.

D. *What This Opinion Isn't.*

Don't misread it. The court is not declaring the absolute safety and efficacy of the vaccines, or for all people. People need to understand the risks, remain informed as the

science evolves, monitor the review before the FDA, and determine whether to take a vaccine. The court must decide this case on the evidence before it. The evidence today shows that the students have little chance of success: Indiana University is reasonably pursuing a legitimate aim of public health for its students, faculty, and staff.

This university policy isn't forced vaccination. The students have options—taking the vaccine, applying for a religious exemption, applying for a medical exemption, applying for a medical deferral, taking a semester off, or attending another university. This policy applies for the fall 2021 semester only. Students may make their choice after being advised of the risks and benefits of the vaccines, thereby giving informed consent. The court recognizes that for certain students this may prove a difficult choice, but a choice nonetheless. The choice isn't so coercive as to constitute irreparable constitutional harm. Although it proves a condition to attend this fall, it is reasonable under the Constitution.

This isn't a decision after a final trial on the merits. The court has made this decision based on evidence, testimony, and briefing that the parties produced on an emergent timetable. They and their skilled counsel should be commended for the quality of their submissions, particularly under tight demands. But not every stone has been unturned by the parties. Not every study has been hashed out or submitted for the court to read. Not every witness has testified. Although constituting more than 100 exhibits and testimony from many individuals, including proposed experts, much of which then refers the court to innumerable studies and articles that it has endeavored to review

carefully, much in these five days, this still is a preliminary record, with an opinion issued urgently given the interests of these parties.

The court also isn't saying Indiana University (or any other State or state entity) may do whatever it wants to address COVID-19. Given the liberty at stake for these students here, the university must act reasonably in achieving a legitimate state goal of public health. The Fourteenth Amendment's due process clause checks that authority. Today's decision doesn't provide *carte blanche* authority for Indiana University to do as it pleases without regard to the Constitution. For instance, in the future, the goal of seeing zero or very low new positive cases as a rolling average in attainment of herd immunity may or may not prove reasonable [*see* Ex. 242 at 62-63], but those aren't the circumstances now facing the university, and those aren't the circumstances now presented to the court. Speculative concerns about hypothetical future events don't show irreparable harm. *Duthie v. Matria Healthcare, Inc.*, 543 F. Supp.2d 958, 960 (N.D. Ill. 2008).

The policy will no doubt evolve. The court questioned the parties about the scope of the university's medical exemption. The university's standard vaccination policy, originating from the General Assembly's mandate that public university students receive certain vaccinations, contains an exemption for medical contraindications,[125] with support from a physician's statement [Ex. 229]. Whereas, curiously, the university's COVID-19 policy preserves medical exemptions only for allergies to vaccine ingredients,

[125] A contraindication is any "condition[] in a recipient that increases the risk for a serious adverse reaction." CDC, *General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)*, https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

not contraindications—ostensibly a narrower basis for exemption for an EUA vaccine than for other decades-existing vaccines.

At oral argument, Indiana University explained that, at the time of adoption, allergies proved the only contraindication and that the university has applied its medical exemption more broadly. There is some evidence for this in the record [*see*, *e.g.*, Ex. 128 at 84-88]. Four physicians on the university medical team consider any requested medical exemption and work with the student's physician to address any immunocompromising condition (and, at times, try to educate the physician on certain pathophysiologies that aren't of concern) [*id.*]. In doing so, the university follows CDC guidance. The university thus has considered for exemption such conditions as vaccine-suppressing medications, pregnancy, steroids, chemotherapy, and organ transplants, to name a few [*id.* at 85-88]. In truth, the medical exemption has been applied more broadly than it is written.

Wisdom might counsel its update to reflect reality and an evolving science. Jumping on this concern, the students call the medical exemption arbitrary in oral argument. The record doesn't bear this out. Indeed, no matter the seeming problematic nature of a narrow medical exemption as written, it has been reasonably broad as applied [*id.*]. The simple truth is that none of the eight students here have sought a medical exemption with the support of a physician's statement to trigger this issue.

Jaime Carini says she wanted a medical exemption, but she never sought one; and she has a religious exemption that she secured in any event [Ex. 121 at 58-60, 69; Tr. 53]. She doesn't present facts that show the university chose to ignore a doctor's recommendation. Margaret Roth has legitimate concerns about taking the vaccine, but

she too hasn't applied for a medical exemption or been denied [Ex. 126 at 26]. Natalie Sperazza believes it unsafe, but she too provides no physician's statement to support this view or shows she applied for a medical exemption [Ex. 127 at 64]. A future case might raise an issue under the medical exemption, but that's not today's case. *See Jacobson*, 197 U.S. at 36-37 (leaving option to challenge vaccine mandate for contraindications). The court won't issue an advisory opinion. *See Brixen*, 908 F.3d at 280.

CONCLUSION

Even assuming in certain respects irreparable harm and an inadequate remedy at law, the students here haven't established a likelihood of success on the merits of their Fourteenth Amendment due process claim, or that the balance of harms or the public's interest favors the extraordinary remedy of a preliminary injunction, before a trial on the merits. The court thus DENIES their preliminary injunction motion [ECF 7].

Recognizing the significant liberty interest the students retain to refuse unwanted medical treatment, the Fourteenth Amendment permits Indiana University to pursue a reasonable and due process of vaccination in the legitimate interest of public health for its students, faculty, and staff. Today, on this preliminary record, the university has done so for its campus communities. That leaves the students with multiple choices, not just forced vaccination.

One might well hale a certain Emersonian self-reliance and self-determination as preference—an unfettered right of the individual to choose the vaccine or not—but, given a preliminary record such as today's, the court must exercise judicial restraint in superimposing any personal view in the guise of constitutional interpretation.

Reasonable social policy is for the state legislatures and its authorized arms, and for the People to demand through their representatives.

SO ORDERED.

July 18, 2021

s/ Damon R. Leichty
Judge, United States District Court

MS-DOH-21-1816-A-000137

From: Health Law360
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TOP NEWS

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Analysis

Avenatti Gains Edge As Feds Show Hand In Mistrial

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POLICY & REGULATION

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PEOPLE

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Epstein Becker Green bolstered its ranks in Boston by luring over a seasoned attorney from Ogletree Deakins who specializes in helping life sciences companies navigate the full gamut of labor and employment issues.

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Pechanga Band of Luiseno Indians
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U.S. District Court for the Eastern District of Kentucky
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greater health concerns and hiccups in transitioning to remote work, according to a recently released report.

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Navy GC Pick Earns $4 Million In Kramer Levin Partner Share

President Joe Biden's selection to be the top lawyer for the U.S. Department of the Navy reported earning more than $4 million from his partner share at Kramer Levin Naftalis & Frankel LLP, according to a financial disclosure obtained by Law360 on Monday.

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ERISA Can't Preclude Atty's Suit Against Law Firm Partners

An attorney who said a law firm's leadership illegally pushed her out of the firm convinced a Louisiana federal judge to kick her lawsuit to state court, despite her former partners' argument that her case was preempted by federal benefits law.

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5th Circ. Vacates Injunction In Legal Tech Spat

The Fifth Circuit has wiped out a preliminary injunction that Houston legal tech company Document Operations had obtained against a one-time Japanese partner it now accuses of ripping off its trade secrets, after finding that the lower court's ruling violated notice requirements and aspects of a U.S.-Japan treaty.

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Ex-Greensill Risk Chief Lands At New Firm, Recounts Collapse

Supply chain finance company Finverity announced it has hired the former chief risk officer of now-defunct Greensill Capital to head up its own risk function, saying the firm intends to learn from the mistakes made by the onetime financial giant.

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Podcast

Pro Say Movie Club: 'Loving'

Richard and Mildred Loving were arrested in their bedroom in the middle of the night back in 1958, for violating a Virginia law that barred interracial marriage.

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Schoen Legal Search
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HEALTH

Wednesday, August 25, 2021

TOP NEWS

SEC Nabs $6M Settlement In Earnings Management Sweep

The U.S. Securities and Exchange Commission on Tuesday announced a $6 million settlement of the third enforcement action to come out of its data-focused initiative targeting violations linked to earnings management practices.

Order attached | Read full article »

FTC, Illumina Clash On Merger's Potential To Win Cancer War

Federal Trade Commission staffers opened their in-house challenge to Illumina's $8 billion reacquisition of Grail with a warning Tuesday that the merger will inhibit competition necessary to win "the war on cancer," painting a picture that served as a mirror image of the companies' arguments.

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11th Circ. Suggests Lab Ignored Mintz Advice Over Fees

Eleventh Circuit judges hinted Tuesday that a lower court properly ended legal malpractice claims against Mintz Levin Cohn Ferris Glovsky and Popeo PC over its advice to a defunct diagnostic lab that ran afoul of federal anti-kickback laws.

2 documents attached | Read full article »

Talc Users Seek Court Order To Bar J&J Liability Spinoff

Amid media reports that Johnson & Johnson may offload its sizable talc legal liabilities into an entity destined for bankruptcy, ovarian cancer patients asked a Missouri court Tuesday for a restraining order against a move they say would deprive them of damages.

2 documents attached | Read full article »

Calif. Jury Clears C.R. Bard Over Design Of Vein Filter Implant

A California federal jury on Tuesday cleared C.R. Bard of a retired carpenter's product liability claims alleging the company negligently designed a blood clot-stopping IVC vein filter that easily broke up and sent metal shards into the plaintiff's lungs and heart.

Verdict attached | Read full article »

Analysis

Avenatti Gains Edge As Feds Show Hand In Mistrial

Michael Avenatti scored a major tactical win in his California fraud case when a federal judge declared a mistrial Tuesday, giving the disgraced lawyer a chance to fortify his defense after seeing a monthlong dress rehearsal by the

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POLICY & REGULATION

Green Card Applicants Must Be Fully Vaxxed Against Virus

Foreigners applying for a U.S. green card must be fully vaccinated against COVID-19 under a new policy from the U.S. Centers for Disease Control and Prevention.
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From:	Tim Hughes
To:	Tim Hughes
Subject:	TFAH"s Ready or Not report releasing this Wednesday - (Sent by Tim Hughes on behalf of Rhea Farberman)
Date:	Monday, March 8, 2021 3:02:58 PM
Attachments:	New Report Measures States" Health Emergency Preparedness[1].pdf TFAH-2021-ReadyOrNot-FnlEmb.pdf

Dear State Health Official,

TFAH will release its annual report *Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism* measuring states' health emergencies preparedness on Wednesday, March 10. Not surprisingly, this year the report has a special focus on the impact of COVID-19, highlighting the need to increase resources for emergency preparedness. We clarify that our report measures all-hazards preparedness and is not a measure of any state's COVID-19 response.

As we have done in past years, we measure 10 health security indicators in each state and discuss the relationship of each to all-hazard preparedness. We placed states into one of three performance tiers (high, middle and low) based on these indicators. Twenty states and the District of Columbia placed in the high-performance tier, 15 states placed in the middle performance tier and 15 states placed in the low performance tier.

Particularly significant in this year's report is our emphasis on how the pandemic demonstrated the importance of the federal government's role in a health emergency on the scale of a pandemic, the impact of structural racism on a community's resilience during a health emergency, and, the critical need for core public health funding including workforce and infrastructure support.

The report is being shared with news media ahead of the Wednesday morning lift of the embargo. It is likely to be covered in news markets across the country. I recommend you share these materials with your communications staff today so they can prepare for any media requests.

I'd be happy to answer any questions.

Thank you,
Rhea

Rhea K. Farberman, Director
Strategic Communications and Policy Research
Trust for America's Health
rfarberman@tfah.org

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Rhea Farberman, 202 494-0860 RFarberman@tfah.org

New Report Finds Gaps in States' Preparedness for Public Health Emergencies

COVID-19 Illuminated critical harm of underinvestment in public health infrastructure

(Washington, DC) --- March 10, 2021 – The COVID-19 pandemic has starkly demonstrated that underinvestment in preparedness to respond to public health emergencies can cost hundreds of thousands of lives and wreak havoc on the economy. A new report released today by Trust for America's Health (TFAH) measured states' performance on 10 key emergency preparedness indicators and found room for improvement in every jurisdiction.

The report, *Ready or Not 2021: Protecting the Public's Health from Diseases, Disasters and Bioterrorism* measured states' readiness for health emergencies of any kind (not just the COVID-19 crisis). It placed 20 states and the District of Columbia in a high level of preparedness category, 15 states in a middle preparation tier and 15 states in a low degree of preparation tier.

State performance, by scoring tier, 2020

Performance Tier	States	Number of States
High Tier	CO, CT, DC, DE, GA, ID, KS, MA, MD, ME, MS, NC, NE, NM, OK, RI, UT, VA, VT, WA, WI	20 states and DC
Middle Tier	AL, CA, FL, IA, IL, KY, LA, MI, MN, MT, ND, NJ, OR, TN, TX	15 states
Low Tier	AK, AR, AZ, HI, IN, MO, NH, NV, NY, OH, PA, SC, SD, WV, WY	15 states

For nearly two decades, TFAH has examined the nation's public health emergency preparedness in this annual report. During that time, all states have made improvements in their emergency preparedness, but all continue to have room for additional strengthening of their public health preparedness and response.

"The importance of this report is that it gives states actionable data to adopt policies that save lives. The COVID-19 crisis shows that we have much more work to do to protect Americans from health threats, particularly in the ways in which structural racism create and exacerbate health risks within communities of color," said John Auerbach, President and CEO of Trust for America's Health. "States need to take aggressive steps to shore up their preparedness for all types of public health emergencies."

While the report's findings are not a measure of any state's COVID-19 response, they demonstrate that while states' readiness is important, national health emergencies on the scale of a pandemic require strong federal leadership and coordination, and long-term investment in public health infrastructure and workforce. States alone, even those that rank high in this report, are not sufficiently equipped to respond to a pandemic without federal help, say the report's authors.

The report found:

A majority of states have made preparations to expand healthcare and public health capabilities in an emergency, often through collaboration. Thirty-four states participated in the Nurse Licensure Compact, up from 26 in 2017. The compact allows registered nurses and licensed practical or vocational nurses to practice in multiple jurisdictions with a single license. In an emergency, this enables health officials to quickly increase their staffing levels. In addition, **hospitals in most states have a high degree of participation in healthcare coalitions**. On average, 89 percent of hospitals were in a coalition and 17 states and the District of Columbia had universal participation, meaning every hospital in the jurisdiction was part of a coalition. Such coalitions bring hospitals and other healthcare facilities together with emergency management and public health officials to plan for and respond to incidents. **Every state and the District of Columbia had public health laboratories that had plans for a large influx of testing needs.** This ability to surge laboratory testing capacity during the COVID-19 crisis was extremely critical.

Most states are accredited in the areas of public health, emergency management, or both. As of December 2020, the Public Health Accreditation Board (PHAB) or the Emergency Management Accreditation Program (EMAP) accredited 42 states and the District of Columbia; 29 states and the District of Columbia were accredited by both groups, a net increase of one since November 2019. Both programs help ensure that necessary emergency preparation and response systems are in place and staffed by qualified personnel.

Seasonal flu vaccination rates, while still too low, have risen significantly. The seasonal flu vaccination rate among Americans ages 6 months or older rose from 42 percent during the 2017–2018 season to 52 percent during the 2019–2020 season but is still below the 70 percent target vaccination rate set by *Healthy People 2030.*

In 2019, only 55 percent of employed state residents, on average, used paid time off, the same percentage as in 2018. Those without paid leave are more likely to work when they are sick and risk spreading infection. This became particularly relevant during the COVID-19 pandemic, as isolation and quarantine are important tools for controlling the outbreak.

Most residents who got their household water through a community water system had access to safe water. On average, just 5 percent of state residents used a community water system in 2019 that did not meet all applicable health-based standards.

The report includes recommendations for actions by federal and state policymakers to improve the nation's public health emergency preparedness in seven priority areas:

- Provide stable, sufficient funding for domestic and global public health security.
- Strengthen policies and systems to prevent and respond to outbreaks and pandemics.
- Build resilient communities and promote health equity generally and in preparedness.
- Ensure effective public health leadership, coordination, and workforce.
- Accelerate development and distribution, including last mile distribution, of medical countermeasures.
- Strengthen the healthcare system's ability to respond and recover during and from health emergencies.
- Prepare for environmental threats and extreme weather.

The *Ready or Not* report series is funded by the Robert Wood Johnson Foundation with additional support from The California Endowment, W.K. Kellogg Foundation and The Kresge Foundation.

###

Trust for America's Health is a nonprofit, nonpartisan organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority. www.tfah.org. Twitter: @healthyamerica1

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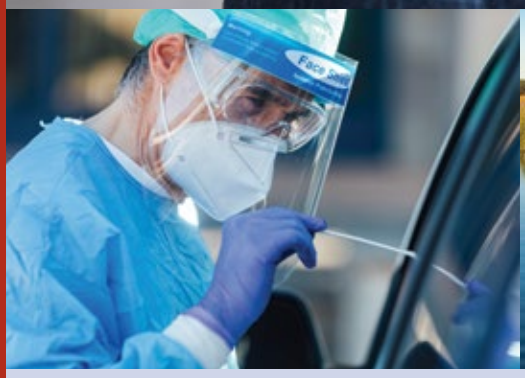
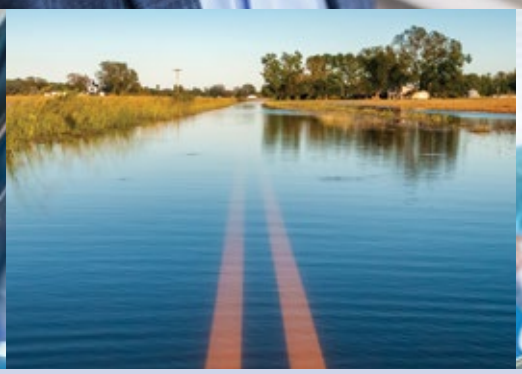
Ready or Not:

PROTECTING THE PUBLIC'S HEALTH FROM DISEASES, DISASTERS, AND BIOTERRORISM 2021





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Trust for America's Health (TFAH) is a nonprofit, nonpartisan public health policy, research, and advocacy organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority.

The Ready or Not report series is supported by generous grants from the **Robert Wood Johnson Foundation**, with additional support from **The California Endowment, W.K. Kellogg Foundation** and **The Kresge Foundation.** Opinions in this report are TFAH's and do not necessarily reflect the views of its funders.

The National Health Security Preparedness Index (NHSPI) is a joint initiative of the Robert Wood Johnson Foundation, the University of Kentucky, and the University of Colorado. TFAH wishes to recognize and thank Glen Mays and Michael Childress of the NHSPI for their collaboration and expertise as well as the Robert Wood Johnson Foundation for its continued funding support.

Ready or Not and the NHSPI are complementary projects that work together to measure and improve the country's health security and emergency preparedness. TFAH looks forward to a continued partnership.

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Editor's note: This report was being prepared during a presidential transition. We have included comments in the report where we have noted action on TFAH policy recommendations by the Biden administration.

View this report online at www.tfah.org/report-details/readyornot2021

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EXECUTIVE SUMMARY

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Executive Summary

The past year, 2020, will long be remembered as the year more than 2 million people lost their lives due to a global pandemic. Not since the 1918 influenza pandemic has a single event so urgently demonstrated the criticality of a strong public health system. This *Ready or Not* report has tracked the country's level of public health emergency preparedness since 2003. For nearly two decades, it has asked the fundamental question: "are we ready?" Unfortunately, the COVID-19 crisis has provided a clear answer: an emphatic "no."

The COVID-19 crisis has illuminated the urgent need for federal, state, local, tribal, and territorial leaders to take aggressive steps to shore up the nation's preparedness for all types of emergency events. The pandemic put a spotlight on a public health system hollowed-out by years of insufficient funding. Health departments were overstretched, responding to the pandemic with archaic technologies[1] and with overworked staff who faced threats and retribution.[2] These gaps were all the more critical in 2020 because the federal government failed to take an evidence based, leadership role in the pandemic response, with many decisions being left to states that would ordinarily be federally coordinated. It also demonstrated the harm that can be done when science and public health expertise are stifled by political interference and misinformation.

In addition, the pandemic has once again demonstrated and exacerbated the impact of structural racism, both historic and current, on the health and well-being of communities of color and Tribal Nations. Acknowledging the lingering health impacts of slavery and the treatment of native peoples and addressing current day racist policies, systems, and attitudes must be part of building the nation's resilience. In short, equity is not separate from preparedness. Ensuring an equitable opportunity for the health and well-being of all residents before a disaster creates more resilient communities during an emergency. Equity must be an explicit and foundational principle in all emergency planning. Achieving equity in all facets of emergency response requires including equity accountability metrics in emergency preparation and management.

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Foundational capabilities are necessary throughout the public health system, from the Centers for Disease Control and Prevention (CDC) to state, local, tribal, and territorial health departments, including:[3]

- Health monitoring and assessment, comprising surveillance, epidemiology, and laboratory capacity;
- All-hazards preparedness and response;
- Policy development and support;
- Public communications;
- Community outreach and partnership development;
- Organizational and administrative competencies (i.e., leadership, governance, and health equity); and
- Accountability and performance management.[4]

Today, only half of Americans are protected by a comprehensive local public health system.[5] The Public Health Leadership Forum estimates a $4.5 billion annual shortfall in the spending necessary to meet the infrastructure needs of public health agencies nationwide.[6] This shortfall was on display throughout the COVID-19 pandemic, as decades of chronic underfunding hindered communications, disease surveillance, contact tracing, vaccine delivery, and other key health department activities.

"A powerful aspect of this report is its long history objectively measuring states' preparedness. This year's recommendations are almost identical to past years. Had the nation paid more attention to pandemic threats and TFAH's commonsense and consistent recommendations, this country would be in a very different place today."

Shelley A. Hearne, DrPH
Johns Hopkins University Bloomberg School of Public Health

It is also important to note that the infusion of COVID-19 emergency funding was onetime funding—critical to the pandemic response but not a solution to the system's longtime underinvestment.

This report is designed to give policymakers at all levels of government actionable data and recommendations with which they can target policies and spending to strengthen their jurisdiction's emergency preparedness. The report's 10 key public health preparedness indicators give state officials benchmarks for progress, point out gaps within their states all-hazards preparedness, and provide data to compare states' performance against like jurisdictions. These data points, or ones similar to them, have been the focus of this report for over a decade and are meant to measure readiness for a broad set of health security threats. They are not tailored to an assessment of a given state's response to the COVID-19 pandemic, as widescale political, funding, economic, and social factors all influenced the virus impact and local responses. A state may do well in terms of its ranking in this report but poorly in its response to the COVID-19 pandemic—and vice versa. While no state has been spared, what seems to have mattered most in the pandemic response is a state's socioeconomic and racial profile, as well as the adherence of elected leaders and residents to evidence-based public health guidelines. The pandemic has illustrated that robust and sustained funding, elected officials' leadership, and federal-state coordination and planning are key to protecting Americans' health security. Moreover, there is no substitute at the state or local level for a strong federal response.

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COVID-19 AND EMERGENCY PREPAREDNESS: TRAGIC LESSONS

TFAH's *Ready or Not: Protecting the Public's Health from Diseases, Disasters and Bioterrorism* report has tracked the nation's readiness to respond to a public health emergency for nearly two decades. During that time, no event highlighted the critical importance of this report's purpose—measuring and promoting readiness to safeguard Americans' health during an emergency—to the degree the COVID-19 crisis has.

The COVID-19 pandemic is an on-the-ground, real-time measure of the nation's public health emergency response system—a test the federal government failed according to most public health experts. An October 2020 report by Columbia University Earth Institute's National Center for Disaster Preparedness estimated that the federal government's inadequate pandemic response led to between 130,000 and 210,00 avoidable deaths. The report submits that if the United States had implemented sufficient testing, earlier lockdowns, a national mask-wearing mandate, and provided federal guidance on social distancing, over 200,000 lives could have been saved.[7]

With a possible single exception (water system safety), all of the readiness indicators measured annually by this *Ready or Not* report played a role in jurisdictions' COVID-19 response. Seven were relevant to the effort to control the pandemic and save lives: (1) nurse licensure compact (allowing jurisdictions to borrow medical personnel when they need to surge capacity), (2) hospital participation in healthcare coalitions, (3) public health and emergency management accreditation, (4) public health funding, (5) access to paid time off, (6) flu vaccination rates (as a proxy for a community's vaccination infrastructure and receptivity), and (7) laboratory surge capacity. TFAH will continue to measure states on these indicators, as they play a central role in the standing-ready, public health protection capacity that every state needs.

The pandemic has also spotlighted a number of issues not currently measured by the report but critical and dramatically apparent if absent during a health emergency: federal and state political leadership, interagency coordination, consistent and well-executed public communications, and health equity.

Importance of Federal Leadership

Government at multiple levels shares responsibility for emergency planning and response. Under this tiered structure, when an event requires a larger response than a local entity can provide, government from the tier above it—typically a tribal, territorial or state agency—provides assistance. When a state's response resources are not enough to meet demands during an emergency, the federal government provides support. For a public health emergency as significant and contagious as COVID-19, clear communication and strong leadership and coordination by the federal government are essential, elements

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that were lacking during the initial months of the pandemic response. Instead, inconsistent messages between federal agencies and the White House; lack of centralized coordination, such as for procurement of personal protective equipment (PPE); and political interference with guidance from scientific agencies—all led to confusion and contradictory policies among states and weakened the emergency response.

TFAH has made a number of policy recommendations designed to ensure robust and nonpartisan federal leadership during future public health emergencies, including:

- Create a White House Health Security Directorate, including senior advisors to the president with public health expertise on health security issues. This directorate would oversee the national biodefense strategy and all interagency emergency responses.
- Ensure full transparency and consistency in federal messaging from the White House, CDC, ASPR, FDA, and National Institutes of Health (NIH) concerning public health issues to ensure message clarity, avoid confusion, and build trust.
- Ensure that federal public health officials are fully empowered to make decisions based on science and without undue political influence. Efforts to infuse politics into public health decision-making puts the public's health at risk.
- HHS should strengthen leadership by working with states and suppliers to ensure adequate stockpiling and distribution of medical countermeasures and ancillary emergency response products, such as personnel protective equipment.

Overcoming the Legacy of Racism

The legacy of slavery, genocide, and centuries of racism, combined with current day interpersonal and structural racism, is at the root of the disproportionate impact COVID-19 has had on communities of color and Tribal Nations. These systemic inequities, in access to healthcare, housing, education, transportation, and employment, existed before the pandemic and have been exacerbated by it. Health inequities due to disadvantages experienced by racial, ethnic, or other population groups are preventable differences in the burden of disease, injury, and health emergencies and to opportunities to achieve good health.[8] Addressing issues at the root of health inequity is imperative to ensuring all people, regardless of their race or ethnicity or where they live, have the opportunity for good health and are protected during a health emergency.

TFAH has called on the administration and Congress to make advancing health equity and eliminating health disparities a national priority by:

- Ensuring that all COVID-19 response actions prioritize advancing health equity, including access to COVID-19 testing and vaccinations.
- Creating a Truth, Racial Healing, and Transformation Commission, and provide funding to communities to begin the process of acknowledging a history of racism and working to dismantle the myth of hierarchy based on race.
- Expanding funding for initiatives serving communities that have been marginalized by disinvestment, and ensure that federal funding supports processes that meaningfully engage the most affected communities in the planning and implementation of such initiatives.
- Developing a White House led strategy focused on addressing the root causes of disease and on promoting health equity.
- Creating a *social determinants of health* line item at the Centers for Disease Control and Prevention (CDC), authorized and fully funded by Congress, with sufficient funding to guarantee grant-funded efforts throughout the nation.
- Requiring all agencies to collect, disaggregate, and report health data in such a way that the impact of health conditions, policies, or interventions on specific population groups are known, including health status data by race, ethnicity, sexual orientation, gender identity, primary language, and disability status.

The tragedy of the COVID-19 pandemic, including over 500,000 deaths in the United States (as this publication was being prepared) and unprecedented harm to the economic security of millions of American families, will forever be a painful reminder of the critical importance of pre-event public health emergency preparations, investments in public health infrastructure, and evidence-based policy and communications. The pandemic has undeniably demonstrated that historical discrimination coupled with current-day racism impacts a community's health status and ability to weather a disaster. The COVID-19 crisis has also painfully reinforced that national leadership must be grounded in science and committed to addressing structural racism, both of which are imperative to saving lives during an emergency.

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This edition of the *Ready or Not series* finds that states have made progress in most of the report's measured areas, especially rates of seasonal flu vaccination. However, improvement in other areas—such as paid time off for workers and hospital patient safety—has stalled. In this 2021 report, Trust for America's Health (TFAH) found that three states improved their standing compared with last year, while eight fell behind. Three states improved by one tier, six states dropped one tier, and two dropped two tiers.

TABLE 1: Top-Priority Indicators of State Public Health Preparedness

INDICATORS			
1	**Incident Management:** Adoption of the Nurse Licensure Compact.	6	**Water Security:** Percentage of the population that used a community water system that failed to meet all applicable health-based standards.
2	**Cross-Sector Community Collaboration:** Percentage of hospitals participating in healthcare coalitions.	7	**Workforce Resiliency and Infection Control:** Percentage of employed population that used paid time off.
3	**Institutional Quality:** Accreditation by the Public Health Accreditation Board.	8	**Countermeasure Utilization:** Percentage of people ages 6 months or older who received a seasonal flu vaccination.
4	**Institutional Quality:** Accreditation by the Emergency Management Accreditation Program.	9	**Patient Safety:** Percentage of hospitals with a top-quality ranking ("A" grade) on the Leapfrog Hospital Safety Grade.
5	**Institutional Quality:** Size of the state public health budget compared with the past year.	10	**Health Security Surveillance:** The public health laboratory has a plan for a six- to eight-week surge in testing capacity.

Notes: The National Council of State Boards of Nursing organizes the Nurse Licensure Compact. The federal Hospital Preparedness Program of the U.S. Office of the Assistant Secretary for Preparedness and Response supports healthcare coalitions. The U.S. Environmental Protection Agency assesses community water systems. Paid time off includes sick leave, vacation time, or holidays, among other types of leave. The Leapfrog Group is an independent nonprofit organization. TFAH drew every indicator, and some categorical descriptions, from the National Health Security Preparedness Index, with one exception: public health funding. See "Appendix A: Methodology" for a description of TFAH's funding data-collection process, including its definition.

Source: National Health Security Preparedness Index [9]

The *Ready or Not* report groups states and the District of Columbia into one of three tiers (high, middle, low) based on their performances across the 10 indicators. This year, 20 states and the District of Columbia scored in the high-performance tier, 15 placed in the middle-performance tier, and 15 were in the low-performance tier (see Table 2). (See "Appendix A: Methodology" for more information on the scoring process.)

Three states showed notable improvement, moving up a tier: Georgia, Montana, and Rhode Island. Georgia, which rose from the middle tier to the high tier, improved its standing by achieving accreditation by the Emergency Management Accreditation Program and by having a greater share of its hospitals receive high marks on patient safety. Montana, which elevated from the low tier to the middle tier, increased its public health funding level in fiscal year 2020. And Rhode Island, which rose from the middle tier to the high tier, did so by dramatically increasing its community drinking-water security.

Two states fell from the high tier to the low tier: Missouri and Pennsylvania. Missouri cut its public health funding in FY 2020 and saw an increase in the share of its residents that used a community water system with one or more health-based violations. Its flu vaccination rate ticked up marginally, but by less than the nation as a whole. Likewise, Pennsylvania also cut its public health funding level, and its share of hospitals that received an "A" rating—one of the highest in the nation—rose by slightly less than the national average. Other steps it could take to improve its standing include joining the Nurse Licensure Compact or increasing its below-average share of residents who take paid time off from work.

Five states fell from the high tier to the middle tier: Alabama, Illinois, Iowa, New Jersey, and Tennessee. These states did not experience significant backsliding overall, but they lost ground, as a number of other states took greater steps that increased their standing.

One state fell from the middle tier to the low tier: Arizona. Arizona's below-average flu vaccination rate rose, but by less than the nation overall, so its overall standing fell back.

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TABLE 2: State Public Health Emergency Preparedness State performance, by scoring tier, 2020		
Performance Tier	**States**	**Number of States**
High Tier	CO, CT, DC, DE, GA, ID, KS, MA, MD, ME, MS, NC, NE, NM, OK, RI, UT, VA, VT, WA, WI	20 states and DC
Middle Tier	AL, CA, FL, IA, IL, KY, LA, MI, MN, MT, ND, NJ, OR, TN, TX	15 states
Low Tier	AK, AR, AZ, HI, IN, MO, NH, NV, NY, OH, PA, SC, SD, WV, WY	15 states

Note: See "Appendix A: Methodology" for scoring details. Complete data were not available for U.S. territories.

TFAH's Analysis Found:

A majority of states have made preparations to expand healthcare and public health capabilities in an emergency, often through collaboration. Thirty-four states participated in the Nurse Licensure Compact, up from 26 in 2017,[10] with Indiana and New Jersey being the most recent adopters.[11] The compact allows registered nurses and licensed practical or vocational nurses to practice in multiple jurisdictions with a single license. In an emergency, this enables health officials to quickly increase their staffing levels. For example, nurses may cross state lines to work at evacuation sites or other healthcare facilities. In addition, **hospitals in most states have a high degree of participation in healthcare coalitions.** On average, 89 percent of hospitals were in a coalition, and 17 states and the District of Columbia had universal participation, meaning every hospital in the jurisdiction was part of a coalition. Such coalitions bring hospitals and other healthcare facilities together with emergency management and public health officials to plan for and respond to incidents or events requiring extraordinary action. This increases the likelihood that providers serve patients in a coordinated and efficient manner during an emergency. What's more, **every state had public health laboratories that had plans for how to manage a large influx of testing needs.** States had a plan to surge public health laboratory capacity for six to eight weeks as necessary during overlapping emergencies or large outbreaks, an increase of six states since 2017.

Most states are accredited in the areas of public health, emergency management, or both. As of December 2020, the Public Health Accreditation Board (PHAB) or the Emergency Management Accreditation Program (EMAP) accredited 42 states and the District of Columbia; 29 states and the District of Columbia were accredited by both groups, a net increase of one since November 2019. (EMAP has now accredited Delaware and Georgia; Maryland transitioned from being accredited by both bodies to the PHAB only, with the EMAP providing conditional accreditation.) Eight states (Alaska, Hawaii, Indiana, New Hampshire, South Dakota, Texas, West Virginia, and Wyoming) were not accredited by either group. Both programs help ensure that necessary emergency prevention and response systems are in place and staffed by qualified personnel.

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Seasonal flu vaccination rates, while still too low, have risen significantly. The seasonal flu vaccination rate among Americans ages 6 months or older rose from 42 percent during the 2017–2018 season to 52 percent during the 2019–2020 season.[12] However, *Healthy People 2030*, a set of federal 10-year objectives and benchmarks for improving the health of all Americans by 2030, set a seasonal influenza vaccination-rate target of 70 percent annually.[13]

In 2019, only 55 percent of employed state residents, on average, used paid time off, the same percentage as in 2018. Those without paid leave are more likely to work when they are sick and risk spreading infection. In the past, the absence of dedicated paid sick leave has been linked to or has exacerbated some infectious disease outbreaks.[14] This became particularly relevant during the COVID-19 pandemic, as isolation and quarantine were important tools for controlling the outbreak. The Families First Coronavirus Response Act helped address this issue during the early stages of the pandemic for employers with fewer than 500 employees and certain public employers, temporarily requiring employees to be paid up to 80 hours of sick leave benefits under certain conditions.[15] In January 2021, the Biden administration economic stimulus package proposal included extending paid sick leave to over 100 million U.S. workers.

Only 31 percent of hospitals, on average, earned a top-quality patient safety grade, up slightly from 30 percent in 2019. Hospital safety scores measure performance on such issues as healthcare-associated infection rates, intensive-care capacity, and an overall culture of error prevention. In January 2021, the Biden administration's economic aid package included extending paid sick leave to over 100 million U.S. workers.

Most residents who received their household water through a community water system had access to safe water. On average, just 5 percent of state residents used a community water system in 2019 (latest available data) that did not meet all applicable health-based standards, down slightly from 7 percent in 2018. Water systems with such violations increase the chances of water-based emergencies in which contaminated water supplies place the public at risk.

Based on its policy research and analysis, consultation with experts, and review of progress and gaps in federal and state preparedness—with a particular focus on the preparation gaps and shortfalls identified by the COVID-19 pandemic—**TFAH is recommending policy action in seven priority areas:**

1. **Provide stable, sufficient funding for domestic and global public health security.**
2. **Strengthen policies and systems to prevent and respond to outbreaks and pandemics.**
3. **Build resilient communities and promote health equity generally and in preparedness.**
4. **Ensure effective public health leadership, coordination, and workforce.**
5. **Accelerate development and distribution, including last-mile distribution, of medical countermeasures.**
6. **Strengthen the healthcare system's ability to respond to and recovery from health emergencies.**
7. **Prepare for environmental threats and extreme weather.**

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Report Purpose and Methodology

TFAH's annual *Ready or Not* report series tracks states' readiness for public health emergencies based on 10 key indicators that collectively provide a checklist of top-priority issues and action items for states and localities to continuously address. By gathering together timely data on all 50 states and the District of Columbia, the report assists states in benchmarking their performance against comparable jurisdictions. TFAH completed this research after consultation with a diverse group of subject-matter experts and practitioners.

Ready or Not and the National Health Security Preparedness Index

The indicators included in this report were drawn from, and identified in partnership with, the National Health Security Preparedness Index (NHSPI),[16] with one exception: a measure of state public health funding-level trends, which reflects how well-resourced key agencies are to prepare and respond to emergencies. The NHSPI is a joint initiative of the Robert Wood Johnson Foundation, the University of Kentucky, and the University of Colorado. (See "Appendix A: Methodology" for a detailed description of how TFAH selected and scored the indicators.)

While state placements in *Ready or Not* and the NHSPI largely align, there are some important differences. The two projects have somewhat different purposes and are meant to be complementary, rather than duplicative. With more than 100 indicators, the Index paints a broad picture of national health security, allowing users to zoom out and holistically understand the extent of both individual states' and the entire nation's preparedness for large-scale public health threats. In slight contrast, *Ready or Not,* with its focus on 10 select indicators, focuses attention on state performances on a subset of the Index and spotlights important areas for stakeholders to prioritize. TFAH and the NHSPI work together to help federal, state, and local officials use data and findings from each project to make Americans safer and healthier.

Earning Vaccine Confidence in Communities of Color

Interview with Claude A. Jacob, Dr.PH(c), MPH, the chief public health officer at the Cambridge, Massachusetts, Public Health Department, and **Maria Lemus,** the executive director of Visión y Compromiso, about barriers—both historic and contemporary—to COVID-19 vaccinations within communities of color. This interview was conducted in December 2020.

TFAH: As this report is being finalized, the United States is nearing a time when many Americans, particularly those at the highest risk of infection or the most serious impact if infected, can be vaccinated. What are the barriers to high rates of vaccination in communities of color and among Tribal nations?

Dr. Jacob: We are fortunate in Cambridge. Flu vaccine participation is strong and childhood vaccine compliance is also very high, which we view as rough proxies for COVID-19 vaccine acceptance. That being said, there is a long and sordid history of abuse and mistreatment of these communities by the U.S. government and healthcare system. That many Black and Brown people continue to feel deep mistrust of the healthcare system is understandable. All of us in healthcare and public health must understand that this mistrust goes back to slavery for Black Americans and the genocide perpetuated against indigenous people that lasted for centuries.

We have strong relationships with community organizations, leaders in the faith community, and others who are well known and trusted among communities of color, and we will partner with them to overcome these barriers to vaccine uptake. Recent national and state surveys have told us that Americans view their personal physician as the most trusted voice on COVID-19. Given this finding, we plan to work closely with our hospitals, ambulatory sites, and healthcare providers to help spread the message.

Ms. Lemus: There are many barriers. The ones I'm most concerned about are myths and misinformation, including crazy social media propaganda, fear of adverse reactions, and problems with vaccine accessibility. High rates of the uninsured among some populations groups and misconceptions about who is at risk are additional concerns.

TFAH: The pace of COVID-19 vaccines development has been quicker than many people expected. In some communities this may mean that the vaccine will be available before communications programs about the vaccine's safety and availability have fully taken root. What do those responsible for vaccine distribution need to do when distributing the vaccine under these circumstances?

Dr. Jacob: First of all, we need to celebrate the news that, so far, two vaccines have received FDA emergency use authorization. That two vaccines were developed, tested, and manufactured in less than 12 months is a breathtaking achievement. While we can't let down our guard on physical distancing, wearing masks,

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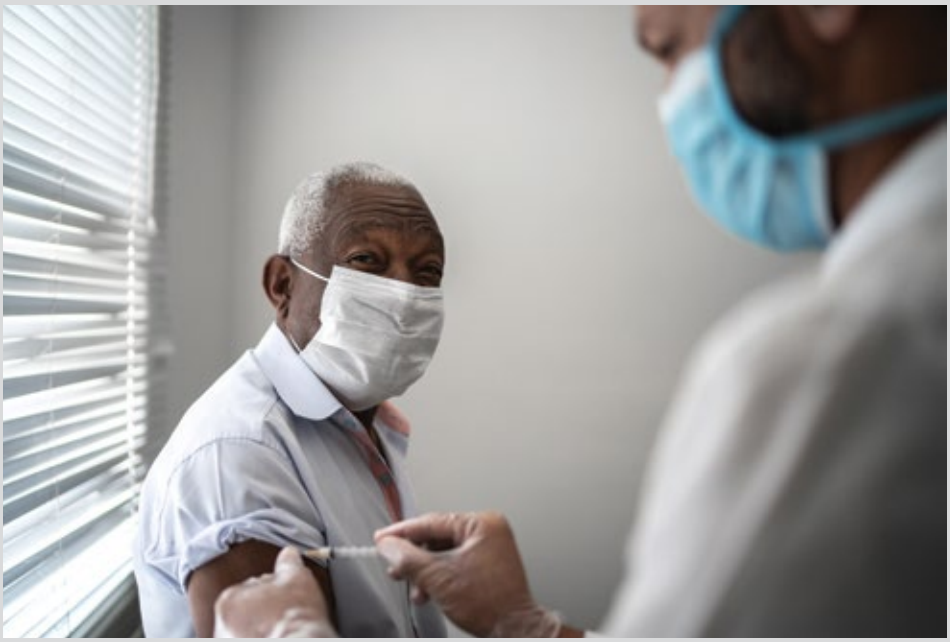
and continuing to practice good hand hygiene, the COVID-19 vaccine marks a watershed moment in the pandemic. We now see the light at the end of the tunnel. At the same time, it's understandable that people have many questions and deep concerns given how quickly the vaccine was developed and approved. For communities of color, the concern over safety comes with a long-standing, entrenched, and well-placed mistrust of the healthcare system.

Communication will be pivotal in educating everyone, especially communities of color, about the safety and importance of this vaccine. To start, we need to have communities of color and physicians of color at the decision-making table to inform and ensure a vaccine rollout that is equitable for all members of our community. Messaging around the vaccine also needs to be informed by, and tested with, communities of color to make sure that these communication efforts resonate. We have a superb opportunity to work with those on the front line of this pandemic, especially doctors, nurses, and physicians' assistants, to help amplify the message in core communities. By all accounts, frontline medical workers are the most trusted source of health information and they are the first to be vaccinated, starting this past December. We should use their voices of trust and reason to speak to communities of color about the safety and critical importance of getting this vaccine.

Ms. Lemus: It will be imperative to share data about the vaccine without jargon and to have trusted messengers deliver the information. I heard a quote recently in response to the question, "Do you know what's in Tylenol?": "No, but I trust it will help me."



TFAH: A woeful history of mistreatment of people of color by government and the healthcare system is at the root of much of the lack of trust in the COVID-19 vaccine within those communities but there are other barriers to vaccine access. What are they and how can they be overcome?

Ms. Lemus: The understandable distrust of government is going to be a huge barrier to the vaccine. A specific example for my community is the Bracero Program, which between 1942 and 1964, based on a series of bilateral agreements between the U.S. and Mexican governments, brought nearly 4.6 million Mexican citizens to work on U.S. farms, railroads, and factories. Those workers experienced racial and wage discrimination and were forced to live and work in substandard conditions. More recently, there have been allegations of unnecessary hysterectomies being performed in ICE detention centers.

The only way to overcome these histories will be to first acknowledge them. Leaders must acknowledge and speak to these injustices; they must denounce them and support remedies. They need to give real-time examples of the efforts being made to engage with and empower communities and to correct past wrongs. Only then will government be able to be heard and only by using trusted messengers and community navigators.

It's also important to remember that the reasons for distrust of government within underrepresented communities is not only about historical legacies; it is based on current-day events and climates. However, it can be corrected. My organization, Visión y Compromiso, has as its mission providing leadership-development and capacity-building opportunities for *promotores* and community health workers in over 4,000 communities. These community-based *promotores* will have a critical role to play in reducing vaccine hesitancy in communities of color. Messaging to convince people to be vaccinated has to feature their heroes, their community leaders, their voices.

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Dr. Jacob: Communities of color have historically had difficulty accessing healthcare. Lack of transportation, work schedules, childcare needs, and competing financial interests—such as paying rent and bills—pose significant barriers to healthcare, as do other social determinants of health, such as poverty and lack of education. Even with the Affordable Care Act—which greatly expanded access to health insurance for everyone—Hispanic, Black, and some Asian communities have lower insurance coverage rates than any other population. Many of them remain uninsured altogether.

The cost of the vaccine is being covered by the federal government through tax dollars, but providers can charge to administer the vaccine, if they choose. We need to do everything we can and work with providers to eliminate fees they may charge in the interest of overcoming this public health emergency. When it is available, we need to bring the vaccine to the public rather than making people come to the vaccine. In Cambridge, the public health department, through its partnership with the city's first-responders and others, have made free COVID-19 testing available to all residents (regardless of symptoms) since July 2020. Starting in November 2020, this "no-barrier," city-funded testing program expanded to seven days a week (from two days/week) and from two neighborhood sites to four. These testing sites are geographically dispersed, and all but one are located in neighborhoods with disproportionately high rates of new COVID-19 infections.

TFAH: What is the importance of where the COVID-19 vaccine is available in your community?

Ms. Lemus: Where the vaccine will be available is another critical issue. The credibility, location, hours, accessibility, relationship to community, their staff, and emissaries are important to individual and families' decision to be vaccinated. *Promotores* are important also in gathering information to contribute to the vaccine distribution and administration, planning implementation, and communications. Community-based organizations must be included in all planning and execution; they are a big part of the solution. Partnering with community-based organizations allows local officials to scale means and resources.

Dr. Jacob: As I have already mentioned, the Cambridge Public Health Department has had enormous success with COVID-19 testing and flu vaccinations by bringing these services to people in the communities where they live and work. We have taken a traditional grassroots approach—going door to door in harder-hit neighborhoods and providing information in eight languages—to build trust and understanding. We need to use this same approach with the COVID-19 vaccine and build on these robust community linkages, which are anchored to the long-standing relationships that we have with partners on the ground.

TFAH: As the chief public health officer for the city of Cambridge, Massachusetts, what is your department's role in increasing vaccine uptake in your community? What resources do you need to be successful?

Dr. Jacob: Local public health has an important role and responsibility in educating communities about the safety and importance of the COVID-19 vaccine, as it does with all vaccinations. Once the vaccine is made available to the general public, the Cambridge Public Health Department, through its partnership with city agencies and the private sector, will be ready to provide vaccines to residents. Throughout the pandemic, our department has worked hand in hand with city partners, especially first-responders, to provide testing and flu shots, and we will rely on this strong, successful relationship to provide the COVID vaccine. It is critically important to note that we could not do our work without strong financial support. Our city manager, Louis A. DePasquale, and the Cambridge City Council have provided financial resources to fight this pandemic and keep our residents and those who work in Cambridge safe. They have long been committed to the important work of the public health department, which is enhanced by the Cambridge Health Alliance led by Dr. Assaad Sayah, who is the commissioner of public health for the city of Cambridge.

Dr. Claude A. Jacob is the chief public health officer for the City of Cambridge, Massachusetts. He served as the president of the National Association of City and County Health Officials in 2016–2017.

Maria Lemus is the executive director of Visión y Compromiso, headquartered in San Francisco, California. Visión y Compromiso provides leadership, advocacy, and capacity-development training to community health workers.

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Assessing State Preparedness

Every state needs to be prepared to respond to a variety of potential public health emergencies; such readiness requires understanding an individual state's preparedness strengths, risks, and vulnerabilities. To help states assess their readiness, and to highlight a checklist of top-priority concerns and action areas, this report examines a set of 10 select indicators. The indicators, used consistently year to year, draw heavily from the National Health Security Preparedness Index (NHSPI), a joint initiative of the Robert Wood Johnson Foundation, the University of Kentucky, and the University of Colorado. They capture core elements of emergency preparedness.

Based on states' standing across the 10 indicators (see "Appendix A: Methodology" for scoring details), TFAH placed states into three performance tiers: high, middle, and low. (See Table 3.)

TABLE 3: State Public Health Emergency Preparedness
State performance, by scoring tier, 2020

Performance Tier	States	Number of States
High Tier	CO, CT, DC, DE, GA, ID, KS, MA, MD, ME, MS, NC, NE, NM, OK, RI, UT, VA, VT, WA, WI	20 states and DC
Middle Tier	AL, CA, FL, IA, IL, KY, LA, MI, MN, MT, ND, NJ, OR, TN, TX	15 states
Low Tier	AK, AR, AZ, HI, IN, MO, NH, NV, NY, OH, PA, SC, SD, WV, WY	15 states

Note: See "Appendix A: Methodology" for scoring details. Complete data were not available for U.S. territories.

Importantly, the implications of this assessment, and responsibility for continuously improving, extend beyond any one state or local agency. Such improvement typically requires sustained engagement and coordination by a broad range of policymakers and administrators. Moreover, some indicators are under the direct control of federal and state lawmakers, whereas improvement in other indicators requires multisector, statewide efforts, including by residents.

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INDICATOR 1: ADOPTION OF NURSE LICENSURE COMPACT

KEY FINDING: 34 states participate in the Nurse Licensure Compact.

Workforce shortages can impair a state's ability to effectively manage disasters or disease outbreaks, potentially resulting in poorer health outcomes for those affected. This reality was starkly illuminated by the COVID-19 pandemic as healthcare capacity in some parts of the country was overwhelmed by the number of people needing care. In an event like a pandemic, the ability to quickly surge qualified medical personnel by bringing healthcare workers from out of state is a key component of healthcare readiness.

This indicator examines whether states have adopted legislation to participate in the Nurse Licensure Compact (NLC). Launched in 2000 by the National Council of State Boards of Nursing, the NLC permits registered nurses and licensed practical nurses to practice with a single multistate license—physically or remotely—in any state that has joined the compact. The NLC provides standing reciprocity, with no requirement that an emergency be formally declared.

Throughout much of 2020, the COVID-19 pandemic placed extraordinary pressure on hospitals across the country as surging infections sent admissions soaring. States that were members of the NLC were well positioned to bring in nurses from other member states, without harmful delays, or to send nurses to other member states that were experiencing acute shortages. For example, New Jersey, which experienced one of the most severe outbreaks in spring 2020, began implementing the NLC, immediately qualifying out-of-state nurses with a multistate license to practice.[17] "I think the COVID-19 outbreak is going to cause the states that are not in the compact now to really take a second look at it," says NLC Director Jim Puente. "If the NLC was expanded to all 50 states, none of the guesswork with emergency orders would be necessary because nurses could travel to other states where they are needed. No applications, fees, or background checks would be necessary."

As of December 2020, 34 states had adopted the NLC, with Indiana and New Jersey being the most recent adopters.[18] This was a net increase of two since 2019 and eight since 2017. Toni Herron, the education compliance officer of the Indiana State Board of Nursing, which joined the compact on July 1, 2020, said that the NLC "presents innovative ways for our Indiana nurses to improve both access to care for patients, while simultaneously reducing the regulatory burden on licensees." [19]

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TABLE 4: 34 States Participate in the Nurse Licensure Compact

Participants and nonparticipants, 2020

Participants			Nonparticipants	
Alabama	Louisiana	North Dakota	Alaska	Nevada
Arizona	Maine	Oklahoma	California	New York
Arkansas	Maryland	South Carolina	Connecticut	Ohio
Colorado	Mississippi	South Dakota	District of Columbia	Oregon
Delaware	Missouri	Tennessee	Hawaii	Pennsylvania
Florida	Montana	Texas	Illinois	Rhode Island
Georgia	Nebraska	Utah	Massachusetts	Vermont
Idaho	New Hampshire	Virginia	Michigan	Washington
Indiana	New Jersey	West Virginia	Minnesota	
Iowa	New Mexico	Wisconsin		
Kansas	North Carolina	Wyoming		
Kentucky				

Note: Indiana and New Jersey joined the NLC in 2020.

Source: National Council of State Boards of Nursing.[20]

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INDICATOR 2: HOSPITAL PARTICIPATION IN HEALTHCARE COALITIONS

KEY FINDING: Widespread hospital participation in healthcare coalitions was common in 2017*; only four states (California, New Hampshire, Ohio, and South Carolina) reported 70 percent or less of their hospitals participated in coalitions supported by the HHS Hospital Preparedness Program.

The federal Hospital Preparedness Program (HPP), which is managed by the HHS Office of the Assistant Secretary for Preparedness and Response, provides cooperative agreements to states, localities, and territories to develop regional coalitions of healthcare organizations that collaborate to prepare for, and in many cases respond to, medical surge events.[21] Coalitions prepare members with critical tools, including medical equipment and supplies, real-time information, enhanced communication systems, and exercises and training for healthcare personnel.[22] A healthcare coalition must contain a minimum of two acute-care hospitals, emergency medical services, emergency management, and public health agencies.[23] Healthcare coalitions invest in local capacity to prepare for and respond to events, reducing jurisdictions' reliance on federal medical assets during disasters.

Broad and meaningful participation by hospitals in healthcare coalitions means that when disaster strikes, systems are in place to coordinate the response, freeing hospitals to focus on clinical care. In the past, healthcare coalitions have assisted in patient transfer, evacuations, and information sharing in events such as Hurricane Harvey in 2017.[24] More recently, the COVID-19 pandemic presented the most intense, widespread, and prolonged test of U.S. hospital systems in a century, threatening at several points to overwhelm facilities' capacities. Healthcare coalitions performed roles such as facilitating the transport of equipment and supplies, sharing information about available beds and ICU capacity, and training healthcare workers on PPE use, treatments, and testing guidelines.[25] During a pandemic, coordination across a region is essential to alleviate pressure on any single facility, to promote cooperation and information sharing for supplies and bed availability, and to facilitate training of healthcare personnel.[26] The extent to which healthcare systems leveraged the resources of their coalitions during the pandemic is a subject that requires further research.

On average, 89 percent of hospitals in states belonged to a healthcare coalition in 2017, with universal participation, meaning every hospital in the state was part of a coalition, in 17 states (Alaska, Colorado, Connecticut, Delaware, Hawaii, Louisiana, Minnesota, Mississippi, Nevada, North Dakota, Oregon, Rhode Island, South Dakota, Utah, Vermont, Virginia, and Washington) and the District of Columbia. (See Table 5.) However, some states, such as Ohio (25 percent) and New Hampshire (47 percent) lagged behind.

The pandemic exposed major gaps in healthcare preparedness, mentioned in TFAH's 2020 report, including coordinating surge capacity across the healthcare system;[27] building and maintaining preparedness for high-consequence infectious diseases;[28] preparedness of facilities that serve people at higher risk, such as long-term care facilities; and lack of training and preparedness for events in healthcare.[29] Experts have also identified additional gaps, such as pediatric surge capacity,[30] burn capacity and other specialty

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care needed for emerging threats, and ongoing stress on the healthcare system's ability to provide emergency care. While healthcare coalitions can help address some of these vulnerabilities, systemwide approaches to preparedness are needed.

**This summary reflects the latest available data (2017). Because these data are no longer being updated, TFAH will consider replacing this measure in future assessments.*

TABLE 5: Widespread Participation of Hospitals in Healthcare Coalitions

Percent of hospitals participating in healthcare coalitions, 2017

States	Percent of Participating Hospitals
AK, CO, CT, DC, DE, HI, LA, MN, MS, NV, ND, OR, RI, SD, UT, VT, VA, WA	100%
ID, WI	98%
GA, WV	97%
KS	96%
AL, NE, NC, OK	95%
ME	94%
KY	93%
WY	92%
TN	91%
MI	90%
MD	89%
IL	88%
MO	87%
NY, PA	86%
MT	83%
MA, NJ	82%
AR	81%
IA, TX	80%
IN	75%
FL	73%
AZ	72%
NM	71%
CA	70%
SC	56%
NH	47%
OH	25%

Note: This indicator measures participation by hospitals in healthcare coalitions supported through the federal Hospital Preparedness Program of the Office of the Assistant Secretary for Preparedness and Response. The latest available data is from 2017.

Source: NHSPI analysis of data from the Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.[31]

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INDICATORS 3 AND 4: ACCREDITATION

KEY FINDING: Most states are accredited by one or both of two well-regarded bodies—the Public Health Accreditation Board and the Emergency Management Accreditation Program—but eight are not accredited by either.

The Public Health Accreditation Board (PHAB), a nonprofit organization that administers the national public health accreditation program, advances quality within public health departments by providing a framework and a set of evidence-based standards against which they can measure their performance. Among standards with direct relevance to emergency preparedness are assurances of laboratory, epidemiologic, and environmental expertise to investigate and contain serious public health problems, policies, and procedures for urgent communications and maintenance of an all-hazards emergency operations plan.[32] Through the process of accreditation, health departments identify their strengths and weaknesses, increase their accountability and transparency, and improve their management processes, which all promote continuous quality improvement.[33]

Emergency management, as defined by the Emergency Management Accreditation Program (EMAP), encompasses all organizations in a given jurisdiction with emergency or disaster functions, which may include prevention, mitigation, preparedness, response, and recovery. The EMAP helps applicants ensure—through self-assessment, documentation, and peer review—that they meet national standards for emergency response capabilities.[34]

The PHAB and the EMAP each provide important mechanisms for improving evaluation and accountability. Accreditation by these entities demonstrates that a state's public health and emergency management systems are capable of effectively responding to a range of health threats. The priority capabilities that the PHAB and the EMAP test include identification, investigation, and mitigation of health hazards; a robust and competent workforce; incident, resource, and logistics management; and communications and community-engagement plans.[35,36] States sometimes aim to meet applicable standards but do not pursue accreditation.

As of December 2020, 29 states and the District of Columbia were accredited by both the PHAB and the EMAP—a net increase of one (Delaware and Georgia are now accredited by the EMAP; Maryland transitioned from being accredited by both bodies to the PHAB only, with the EMAP providing conditional accreditation) since November 2019. Nevada is once again accredited by the EMAP, alongside an additional 12 states that have received accreditation from one or the other. (See Table 6.) "Over the last eighteen months we have worked diligently to review our processes, plans, and relationships," said the director of Delaware's Emergency Management Agency, A.J. Schall. "Over that time, we learned a tremendous amount and modernized procedures."[37]

Just eight states (Alaska, Hawaii, Indiana, New Hampshire, South Dakota, Texas, West Virginia, and Wyoming) received no accreditation from either body. A state without an accreditation has not necessarily been denied accreditation; the state may not have pursued accreditation. This analysis includes state-level accreditations only, it does not include accredited local or tribal health departments. In some instances, local public health departments have an accreditation in states that do not.

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TABLE 6: 42 States and the District of Columbia Accredited by the PHAB and/or EMAP

Accreditation status by state, December 2020

PHAB and EMAP			PHAB only	EMAP only	No Accreditation
Alabama	Idaho	New Mexico	Maine	Kentucky	Alaska
Arizona	Illinois	New York	Maryland	Michigan	Hawaii
Arkansas	Iowa	North Dakota	Minnesota	Nevada	Indiana
California	Kansas	Ohio	Montana	North Carolina	New Hampshire
Colorado	Louisiana	Oklahoma	Oregon	South Carolina	South Dakota
Connecticut	Massachusetts	Pennsylvania	Washington	Tennessee	Texas
Delaware	Mississippi	Rhode Island		Virginia	West Virginia
District of Columbia	Missouri	Utah			Wyoming
Florida	Nebraska	Vermont			
Georgia	New Jersey	Wisconsin			
29 states + DC			**6 states**	**7 states**	**8 states**

Note: These indicators track accreditation by the PHAB and the EMAP. TFAH classified states with conditional or pending accreditation at the time of data collection as having no accreditation. States sometimes aim to meet applicable standards but do not pursue accreditation.

Sources: NHSPI analysis of data from the PHAB and the EMAP.[38]

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INDICATOR 5: STATE PUBLIC HEALTH FUNDING TRENDS

Key Finding: Most states held their public health funding steady or increased it in FY 2020, but seven reduced funding.

The COVID-19 pandemic showed how sufficient and sustained funding for a comprehensive public health system is integral to preparedness and response, including the ability to detect, prevent, and control disease outbreaks and mitigate the health consequences of disasters. General public health capabilities—such as those pertaining to epidemiology, environmental hazard detection and control, infectious disease prevention and control, and risk communications—and targeted emergency response resources are necessary to ensure that officials maintain routine capabilities and that surge capacity is readily available for emergencies. A trained and standing public health workforce, and one that knows its community, is critical to the surge capacity that is so often necessary during an emergency.

According to the Public Health Activities and Services Tracking project at the University of Washington, state public health programming and services span six core areas:[39]

1. **Communicable disease control.** Public health services related to communicable disease epidemiology, hepatitis, HIV/AIDS, immunization, sexually transmitted diseases, tuberculosis, etc.
2. **Chronic disease prevention.** Public health services related to asthma, cancer, cardiovascular disease, diabetes, obesity, tobacco, etc.
3. **Injury prevention.** Public health services related to firearms, motor vehicles, occupational injuries, senior fall prevention, substance-use disorder, other intentional and unintentional injuries, etc.
4. **Environmental public health.** Public health services related to air and water quality, fish and shellfish, food safety, hazardous substances and sites, lead, onsite wastewater, solid and hazardous waste, zoonotic diseases, etc.
5. **Maternal, child, and family health.** Public health services related to the coordination of services; direct service; family planning; newborn screening; population-based maternal, child, and family health; supplemental nutrition; etc.
6. **Access to and linkage with clinical care.** Public health services related to beneficiary eligibility determination, provider or facility licensing, etc.

The overall infrastructure of public health supports states' ability to promote health equity, build resilience in the population, and carry out emergency response activities. But public health funding is typically discretionary, making it vulnerable to neglect or retrenchment, especially when times are tight. This can undermine emergency preparedness activities and weaken response and recovery efforts. State investment in public health is important for the operations of health agencies: about 28 percent of state and territorial health department revenues are from state sources,[40] while 21 percent of local health department revenue is from state sources, on average.[41]

Fortunately, 43 states and the District of Columbia maintained or increased public health funding in FY 2020. (See Table 7.) But seven states reduced the money they directed to these vital activities, increasing the likelihood that they will be less prepared and less responsive in the moments that matter most. (This indicator does not assess the adequacy of states' public health funding. It should also be noted that due to inflation and population growth, stable funding is in some cases a funding reduction.) The COVID-19 economic recession has already had a severe impact on state revenue,[42] which could constrain state public health funding levels over the coming years.

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TABLE 7: State Public Health Funding Held Stable or Increased in 43 states and DC

Public Health Funding, by state FY 2019 – 2020

State	Percentage Change
Alabama	-4%
Alaska	118%
Arizona	52%
Arkansas	-2%
California	40%
Colorado	9%
Connecticut	8%
Delaware	8%
District of Columbia	2%
Florida	8%
Georgia	3%
Hawaii	-2%
Idaho	2%
Illinois	7%
Indiana	0%
Iowa	-3%
Kansas	13%
Kentucky	1%
Louisiana	3%
Maine	24%
Maryland	4%
Massachusetts	4%
Michigan	14%
Minnesota	78%
Mississippi	2%
Missouri	-1%
Montana	2%
Nebraska	7%
Nevada	15%
New Hampshire	11%
New Jersey	2%
New Mexico	8%
New York	0.3%
North Carolina	2%
North Dakota	31%
Ohio	13%
Oklahoma	29%
Oregon	0.5%
Pennsylvania	-0.4%
Rhode Island	3%
South Carolina	3%
South Dakota	2%
Tennessee	9%
Texas	28%
Utah	9%
Vermont	7%
Virginia	-6%
Washington	6%
West Virginia	6%
Wisconsin	2%
Wyoming	8%

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Note: While states received federal one-time COVID response funding, those funds are not included in these tallies, as all federal funds are excluded from this measure. However, in some cases, state funding for pandemic response may have been included in the data reported to TFAH. For some states, COVID response funding may have resulted in an increase in the state's overall public health expenditure for the year. Other states may have reallocated money from one line to another with little impact on the overall funding level.

Owing to differences in organizational responsibilities and budgeting, funding data are not necessarily comparable across states. See "Appendix A: Methodology" for a description of TFAH's data-collection process, including its definition of public health funding.

Source: TFAH analysis of states' publicly available funding data.

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INDICATOR 6: COMMUNITY WATER SYSTEM SAFETY

KEY FINDING: Few Americans drink from community water systems that are in violation of applicable health-based standards required by the Safe Drinking Water Act. But room for improvement remains.

Access to safe water is essential for consumption, sanitation, and the efficient operation of the healthcare system. In the United States, the vast majority of the population gets water from a public water system,[43] and the U.S. Environmental Protection Agency (EPA) sets legal limits on contaminants in drinking water, including microorganisms, disinfectants, and their byproducts, chemicals, and radionuclides;[44] the EPA also requires states to periodically report drinking-water quality information.[45] Water systems must report any violations, such as failing to follow established monitoring and reporting schedules, failing to comply with mandated treatment techniques, violating any maximum contaminant levels, and failing to meet customer-notification requirements.[46]

The United States has one of the safest public drinking-water supplies in the world, but some communities, particularly low-income communities, struggle to maintain constant access to safe water. When water safety issues occur, it can require a multisector emergency response, as well as a long-term public health response. The most prominent water-contamination crisis in recent years occurred in Flint, Michigan, where a 2014 change in water supply caused distribution pipes to corrode and to leach lead and other contaminants into the drinking water. Tens of thousands of residents, including young children, were exposed to high levels of lead and other toxins.[47] In 2019, residents of Newark, New Jersey, had to rely on bottled water due to high levels of lead in their tap water.[48] In children, even low levels of lead exposure can damage the nervous system and contribute to developmental delays, learning disabilities, weight and hearing loss.[49] These incidents could have long-term consequences on the health and brain development of children, as well as the mental health and trust of the community.

As climate change contributes to more frequent wildfires, a residual danger is the release of toxic chemicals into community water systems. For example, months after the deadly Camp Fire in Paradise, California, in 2018, experts still advised residents not to drink or cook with the water due to concerns about benzene contamination.[50,51] Among the health effects of long-term exposure to unsafe levels of benzene is a decrease in red blood cells, which can lead to anemia. It can also cause excessive bleeding and can affect the immune system, increasing the chance for infection.[52]

Other water-related emergencies and concerns in the United States include harmful algal blooms,[53] which can impact human and animal health, the safety of seafood, damage the economies of affected communities, increase the presence of toxic chemicals like per- and polyfluoroalkyl substances (PFAS), and reduce the availability of clean water during power outages,[54] a particular concern in rural areas where smaller utilities may not have enough backup power to meet the demands of the water and sewage services. Water shortages can have a particularly dire impact on healthcare systems, which rely on clean water for many procedures and hygiene practices.

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New CDC data indicate waterborne pathogens cause nearly 7,000 deaths, seven million illnesses and more than $3 billion in healthcare costs each year. The risks around drinking water disproportionately threaten communities of color, highlighting the impact historical structural racism and continued institutional bias can have on a critical resource most Americans take for granted. In some areas, redlining has kept peri-urban communities of color, tribal lands and rural agricultural areas out of municipal water systems, thereby increasing their potential exposure to waterborne illness. In addition, older buildings are more vulnerable to waterborne pathogens in their pipes.[55]

According to the EPA, across the nation, 5 percent of state residents on average used a community water system in 2019 that failed to meet all applicable health-based standards, down from 7 percent in 2018. That share was 0 to 1 percent in Hawaii, Maryland, Minnesota, Nevada, North Dakota, Vermont, and Washington. (See Table 8.) But in four states (New Jersey, New York, Oregon, and West Virginia), more than 15 percent of residents used a community water system with health-based violations.

TABLE 8: Few Americans Used Contaminated Community Water Systems
Percent of state populations who used a community water system in violation of health-based standards, 2019

States	Percent of Population
HI, MD, MN, ND, NV, VT, WA	0%
CA, ID, IL, IN, ME, OH	1%
AL, CO, DE, MI, NC, NE, NH, WY	2%
CT, FL, SC, VA	3%
AK, IA, KY, RI, SD, TN, TX,	4%
AZ, DC, KS, UT, WI	5%
NM	6%
GA, MA	7%
AR, MS, MT	8%
MO, PA	9%
LA	13%
OK	15%
NJ, OR, WV	16%
NY	45%

Note: The EPA estimates that more than 13 million American households get their drinking water from private wells.[56] The data reported by this indicator do not reflect the water quality of those households. Only regulated contaminants are measured. These data do not include water safety on Indian reservations.

According to health officials in New York, a drinking water system in New York City is in violation because of an uncovered reservoir, but it has no current violations with respect to contaminants.

Source: NHSPI analysis of data from the EPA.[57]

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INDICATOR 7: USE OF PAID TIME OFF

KEY FINDING: Just over half of workers in states, on average, used some type of paid time off—sick leave, vacation, holidays—in 2019. Most states were closely clustered to that midpoint, with few outliers.

Note: The specification of this indicator has been adjusted slightly from a measure of those who received paid time off to a measure of those who used it.

The need for paid time off was obvious during the pandemic, when frontline and essential workers—people who could not work from home during the outbreak—were often compelled to work when sick themselves or caring for a sick family member. Black and Hispanic workers typically have less access to paid sick leave and are overrepresented in groups of frontline workers.[58]

When workers without paid leave get sick, they face the choice of going to work and potentially infecting others or staying home and losing pay—or even their jobs. They encounter similarly impossible decisions when a child or another dependent family member gets sick. Therefore, access and the ability to use job-protected paid time off, especially dedicated paid sick leave, can strengthen infection control and resilience in communities by reducing the spread of contagious diseases and bolstering workers' financial security. This is particularly important for industries and occupations that require frequent contact with the public. For example, people working in food service, older adults and nursing care facilities and childcare commonly have no paid sick leave.[59] Low-wage workers[60] and workers of color are also less likely to have access to paid leave compared with white and higher-earning workers.[61] This often leads employees to work throughout an illness or return to work before their symptoms have fully subsided, when time off could have dramatically reduced the potential of workplace infections.[62,63]

The public health benefit is clear: at a societal level, flu rates have been shown to be lower in cities and states that mandate paid sick leave.[64,65] When employees who previously did not have access are granted paid or unpaid sick leave, rates of flu infections decrease.[66]

During the COVID-19 pandemic, studies consistently showed that access to paid sick leave helped slow the spread of the virus.[67] The Families First Coronavirus Response Act helped temporarily address this issue for employers with fewer than 500 employees and certain public employers, temporarily requiring employees to be paid sick leave benefits under certain conditions. This helped reduce the spread of the virus in workplaces and communities by removing a barrier to employees staying home when necessary. However, these protections expired on December 31, 2020, despite the ongoing need for the use of paid leave to control the pandemic; instead, Congress provided a tax credit for employers to offer paid sick leave.[68]

But many workers, particularly low-wage workers, did not have access to paid sick leave during the pandemic and were therefore left to make impossible choices between protecting their health and that of their family or protecting their financial security. State paid leave laws helped in a few jurisdictions. Beginning in March 2020, two states with existing state paid sick leave policies, California and Rhode Island, experienced large increases in temporary disability and family caregiving leave claims. California claims rose by 43 percent between February and March 2020.[69] Rhode Island claims nearly tripled between February and March 2020.[70] A January Biden administration proposal, if adopted by Congress, would provide paid leave to people who are: sick with

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Covid-19 symptoms; quarantining because of Covid-19 exposure; needing time off to get the vaccine; caring for family members who are sick with Covid-19 symptoms; caring for children whose school or day care center is closed because of the pandemic; caring for older relatives or adult dependents whose long-term care facility is closed because of the pandemic.[71]

Paid time off also increases access to preventive care among workers and their families, including routine checkups, screenings, and immunizations. Delaying or skipping such care can result in poor health outcomes and can ultimately lead to costlier treatments. Workers without paid sick days are less likely to get a flu shot, and their children are less likely to receive routine checkups, dental care, and flu shots.[72]

In 2019, 55 percent of workers in states, on average, took some type of paid time off—the same percentage as in 2018—according to the Current Population Survey, which is sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics.[73] Connecticut (64 percent), the District of Columbia (65 percent), Mississippi and Oregon (63 percent), and Texas (68 percent) stood out as states where relatively high percentages of workers used such benefits, whereas fewer workers used them in Arkansas (45 percent), South Carolina (45 percent), South Dakota (44 percent), Utah (45 percent), and Wyoming (47 percent).[74] (See Table 9.)

TABLE 9: 55 Percent of Workers, On Average, Used Paid Time Off
Percent of employed population that took paid time off, 2019

States	Percent of Workers
TX	68%
DC	65%
CT	64%
MS, OR	63%
MD, NM, NY	61%
AK, IA, WA	60%
GA, HI, MA	59%
MT, VA	58%
NE	57%
CA, CO, KS, RI, VT, WI	56%
AL, IL, NV, OK, WV	55%
FL, NH	54%
LA, MO, TN	53%
MN, NJ	52%
ID, IN, ME, NC, ND, PA	51%
MI, OH	49%
AZ, DE, KY	48%
WY	47%
AR, SC, UT	45%
SD	44%

Note: Paid time off includes sick leave, vacations, and holidays. The data are measured based on a survey of a sample of the general population. The specification of this indicator has been adjusted slightly from a measure of those who received paid time off to a measure of those who used it.

Source: NHSPI analysis of data from the Annual Social and Economic Supplement of the Current Population Survey.[75]

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INDICATOR 8: FLU VACCINATION RATE

KEY FINDING: Flu vaccination coverage rose for the second consecutive year during the 2019–2020 season, with a greater share of every age group analyzed receiving a vaccine. Overall, 52 percent of U.S. residents ages 6 months or older received vaccinations—still well below the overall target level of 70 percent of the population vaccinated annually.

The CDC recommends that, with few exceptions, everyone ages 6 months or older get vaccinated for seasonal influenza annually; yet, year after year, even with a steady increase among adults over the past three decades, coverage estimates indicate that just over half of Americans do.[76] *Healthy People 2030* set federal 10-year benchmarks for improving the health of all Americans, including an overall seasonal influenza vaccination-rate target of 70 percent annually.[77]

Vaccination is the long-standing best prevention against the seasonal flu, particularly for people at high risk of severe flu-related outcomes, including people with certain chronic health conditions and older adults, groups that are also at higher risk from COVID-19. In addition to protecting Americans from the seasonal flu, establishing a cultural norm of vaccination, building vaccination infrastructure, and establishing policies that support vaccinations can help prepare the country to vaccinate all Americans quickly during the pandemic. A major concern as the 2020–2021 flu season opened was that a high incidence of seasonal flu coupled with the amount of illness caused by the pandemic would overwhelm health systems. During 2021, as the country works to deliver the COVID-19 vaccine, seasonal flu vaccination programs provide important process lessons, networks, communications strategies, and goals for the COVID-19 vaccination effort.

Under the Affordable Care Act, all routine vaccines recommended by the Advisory Committee on Immunization Practices, including flu vaccines, are fully covered when provided by in-network providers, except in states that have not expanded their Medicaid programs in accordance with the act. Some barriers to flu vaccination may

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include a belief that the vaccine does not work very well; misconceptions about the safety of the vaccine;[78] or a belief that the flu does not carry serious risks.[79] State laws may also make it more difficult for parents to get their children vaccinated by a pharmacist, as some states do not allow children to get flu vaccines at a pharmacy and even more have age restrictions and/or require a physician's prescription.

During the 2019–2020 flu season, 52 percent of residents ages 6 months or older were vaccinated, according to the CDC, the highest rate in at least a decade. This was a notable uptick from 42 percent during the 2017–2018 flu season. One possible explanation is the increased awareness of the public, clinicians, and public health officials about the importance of vaccination, owing to the high number of illnesses and deaths two years prior. The major role that vaccination will play in the country's—and the world's—recovery from the extraordinarily deadly COVID-19 pandemic will, hopefully, make an indelible impression on all Americans about the value of vaccination.

Across the country, states have taken noteworthy actions to vaccinate residents against seasonal flu. For example, during the 2018–2019 flu season, the Tennessee Department of Health organized statewide Fight Flu TN events with vaccination clinics, and last year, it launched a statewide media campaign.[80] The state's flu vaccine rate (ages 6 months or older) increased from 36 percent during the 2017–2018 flu season to 49 percent during the 2019–2020 season. Indiana's Department of Health has also engaged in focused efforts to increase vaccination rates, particularly among people who are uninsured or underinsured. One way it has done this is by partnering with local health departments and pharmacies to provide vaccinations, and by working with the Indiana Immunization Coalition to create education and outreach materials and social media messaging.[81] Indiana's flu vaccination rate (ages 6 months or older) improved from 37 percent for the 2017–2018 flu season to 51 percent for the 2019–2020 season.

Rhode Island (61 percent), Connecticut (61 percent), and Massachusetts (61 percent) had the highest coverage, while vaccination rates were lowest in Nevada (44 percent), Florida (45 percent), and Idaho (45 percent). (See Table 10.)

Children, particularly young children, were more likely to receive vaccinations than were adults. Nearly 64 percent of those ages 6 months to 17 years received vaccinations in 2019–2020, compared with 48 percent of adults.[82]

TABLE 10: Just Over Half of Americans Received a Seasonal Flu Vaccination

States' seasonal flu vaccination rates for people ages 6 months or older, 2019–2020

State	Vaccination Rate, Ages 6 Months or Older
Rhode Island	60.9
Connecticut	60.7
Massachusetts	60.6
Virginia	58.8
South Dakota	58.7
Nebraska	58.3
Wisconsin	58.3
Maryland	57.8
District of Columbia	57.6
New Hampshire	57.6
Vermont	57
Iowa	56.6
North Dakota	56.5
Minnesota	56.3
Washington	56.3
Pennsylvania	56.1
North Carolina	55.8
Colorado	55.6
Maine	55.6
Delaware	55
Arkansas	54.9
Kansas	54.5
New Jersey	54
Oklahoma	54
New Mexico	53.2
New York	52.9
Illinois	52.2
West Virginia	52.2
Utah	51.9
Oregon	51.4
California	51.3
Hawaii	51
Ohio	51
Kentucky	50.9
Indiana	50.8
South Carolina	50.7
Missouri	50.2
Michigan	49.7
Montana	49.6
Tennessee	49.1
Alabama	48.4
Louisiana	47.5
Texas	47.3
Wyoming	47.3
Arizona	46.5
Georgia	45.9
Mississippi	45.9
Alaska	45.8
Idaho	44.9
Florida	44.5
Nevada	44.4

Note: Data are calculated from a survey sample, with a corresponding sampling error.

Source: Centers for Disease Control and Prevention.[83,84]

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INDICATOR 9: PATIENT SAFETY IN HOSPITALS

KEY FINDING: On average, 31 percent of hospitals received an "A" grade in the fall 2020 hospital safety assessment administered by the Leapfrog Group, a nonprofit advocate for safety, quality, and transparency in hospitals.

Every year, hundreds of thousands of people die from hospital errors, injuries, accidents, and infections, collectively making such incidents a leading cause of death in the United States.[85,86] Keeping hospital patients safe from preventable harm is an important element of preparedness; those hospitals that excel in safety are less likely to cause or contribute to a public health emergency and are better positioned to handle any emergencies that put routine quality standards to the test.

During the COVID-19 pandemic, hospitals were an active setting for viral transmission, threatening the safety of patients, staff and visitors, and also discouraging people in need of urgent or emergency care from going to the ER, likely contributing to overall excess mortality.[87] But universal masking and availability and proper use of PPE, in addition to other steps, such as adequate ventilation, limiting the sharing of patient rooms, and universal hand hygiene, proved to be critical in preventing outbreaks in hospitals.

The Leapfrog Group calculates its hospital safety score by using 28 evidence-based metrics that measure the success of healthcare processes and outcomes. The measures track such issues as healthcare-associated infection rates, the number of available beds and qualified staff in intensive-care units, patients' assessments of staff communications and responsiveness, and a hospital's overall culture of error prevention.[88] These measures are especially critical for health systems' readiness for emergencies and outbreak prevention and control, which include workforce training and availability, surge capacity, and infection-control practices.

In the Leapfrog Group's fall 2020 assessment, 31 percent of general acute-care hospitals across the United States, on average, met the requirements for an "A" grade—a slight increase from fall 2018, when the share was 28 percent. But results varied widely state to state, from no hospitals in Alaska, North Dakota, or South Dakota receiving the top score, to a majority of hospitals doing so in Maine (63 percent), Idaho (58 percent), Delaware (57 percent), Massachusetts (57 percent), Oregon (55 percent), Virginia (53 percent), and North Carolina (52 percent). (See Table 11.)

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TABLE 11: Hospital Patient Safety Scores Vary Significantly by State

States percentage of hospitals with "A" grade, fall 2020

State	Percent of Hospitals
Maine	63%
Idaho	58%
Delaware	57%
Massachusetts	57%
Oregon	55%
Virginia	53%
North Carolina	52%
Vermont	50%
Colorado	48%
Pennsylvania	47%
Utah	46%
Hawaii	45%
Texas	43%
Michigan	43%
Washington	40%
Maryland	38%
New Jersey	37%
Ohio	37%
Florida	36%
California	36%
Kentucky	36%
South Carolina	34%
Illinois	34%
Tennessee	33%
Wyoming	33%
Georgia	32%
Kansas	32%
Connecticut	32%
Mississippi	30%
Louisiana	29%
Rhode Island	29%
Arizona	26%
Wisconsin	24%
Missouri	24%
Minnesota	23%
Oklahoma	23%
Montana	22%
Nevada	21%
District of Columbia	20%
Alabama	20%
Indiana	19%
New Mexico	17%
Iowa	16%
New Hampshire	15%
New York	10%
Arkansas	7%
Nebraska	6%
West Virginia	5%
Alaska	0%
North Dakota	0%
South Dakota	0%

Note: This measure captures only general acute-care hospitals.

Source: The Leapfrog Group.[89]

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INDICATOR 10: STATE SURGE CAPACITY

KEY FINDING: Every state reported having a plan in 2020 for a six- to eight-week surge in laboratory-testing capacity to respond to an outbreak or other public health event.

Public health laboratories have been essential to emergency response and effective disease surveillance systems throughout the pandemic. They help detect and diagnose health threats as they emerge, and they track and monitor the spread of those threats, which can help public health officials learn how to control them. Public health labs exist in every state and territory and are the backbone of the Laboratory Response Network (LRN), a national network of laboratories that provide the infrastructure and capacity to respond to public health emergencies.[90]

When a disaster or disease outbreak strikes, public health laboratories must be able to surge to meet increased demand, just like hospitals and other responders. The Association of Public Health Laboratories defines internal surge capacity as a "sudden and sustained increase in the volume of testing that a LRN reference laboratory can perform in an emergency situation, implementing substantial operational changes as defined in laboratory emergency response plans and using all resources available within the laboratory."[91] Surging capacity can require staff movement or reassignment, extra shifts, and hiring. Labs also have to plan for infrastructure factors, such as sufficient biological safety cabinets and chemical fume hoods; amount and type of supplies; space for intake, processing, and storage of samples; versatility and capacity of analytical equipment and instruments; availability of PPE; and power supply.[92] It should also be noted that while the existence of surge plans are important, these plans have to be funded, tested, and regularly updated.

State public health laboratories have been critical assets throughout the COVID-19 pandemic, especially in early 2020, when they were the only laboratories outside the CDC authorized to conduct testing.[93] Despite early challenges in the tests rolled out to states, at least one public health laboratory in every state, DC, Puerto Rico, and Guam was able to test for COVID-19 as of June 2020.[94] Testing capacity increased over time, as private labs received authorization and ramped up capacity, and as a variety of rapid molecular tests were manufactured and approved for use at home; but the processing of the CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel assisted officials throughout with monitoring the course of the pandemic. Still, the country's testing capacity never reached what most experts argued was necessary to allow for comprehensive, timely surveillance of the virus's spread during the height of the pandemic. This problem was most acute in spring 2020, when an estimated one in 10 infections were confirmed, improving somewhat to roughly one in three in late 2020.[95,96]

In addition, public health laboratories are studying the genetic sequencing of the COVID-19 virus to identify variants. Such genomic surveillance is critical to understanding and preventing the spread of the virus but more federal funding is needed to support the work.[97]

Going forward, some challenges to the effectiveness of public health laboratory preparedness include funding gaps to invest in infrastructure and modernization, workforce shortages, a lack of standardized platforms to exchange data electronically, and a limited ability to detect radiological, nuclear, and chemical threats.[98]

In 2020, the District of Columbia and all states reported to the Association of Public Health Laboratories that they had a plan for a six- to eight-week surge in testing capacity, a net increase of six since 2017 and 2018. (See Table 12.)

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TABLE 12: Every State Planned for a Laboratory Surge.

State public health laboratories with a plan for a six- to eight-week surge in testing capacity, 2020

Had a Plan			
Alabama	Illinois	Montana	Rhode Island
Alaska	Indiana	Nebraska	South Carolina
Arkansas	Iowa	Nevada	South Dakota
Arizona	Kansas	New Hampshire	Tennessee
California	Kentucky	New Jersey	Texas
Colorado	Louisiana	New Mexico	Utah
Connecticut	Maine	New York	Vermont
Delaware	Maryland	North Carolina	Virginia
District of Columbia	Massachusetts	North Dakota	Washington
Florida	Michigan	Ohio	West Virginia
Georgia	Minnesota	Oklahoma	Wisconsin
Hawaii	Mississippi	Oregon	Wyoming
Idaho	Missouri	Pennsylvania	Vermont

Note: This indicator tracks only the existence of a plan, not its quality or comprehensiveness, or the frequency with which it is used or tested.

Source: Association of Public Health Laboratories.[99]

TABLE 13: INDICATORS OF PUBLIC HEALTH EMERGENCY PREPAREDNESS

	Nurse Licensure Compact (NLC)	Hospital Preparedness Program	Public Health Accreditation Board (PHAB)	Emergency Management Accreditation Program (EMAP)	Public Health Funding	Water Security	
	State participates in NLC, 2020	Percent of hospitals participating in health care coalitions, 2017	Accredited by PHAB, 2020	Accredited by EMAP, 2020	Percentage change, FY 2019-20	Percent of population who used a community water system in violation of health-based standards, 2019	
Alabama	✓	95%	✓	✓	-4%	2%	
Alaska		100%			118%	4%	
Arizona	✓	72%	✓	✓	52%	5%	
Arkansas	✓	81%	✓	✓	-2%	8%	
California		70%	✓	✓	40%	1%	
Colorado	✓	100%	✓	✓	9%	2%	
Connecticut		100%	✓	✓	8%	3%	
Delaware	✓	100%	✓	✓	8%	2%	
D.C.		100%	✓	✓	2%	5%	
Florida	✓	73%	✓	✓	8%	3%	
Georgia	✓	97%	✓	✓	3%	7%	
Hawaii		100%			-2%	0%	
Idaho	✓	98%	✓	✓	2%	1%	
Illinois		88%	✓	✓	7%	1%	
Indiana	✓	75%			0%	1%	
Iowa	✓	80%	✓	✓	-3%	4%	
Kansas	✓	96%	✓	✓	13%	5%	
Kentucky	✓	93%		✓	1%	4%	
Louisiana	✓	100%	✓	✓	3%	13%	
Maine	✓	94%	✓		24%	1%	
Maryland	✓	89%	✓		4%	0%	
Massachusetts		82%	✓	✓	4%	7%	
Michigan		90%		✓	14%	2%	
Minnesota		100%	✓		78%	0%	
Mississippi	✓	100%	✓	✓	2%	8%	
Missouri	✓	87%	✓	✓	-1%	9%	
Montana	✓	83%	✓		2%	8%	
Nebraska	✓	95%	✓	✓	7%	2%	
Nevada		100%		✓	15%	0%	
New Hampshire	✓	47%			11%	2%	
New Jersey	✓	82%	✓	✓	2%	16%	
New Mexico	✓	71%	✓	✓	8%	6%	
New York		86%	✓	✓	0%	45%	
North Carolina	✓	95%		✓	2%	2%	
North Dakota	✓	100%	✓	✓	31%	0%	
Ohio		25%	✓	✓	13%	1%	
Oklahoma	✓	95%	✓	✓	29%	15%	
Oregon		100%	✓		0%	16%	
Pennsylvania		86%	✓	✓	0%	9%	
Rhode Island		100%	✓	✓	3%	4%	
South Carolina	✓	56%		✓	3%	3%	
South Dakota	✓	100%			2%	4%	
Tennessee	✓	91%		✓	9%	4%	
Texas	✓	80%			28%	4%	
Utah	✓	100%	✓	✓	9%	5%	
Vermont		100%	✓	✓	7%	0%	
Virginia	✓	100%		✓	-6%	3%	
Washington		100%	✓		6%	0%	
West Virginia	✓	97%			6%	16%	
Wisconsin	✓	98%	✓	✓	2%	5%	
Wyoming	✓	92%			8%	2%	
51-state average	**N/A**	**89%**	**N/A**	**N/A**	**12%**	**5%**	

Note: See "Appendix A: Methodology" for a description of TFAH's data-collection process and scoring details. States with conditional or pending accreditation at the time of data collection were classified as having no accreditation. Some state residents use private drinking-water sources, rather than community water systems. Private sources are not captured by these data. Only regulated contaminants are measured. Paid time off includes sick leave, vacations, and holidays. The patient safety measure captures only general acute-care hospitals.

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TABLE 13: INDICATORS OF PUBLIC HEALTH EMERGENCY PREPAREDNESS

		Paid Time Off	Seasonal Flu Vaccination	Patient Safety	Public Health Lab Capacity	State Performance
		Percent of employed population who used paid time off, 2019	Seasonal flu vaccination rate for people ages 6 months or older, 2019–20	Percentage of hospitals with "A" grade, fall 2020	Public health laboratories had a plan for a six- to eight-week surge in testing capacity, 2020	Scoring tier, 2020
	Alabama	55%	48.4	20%	✓	Middle
	Alaska	60%	45.8	0%	✓	Low
	Arizona	48%	46.5	26%	✓	Low
	Arkansas	45%	54.9	7%	✓	Low
	California	56%	51.3	36%	✓	Middle
	Colorado	56%	55.6	48%	✓	High
	Connecticut	64%	60.7	32%	✓	High
	Delaware	48%	55	57%	✓	High
	D.C.	65%	57.6	20%	✓	High
	Florida	54%	44.5	36%	✓	Middle
	Georgia	59%	45.9	32%	✓	High
	Hawaii	59%	51	45%	✓	Low
	Idaho	51%	44.9	58%	✓	High
	Illinois	55%	52.2	34%	✓	Middle
	Indiana	51%	50.8	19%	✓	Low
	Iowa	60%	56.6	16%	✓	Middle
	Kansas	56%	54.5	32%	✓	High
	Kentucky	48%	50.9	36%	✓	Middle
	Louisiana	53%	47.5	29%	✓	Middle
	Maine	51%	55.6	63%	✓	High
	Maryland	61%	57.8	38%	✓	High
	Massachusetts	59%	60.6	57%	✓	High
	Michigan	49%	49.7	43%	✓	Middle
	Minnesota	52%	56.3	23%	✓	Middle
	Mississippi	63%	45.9	30%	✓	High
	Missouri	53%	50.2	24%	✓	Low
	Montana	58%	49.6	22%	✓	Middle
	Nebraska	57%	58.3	6%	✓	High
	Nevada	55%	44.4	21%	✓	Low
	New Hampshire	54%	57.6	15%	✓	Low
	New Jersey	52%	54	37%	✓	Middle
	New Mexico	61%	53.2	17%	✓	High
	New York	61%	52.9	10%	✓	Low
	North Carolina	51%	55.8	52%	✓	High
	North Dakota	51%	56.5	0%	✓	Middle
	Ohio	49%	51	37%	✓	Low
	Oklahoma	55%	54	23%	✓	High
	Oregon	63%	51.4	55%	✓	Middle
	Pennsylvania	51%	56.1	47%	✓	Low
	Rhode Island	56%	60.9	29%	✓	High
	South Carolina	45%	50.7	34%	✓	Low
	South Dakota	44%	58.7	0%	✓	Low
	Tennessee	53%	49.1	33%	✓	Middle
	Texas	68%	47.3	43%	✓	Middle
	Utah	45%	51.9	46%	✓	High
	Vermont	56%	57	50%	✓	High
	Virginia	58%	58.8	53%	✓	High
	Washington	60%	56.3	40%	✓	High
	West Virginia	55%	52.2	5%	✓	Low
	Wisconsin	56%	58.3	24%	✓	High
	Wyoming	47%	47.3	33%	✓	Low
	51-state average	**55%**	**52.8**	**31%**	**N/A**	**N/A**

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Recommendations for Policy Actions

As 2020 has shown, saving lives and protecting the country's economic stability during a pandemic requires pre-event investment and planning, a strong public health system, federal leadership, and a coordinated response. The same is true for all types of public health emergencies. Effective preparedness and response require sufficient funding, a trained workforce, and multisector teamwork. Authentic engagement with community-based leaders and organizations are also necessary.

TFAH based the following policy recommendations on research and analysis, consultation with experts, and a review of gaps in federal and state preparedness. TFAH offers the following recommendations for federal, state, local, tribal, and territorial policymakers and other stakeholders to improve public health emergency readiness.

Priority Area 1: Provide Stable, Sufficient Funding for Domestic and Global Public Health Security

The COVID-19 pandemic has uncovered the tragic consequences of the nation's long-term neglect of public health capacity at the global, federal, state, local, tribal, and territorial levels. Understaffed health departments are in some cases using 20th-century tools, such as telephones and fax machines,[100,101] to respond to a 21st-century pandemic.[102] At the same time, funding for the Public Health Emergency Preparedness cooperative agreement, a critical source of funding for health departments to build capabilities to effectively respond to a range of public health threats, has been cut by just over one-quarter since FY 2003, or about half, after adjusting for inflation.[103] The HPP, the only federal source of funding to help the healthcare delivery system prepare for and respond to disasters, has been cut by nearly half over the same time period, or by nearly two-thirds, after adjusting for inflation.[104] Therefore, health departments were already working from a deficit when the pandemic emerged. Federal policymakers need to rapidly improve the COVID-19 response and build back a system currently unprepared to address future emergencies. Short-term investments made through COVID response funding legislation cannot fill the gap left by ongoing public health funding shortfalls, nor can they address underlying health inequities that are making the nation less resilient.

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RECOMMENDATIONS FOR FEDERAL GOVERNMENT:

- **Rebuild and modernize the public health system, including by creating a mandatory $4.5 billion per year Public Health Infrastructure Fund to support foundational public health capabilities at the state, local, territorial, and tribal levels (STLT).** Strong foundational capabilities would improve the protection of all communities across a range of threats. However, a nationwide funding shortage, exacerbated by the pandemic, has prevented health departments across the country from developing and maintaining these capabilities. An additional funding limitation is that health departments receive very little funding that is not tied to specific diseases or categories. Congress should invest in cross-cutting public health capabilities, such as proposed in the Public Health Infrastructure Saves Lives Act.[105] Congress must also increase funding for specific programs that support health security, including the Public Health Emergency Preparedness and the HPP cooperative agreements. These state and local preparedness programs have demonstrated their value by saving lives, improving the speed and quality of response during emergencies, and ensuring that local authorities can adequately respond to most local health emergencies and outbreaks without federal assistance. Congress should provide additional funding to modernize public health and response functions at the CDC and ensure the agency has the capacity to respond to any event.

- **Invest in sustained public health data modernization.** Sustained investment in health data systems at the federal, state, and local levels is imperative. The CDC is the world's premier public health agency, yet years of inadequate funding has meant that the agency and its partners are reliant on archaic data systems. Americans felt the pain of delayed and disjointed disease surveillance throughout the pandemic, as the public health surveillance infrastructure relied on antiquated, disconnected systems and methods for tracking and responding to diseases. Congress wisely invested $500 million in the Coronavirus Aid, Relief, and Economic Security Act (P.L.116-136) and $50 million in the FY 2020 and FY 2021 appropriations bills as a down-payment on the CDC's data modernization initiative. These investments will help build the foundations for data sharing across public health, modernize the CDC's services and systems, leverage new data sources, and ensure public health can act on innovative data analytics. However, these advancements must be augmented and sustained, making up for decades of neglect. Congress should build on these initial investments with at least $450 million in immediate funding and at least $100 million per year to the CDC's data modernization initiative to modernize and sustain these systems. New data systems should be interoperable and cloud-based.

- **Ensure complete, disaggregated demographic data collection and reporting during public health emergencies.** The gaps in COVID-19 data reporting by race, ethnicity, sexual identity, gender identity, primary language, disability status, the intersections of these demographics, and other factors hindered the response and masked the true breadth of inequities during the pandemic. These gaps exposed long-standing shortcomings in demographic data collection and reporting in public health. Congress should invest in data modernization for STLT public health to enable accurate and comprehensive data collection. In addition, HHS should stand up a task force—including the Office of the Assistant Secretary for Planning and Evaluation, CDC, Office of the National Coordinator on Health Information Technology, Office of Minority Health,

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and CMS, in consultation with state, local, territorial and tribal agencies and private-sector stakeholders—to identify and address barriers to the collection and regular reporting of disaggregated, detailed demographic data during the pandemic and beyond. If needed, Congress should provide HHS agencies the authority to require jurisdictions to report race and ethnicity during public health emergencies.[106]

- **Accelerate crisis responses through a standing public health emergency response fund and faster supplemental funding.** In addition to stable core funding, the federal government needs readily available funds on hand to enable a rapid response while Congress assesses the necessity for supplemental funding. Congress should continue a no-year infusion of funds into the Public Health Emergency Rapid Response Fund and/or the Infectious Disease Rapid Response Fund to serve as available funding that would provide a temporary bridge between preparedness and supplemental emergency funds. Congress should replenish such funding on an annual basis, and funding should not come from existing preparedness resources, as response capacity cannot substitute for adequate readiness. The HHS secretary should only use such funding for acute emergencies that require a rapid response to save lives and protect the public.

- **Demonstrate a long-term commitment to global health security.** The United States should recommit to partnerships with international bodies such as the WHO, and Congress should solidify America's role as a global health leader, commit to implementing the Global Health Security Strategy,[107] and provide sustained annual funding for global health security programs at the CDC and the U.S. Agency for International Development. Congress should fund and the CDC should implement the modernization of the U.S. quarantine system, including IT systems, quarantine stations, regulatory framework, and traveler engagement and information.

Editor's note: on January 21, 2021, the Biden administration restored U.S. membership in the WHO.

RECOMMENDATION FOR FEDERAL AND STATE GOVERNMENT:

- **Enable efficient use of emergency funding.** During an emergency, responding agencies at all levels of government must be able to adapt spending policies. States should review their administrative preparedness to ensure they can efficiently use emergency monies, including speeding up contracting and hiring procedures. In addition, Congress may allocate emergency funding to multiple federal agencies. However, differing agency policies and practices can impede speed and coordination of funding across agencies. This can lead to disconnected and less effective emergency responses on the ground. The Office of Management and Budget, HHS, and FEMA should allow waivers of regulatory or administrative requirements to awardees of emergency response funding to allow funding braiding, to encourage coordination between programs and funding streams with similar goals, to provide flexibility to best meet the needs of the affected populations, and to increase efficiencies and reduce administrative duplication, such as in grant reporting.

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Priority Area 2: Prevent Outbreaks and Pandemics

Infectious diseases represent a threat to the health, safety, and economic and social stability of the country. The COVID-19 pandemic has cost the nation hundreds of thousands of lives and at least $16 trillion in losses to the U.S. gross domestic product as of October 2020.[108] The toll in lost educational achievement and long-term mental health impacts have yet to be fully understood. As TFAH, scientists, and public health experts have warned for many years, the nation was not prepared for a severe pandemic. At the same time as the nation battles the worst pandemic in a century, public health and medical providers continue to respond to "everyday" outbreaks: seasonal influenza, vaccine-preventable diseases, healthcare-associated infections, and antibiotic resistance continue to pose threats to health and safety. The United States must be able to prevent and respond to both major pandemics and localized outbreaks.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT, HEALTHCARE, AND AGRICULTURE:

- **Support the vaccine infrastructure.** The CDC's immunization program, sometimes called the "317 program," supports state and local immunization systems to increase vaccination rates among uninsured and underinsured adults and children, to respond to outbreaks, to educate the public, to target hard-to-reach populations, to improve vaccine confidence, to establish partnerships, and to improve information systems. Yet, funding has not kept up with needs, as states have to spend immunization dollars to respond to outbreaks,[109] deal with increases in the numbers of residents who lack health insurance,[110] and attempt to manage the impact of vaccine underutilization. State, local, and tribal health departments are depending on this underfunded infrastructure to distribute and dispense the COVID-19 vaccine, yet COVID funding was not distributed until January 2021. Congress should monitor the COVID-19 vaccination progress and provide additional funding, if needed. Congress should also increase annual funding for the CDC's immunization program as well as the seasonal influenza program and post-licensure vaccine safety monitoring. Congress should also provide needed resources to HHS to study the causes of vaccine resistance and to educate clinical providers on methods for improving vaccine acceptance, such as those proposed in the VACCINES Act.[111]
- **Ensure first-dollar coverage for recommended vaccines under Medicaid, Medicare, and commercial insurance.** Public and private payers should ensure that all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are fully covered, as cost sharing, such as co-pays, can be a significant barrier to vaccination.[112] Congress should require zero cost sharing in Medicare Part D and B plans, and CMS should incentivize Part D plans to eliminate cost sharing and increase receipt of vaccines.[113] An example of legislation that takes steps to improve senior vaccination rates is the Protecting Seniors Through Immunization Act. CMS should encourage state Medicaid plans in states that have not expanded Medicaid to cover all ACIP-recommended vaccines without cost sharing.[114]
- **Significantly increase investments in public health initiatives to combat antibiotic resistance.** Congress should increase funding for innovative prevention methods of detecting and containing outbreaks supported by the Antibiotic Resistance Solutions Initiative at the CDC. The CDC is investing in prevention measures in every state to strengthen lab capacity, track infections across healthcare systems, detect new threats, disrupt pathogens, coordinate prevention strategies, educate healthcare providers on appropriate antibiotic use, and advocate for other innovations. To fully address the scope of AR spread, particularly in healthcare settings, Congress should increase funding for healthcare associated infection/antibiotic resistance programs and activities at state and local health departments. In addition, increases in funding are necessary to build global capacity to prevent and detect resistant infections and to combat the threat to national security.
- **Create incentives for new-product discovery to fight resistant infections.** It is extremely challenging for companies to earn a return on their investments for the development of new antibiotics: (1) antibiotics are typically given for a short duration; (2) the most highly resistant infections are still relatively rare; and (3) new antibiotics must be used judiciously to preserve their effectiveness. These

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factors have resulted in nearly all major pharmaceutical companies exiting the antibiotics market, leaving the critical innovation domain of discovering and developing new antibiotics to small biotech companies with limited budgets and limited research and development capacity. Legislation, such as the DISARM Act, would strengthen the market for antibiotic developers, improving patient access for those who need it most.

- **Eliminate overuse of antibiotics in agriculture.** The FDA should enforce rules regarding veterinary oversight and the judicious use of antibiotics in food animals, ensure data collection and publication, promote antibiotic stewardship programs, and track the impact of these policies on resistance patterns. Farmers and the food industry should stop using medically important antibiotics to promote growth and prevent disease in healthy animals, as recommended by the WHO,[115] and they should invest in research to develop and adopt husbandry practices that reduce the need for routine antibiotics.
- **Decrease over-prescription of antibiotics through implementation of antibiotic stewardship and antibiotic-use reporting.** The CDC estimates that improving prescribing practices and preventing infections could save 37,000 lives over five years.[116] CMS should finalize, implement, and enforce requirements for all CMS-enrolled facilities to have effective antibiotic stewardship programs that align with the CDC's Core Elements guidance and to work with public health stakeholders to track progress in prescribing rates and resistance patterns.[117] All relevant facilities must drastically improve their reporting of antibiotic use and resistance through the National Healthcare Safety Network and should adopt stewardship programs that meet the CDC's Core Elements.[118]
- **Fund the CDC to support state and local public health laboratories.** The CDC should be sufficiently funded to strengthen the Laboratory Response Network and to support state and local public health laboratories; currently, the Epidemiology and Laboratory Capacity grant is only funding approximately half of what laboratories and health department epidemiologists nationwide have requested.

RECOMMENDATIONS FOR FEDERAL AND STATE GOVERNMENT:

- **Provide job-protected paid leave.** The pandemic has called attention to the fact that paid family and medical leave are important infection-control measures, protecting both workers and customers, in addition to creating economic security. Workers are unable to adhere to public health guidance to isolate if they risk losing their jobs or paychecks. While Congress temporarily expanded access to paid leave during the pandemic, a permanent fix is needed. Congress should enact a permanent federal paid family and medical leave policy and dedicated paid sick days protections, and states should ensure effective implementation by passing paid leave laws and/or removing preemption exemptions.
- **Minimize state vaccine exemptions for schoolchildren and increase vaccination of healthcare workers.** States should enact policies that enable universal childhood vaccinations to ensure children, their classmates, educators, and the general public are protected from vaccine-preventable diseases. This includes eliminating nonmedical exemptions and opposing legislation to expand exemptions.[119] States should ensure medical vaccine exemptions are only given when appropriate and are not used as a de facto personal-belief exemption in states where those exemptions have been eliminated. States should require healthcare personnel to receive all ACIP-recommended vaccinations to protect staff and patients, assure continuity of operations in the event of an outbreak, and achieve necessary healthcare infection control. As this report was being prepared for publication, the COVID-19 vaccine was not an ACIP-required vaccine. Healthcare facilities should ensure access to vaccines for all staff and contractors, and they should remove any barriers to staff receiving vaccines. Healthcare facilities should also report healthcare worker vaccination status, such as for seasonal flu and COVID-19, to the CDC's National Healthcare Safety Network.

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Priority Area 3: Build Resilient Communities and Promote Health Equity in Preparedness

Social, economic, and health disparities impact how people within specific communities' experience disasters and how quickly they can recover. Unfortunately, the disproportionate impact of COVID-19 on communities of color and Tribal Nations was foreseeable: underlying health conditions driven by years of structural racism; uneven access to prevention and care during the pandemic; increased risk of exposure due to being frontline workers, such as in food processing, food service, or healthcare;[120] increased risk of exposure due to living in crowded or inadequate housing;[121] and more severe economic impacts for lower-income workers has meant that people of color and Tribal Nations are bearing a disproportionate burden from the pandemic. When intersectional issues, such as homelessness, incarceration, disability, age, lack of access to paid leave, LGBTQ+ status, and immigration status are also at play, the inequities are more pronounced. Addressing underlying inequities and intentionally and meaningfully engaging with the people and communities most likely to be impacted throughout the emergency planning and response process are critical to reducing vulnerability and ensuring that all receive appropriate services, regardless of circumstance. Equity must be an explicit and foundational principle in all emergency planning. Some communities have taken steps to integrate principles of equity throughout public health emergency activities,[122] but more needs to be done.

RECOMMENDATIONS FOR FEDERAL, STATE, AND LOCAL GOVERNMENT:

- **Examine and address gaps in equity in response capabilities.** An external body (such as the GAO or the National Academy of Sciences, Engineering and Medicine) should conduct an assessment of the pandemic specifically focused on gaps in equitable response, including inequities in allocation of scarce resources, healthcare capacity, data collection and reporting, and planning for communities at higher risk, underserved communities, and communities of color.
- **Invest in policies and capacity to address the social determinants of health (SDOH):** People at highest risk during disasters and those who have the hardest time recovering are often those with unstable or unhealthy housing, those with limited access to transportation, and those who live in low-socioeconomic-status communities,[123] all of which bore out during the COVID-19 pandemic. Addressing SDOH can improve resilience, but it must be a cross-sector effort to increase healthy, affordable housing; improve transportation access; fight poverty; and implement other policies proven to advance health. Congress should fund a public health approach to address SDOH, such as the approach proposed in the Improving Social Determinants of Health Act. The legislation would strengthen SDOH capacity at the CDC and enable grants to public health agencies to build cross-sector partnerships and develop community solutions to SDOH. For further discussion on policy options to address SDOH, see TFAH's Blueprint and PHACCS reports.[124,125]
- **Provide resources and technical assistance to communities to enhance equity and resilience before, during, and after an event.** Rather than a top-down approach to promote equity and resilience, policymakers should support an asset-based approach that relies on communities identifying and leveraging their assets. Congress should direct targeted resources to community-based organizations and existing community health networks that focus on the health of communities of color and other groups that bear a disproportionate burden during disasters. Evacuation plans should be inclusive of the community as a whole by meeting and enforcing the requirements of the Americans with Disabilities Act. Grants should support culturally and linguistically appropriate public health campaigns that address prevention and treatment, providing community leaders the opportunity to fully participate in planning activities, allowing organizations to hire and engage community members so emergency plans better reflect the community, and improving data collection and sharing. Federal and other grant makers and states should ensure that existing grants and sub-awards reach the grassroots level and communities most in need.
- **Public health agencies should strengthen their health equity leadership and adopt strategies and accountability metrics to incorporate equity into preparedness.** Equity must not be considered separate from preparedness activities but must serve as the foundation for a more resilient

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community. Ensuring equity is central to all preparedness activities and requires integrating equity accountability measures into all elements of emergency response. Congress should provide the CDC funding to extend its COVID-19 Health Equity Strategy[126] to ongoing preparedness and response work at the agency and with partners. All state and local governments, including health departments, should build up internal infrastructure to drive equity, including by identifying a chief health equity officer who has a leadership role in the emergency operations center and/or incident command structure for all-hazards events and is engaged in every emergency operation center activation. Health equity and emergency preparedness officials should work across programs to incorporate equity issues and goals into preparedness policies and plans;[127] to improve staff capacity to understand how the legacies of discrimination, current-day racial trauma, and other structural inequities affect disaster resilience and recovery; develop and disseminate communications materials that are culturally and linguistically tailored; and to collect and leverage data to identify unique community assets and advance equity before and during events.

RECOMMENDATIONS FOR STATE AND LOCAL GOVERNMENT AND COMMUNITY LEADERS:

- **Plan *with* communities, not for them, and empower their involvement with resources.** Emergency planners must conduct meaningful engagement, partnerships, and listening efforts as well as ongoing inclusion and local hiring (especially from communities typically at higher risk in disasters) in emergency planning and response. Officials should establish relationships with services and organizations that serve these populations before emergencies take place, and government should fund community leaders and community-based organizations to participate in preparedness efforts. Health departments and emergency management agencies should rely on the expertise, community trust, and networks of those who may bear a disproportionate risk, such as older adults, people with disabilities, and individuals with chronic health conditions to ensure emergency plans, procedures, and evacuation shelters meet the needs of all in the community.
- **Address mental health and substance use gaps, bolster crisis resources, and incorporate mental health first-aid and long-term treatment into disaster response and recovery strategies.** Emergencies can exacerbate existing mental health and substance use concerns and disrupt access to care. During the COVID-19 pandemic, there have been reports of increases in a number of mental health concerns,[128] including suicide ideation[129] and drug overdoses.[130] Short-term regulatory relief, like take-home medication for opioid use disorder[131] and waivers for telehealth,[132] have helped, but coordination among state, local, and federal agencies remains vital to delivering resources to affected communities. Policymakers should also incorporate behavioral health needs into disaster planning, as required by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act.

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Priority Area 4: Ensure Effective Leadership, Coordination, and Workforce

The political polarization and contradictory messaging exhibited throughout the pandemic contributed to a wide variation in how individuals and communities responded. Issues such as face coverings, business- and school-closure decisions, and even the mortality numbers became matters for debate by a vocal minority of Americans.[133] Clear national leadership and communication, following the advice of public health and scientific experts, is needed to ensure consistent policies and messaging during a situation as complicated and dangerous as a public health emergency. Perhaps more important than any technology or invention is the presence of trained, experienced people, from the frontline responder to the top of government. The nation's local public health departments responded to the pandemic with an estimated 26,000 fewer public health workers compared with before the 2008 recession.[134] The state budget cuts likely to continue in the years following the pandemic threaten to intensify this workforce shortage. Effective crisis response requires coordination, cooperation, and leadership—elements that governments must build and sustain over time.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT:

- **Strengthen federal leadership, guidance and regulatory authorities for public health emergencies.** During the COVID-19 pandemic, authority and decision-making over the response was ceded to states to an unprecedented degree. This diffusion of responsibility meant wide variation in policy and response decisions regarding business closures, mask mandates, testing strategies, and other tactics. The CDC must be empowered to lead the public health response during a pandemic and issue clear, feasible guidance and regulations for state, local, tribal, and territorial officials and to the public to minimize variation across jurisdictions. The optimal approach is a federal-state partnership rooted in shared decision-making and a clear division of labor.
- **Rebuild trust in federal public health agencies.** The COVID-19 pandemic has damaged faith in federal agencies, including public health agencies such as the CDC and the FDA. Policy decisions from the federal to the local level should be based on the best available science, led by public health experts, and free from any perception of political interference. The president, the HHS secretary, and the leadership of federal public health and emergency response agencies, including the CDC, ASPR, DHS, FEMA and the FDA, must conduct a thorough review on the independence and performance of these agencies. Leaders should establish procedures and policies to ensure the scientific integrity and independence of the agencies, without political interference, and they must correct any errors made during the COVID-19 response. At the same time, elected leaders must publicly support public health to rebuild confidence in those agencies and officials. All federal messages and messengers about public health issues must be consistent and based in science.

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- **Invest in public health communications.** Congress must make a significant investment in effective public health communications, including research into best practices for different audiences. The CDC and other federal, state, and local public health agencies should engage with a diverse group of stakeholders to research and test effective public health messaging. From vaccines to mask-wearing, there are subgroups of Americans who are skeptical, hesitant, or confused about COVID-19 public health guidance for various reasons. While some will be recalcitrant, many Americans are simply hesitant or have not been properly engaged. While the substance of communications should be consistent, messages must acknowledge the historical context of distrust and be linguistically and culturally tailored for different populations, and trusted, nongovernmental messengers should receive funding to help deliver messages.

- **The White House should reestablish a health security directorate with public health expertise.** The White House should ensure senior advisors to the president have a strong background in public health and/or biodefense, and the White House should ensure that senior-level interagency cooperation is progressing before, during, and after public health emergencies.

Editor's note: on January 20, 2021, the Biden administration reestablished a National Security Council Directorate for Global Health Security and Biodefense.

- **Clarify and restore roles and responsibilities for government's emergency support functions.** The White House, HHS, CDC, ASPR, U.S. Department of Homeland Security, FEMA, and FDA should work together to clarify roles and responsibilities to improve the nation's emergency preparedness and response capacity.

- **Fund the recruitment and training of public health personnel.** The health security enterprise requires trained, experienced personnel. Federal, state, and local governments must prioritize stable, long-term funding for recruitment and retention of a diverse workforce, including one with experience in public health informatics, laboratory science, health equity, and epidemiology. Congress should also invest in public health workforce development and retention programs, such as student loan repayment and other incentives, especially in underserved areas. Public health schools should incorporate health equity and cultural competency into their preparedness curricula.

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Priority Area 5: Accelerate Development and Distribution of Medical Countermeasures

A robust Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)[135] could negate a range of health threats, but a drug or vaccine is only effective if it reaches the right person at the right time. Medical countermeasures (MCM) are FDA-regulated products that could be used in the event of a public health emergency; they include biologics, drugs, and devices.[136] The challenges faced in distributing scarce medical resources during the pandemic as well as the deployment of COVID-19 vaccine demonstrate the urgency of the right-product/right-time equation. During the first ten months of the pandemic, there was a notable gap in federal coordination, with many federal responsibilities being left to states or to the private sector. The federal government circumnavigated or significantly modified established MCM and medical supply-chain coordination and distribution channels at various points in the pandemic, contributing to confusion and chaos. For example, the lack of federal coordination and transparency left individual hospitals and states to compete with each other for scarce resources,[137] and FEMA and the U.S. Department of Defense were brought in to manage some supply-chain operations despite long-standing systems in place at HHS. Clear federal coordination is necessary during the pandemic, with an eye toward preventing future shortages and shortfalls.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT:

- **Provide significant, long-term funding for the entire MCM enterprise.** The MCM enterprise involves research, manufacturing, surveillance, delivery, training, and monitoring. Long-term coordinated and transparent funding to the Biomedical Advance Research and Development Authority, Strategic National Stockpile, CDC, FDA, NIH, and other components of the PHEMCE would offer more certainty to the biotechnology industry and researchers, would strengthen public-private partnerships, and would enable the purchase of ancillary medical supplies, such as PPE. The United States should grow its investment in innovative, flexible technologies and platforms that will enable faster production of products for a range of biothreats, rather than focusing on products for a single pathogen.[138]

- **Prioritize the distribution and dispensing of MCMs.** It is important that MCMs reach the right person at the right time during emergencies; the challenges in mass vaccination were predicted by the CDC's MCM Operational Readiness Review.[139,140] HHS along with state, local, tribal, and territorial health departments should be properly resourced and require integration of private-sector healthcare supply distributors and supply-chain partners into planning, exercises, and emergency responses to better leverage existing systems and resources. Once

the COVID-19 vaccination campaign is complete, HHS should access and address gaps in vaccine development, procurement, maintenance, deployment and administration; and improve the training of state and local personnel to ensure vaccine administration is well-coordinated.

- **Clarify and strengthen MCM and supply-chain management for emergencies.** HHS must maintain primary authority over public health emergency response, including deployment of the Strategic National Stockpile and emergency medical supply-chain management, in coordination with other federal agencies and in consultation with private-sector and public health partners. Federal agencies should also explore all available authorities, such as through the Defense Production Act, and communicate strategies with stakeholders to bolster the supply chain during emergencies. The HHS secretary should clarify roles and responsibilities for supply-chain management throughout the pandemic and, moving forward, should develop and disseminate best practices for supply management.[141] HHS should strengthen the PHEMCE's work, including regular interagency meetings; engagement with private-sector, supply-chain partners; and improved transparency and communication with state, local, tribal, and territorial partners.

RECOMMENDATIONS FOR FEDERAL, STATE, AND LOCAL GOVERNMENTS AND PARTNERS:

- **Improve MCM guidance and communications for groups at higher risk during an event.** HHS, including the CDC, should consult with experts and work with healthcare professionals and state, local, and tribal partners to develop standardized guidance for dispensing MCMs to groups such as children, older adults, people with disabilities, and people who are homebound. And HHS and state, local, and tribal agencies should work with organizations that reach the public, especially communities at disproportionate risk—such as groups representing older Americans, people with disabilities, and limited English-proficient communities—to improve communications around MCM issues before an event. Communities need to be engaged before an outbreak or event to ensure their understanding of the risks, benefits, and distribution challenges of introducing a medical product to a large portion of the population and ultimately improving acceptance and access to MCMs. It is important to provide clear and accurate guidance to the public in multiple formats and languages, via trusted sources and multiple communications channels, including formats that are accessible to people with hearing or vision loss.

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Priority Area 6: Ready the Healthcare System to Respond and Recover

In the 2019 and 2020 *Ready or Not* reports, TFAH warned that medical surge capacity for a pandemic remained a major gap in the nation's preparedness. The COVID-19 pandemic has placed tremendous strain on the healthcare system, from acute-care facilities[142] to long-term care facilities[143] to small outpatient clinics.[144] Overcrowded facilities, exhausted workforces, disruptions in the supply chain, shortages of PPE and other supplies, interruptions in primary and preventive care, lack of situational awareness, and loss of revenue have been among the significant challenges to the nation's healthcare system. The toll in lives lost due to these compounding issues has yet to be calculated. The NHSPI has consistently found that healthcare delivery readiness scores are in the lowest levels among preparedness domains, with little progress in the past five years.[145] Policymakers need to strengthen existing systems and consider long-term mechanisms to create sustainable healthcare readiness across systems and across geographic borders.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT AND HEALTHCARE:

- **Strengthen the Hospital Preparedness Program and fund regional coordination.** HPP can help build strong healthcare coalitions capable of engaging and supporting members during disaster responses, but the program has been severely underfunded. Congress must provide more robust annual funding—which it has cut in half over the past decade. HHS and the awardees should ensure healthcare leaders takes the lead on HPP planning and implementation to the extent possible, with support and coordination from public health, emergency management, and others, and awardees should ensure as much funding as possible is reaching healthcare coalitions. Healthcare administrators should ensure their facilities have tools and support for meaningful participation in healthcare coalitions, including the ability to share information and resources across the coalition and with public health agencies. Congress should provide additional funding for a tiered regional disaster system to coordinate across coalitions and states,[146] to map specialized disaster care (such as burn or pediatric care) across the country, and to leverage those assets in a coordinated way.[147] Congress should also provide increased funding for healthcare surveillance through CDC's National Healthcare Safety Network—which is the nation's domestic tracking and response system to identify emerging and enduring threat across 37,000 healthcare facilities, including COVID-19, healthcare-associated infections (HAIs), and antibiotic-resistant (AR) infections. These data drive improvements in patient safety and monitor the surge capacity of healthcare facilities to confront new threats.
- **Create incentives and ramifications to build sustainable preparedness and surge capacity across healthcare systems.** The shortages of beds, healthcare personnel, and equipment during the pandemic underscores the need for cooperation among healthcare entities, across systems, and across geographic borders. Although there has been progress in developing healthcare coalitions in many regions and progress in meeting CMS and other accreditation preparedness standards by individual healthcare facilities, these existing mechanisms have not provided enough incentive for many healthcare facilities to create meaningful surge capacity and cooperation across competing entities. Similarly, the Joint Commission's preparedness standards apply to individual facilities and not to the readiness of the healthcare system as a whole.[148] In addition to strengthening existing systems, Congress and HHS should consider long-term sustainability for building healthcare readiness across the system, including meaningful incentives and disincentives, including:
  - An external self-regulatory body, in alignment with federal policy goals, could set, validate, and enforce standards for healthcare facility readiness, stratified by facility type, with authority for financial ramifications.[149]
  - Payment incentives could sustain preparedness, surge capacity, regional disaster partnerships, and reward facilities that maintain specialized disaster care.

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- **Expand access to healthcare.** Access to healthcare is always important and particularly so during a pandemic or disaster. Federal and state governments must ensure every person has access to healthcare, including robust insurance coverage. Millions of Americans still lack insurance coverage, and disparities by race, ethnicity, sexual or gender identity, and other factors have been exacerbated by the pandemic-induced recession.[150] Congress and the administration should strengthen incentives for states to expand Medicaid, make marketplace coverage more affordable, and improve outreach and marketing for enrollment.[151]

- **Assess impact of CMS Preparedness Standards and improve transparency.** An external review by the GAO or a similar entity should assess how CMS preparedness standards have affected overall healthcare readiness, and HHS should begin tracking progress on preparedness measures over time. CMS should also strengthen preparedness standards by adding medical surge capacity and other capabilities, including infection prevention and control, stratified by facility type, as a necessary requirement within the next iteration of the rule.[152]

RECOMMENDATIONS FOR STATE GOVERNMENT AND HEALTHCARE:

- **Integrate healthcare delivery into emergency preparedness and response.** Jurisdictions should engage and integrate the healthcare sector into emergency planning and responses, including plugging healthcare coalitions and other entities representing private healthcare and the healthcare supply chain into emergency planning and response and incident command. Health systems, healthcare coalitions, and public health should develop memoranda of understanding ahead of disasters to improve situational awareness across healthcare and to enable movement of patients, personnel, and supplies. Private-sector healthcare leadership should prioritize preparedness moving forward, including training and workforce protections, surveillance for emerging threats, stockpiling of supplies ahead of disasters, and full engagement in regional collaborations and coalitions.

- **Strengthen state policies regarding disaster healthcare delivery.** States should review credentialing standards to ensure healthcare facilities can call on providers from outside their states, and health systems should ensure they can receive outside providers quickly during a surge response. States should also adopt policies that promote healthcare readiness and ease the ability to surge care and services, such as the NLC, the Interstate Medical License Compact, the Recognition of EMS Personnel Licensure Interstate CompAct,[153] the Uniform Emergency Volunteer Health Practitioners Act,[154] emergency prescription refill laws and protocols, and implementation and education of providers regarding crisis standards of care guidelines.[155,156]

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Priority Area 7: Prepare for Environmental Threats and Extreme Weather

Climate change, environmental hazards, and extreme weather pose serious threats to human health. According to a December 2020 report by TFAH and the Johns Hopkins Bloomberg School of Public Health, many of the states most at risk from climate change are also the least ready to deal with it (see sidebar on page 60). Environmental health involves detecting and protecting communities from hazardous conditions in air, water, food, and other settings, and it is therefore a critical component of the nation's health security. Environmental hazards impact communities differently and exacerbate disparities among people living in poverty, people of color, people with underlying health conditions, and children and older people—all of whom are at particular risk.[157]

RECOMMENDATIONS FOR FEDERAL AND STATE GOVERNMENT:

- **Enact legislation requiring a national strategic plan.** The United States urgently needs a strategic action plan to address the health impacts of climate change. Policymakers should enact legislation requiring HHS to develop such a plan and to fund development and ongoing maintenance of health system capacity specifically for this purpose.
- **Support public health climate-adaptation efforts.** Funding for the CDC's Climate and Health program stands at $10 million per year, while the annual health costs of climate change events were estimated to be more than $14 billion in 2008.[158] Climate-informed health interventions include identifying likely climate impacts, potential health effects associated with these impacts, and the most at-risk populations and locations.[159] Congress should increase funding for environmental health programs, including the CDC's Climate and Health program and environmental health tracking to conduct surveillance and target interventions.
- **Develop sustainable state and local vector-control programs.** As the threat and geographic distribution of mosquitos, ticks, and other vectors changes, Congress should expand funding for the vector-borne disease program at the CDC to support state and local capacity to prevent and detect vector-borne diseases, such as Zika, West Nile Virus, and Lyme disease.
- **Guarantee clean water for all U.S. residents, including after disasters.** The administration and Congress should restore the Clean Water Rule, which includes measures to protect a safe water supply, such as addressing the ongoing problem of lead, per- and polyfluoroalkyl substances, and other toxins in drinking water; taking steps to reduce the potential for waterborne illnesses; and increasing protection against potential acts of terrorism on America's drinking and agricultural water. All states should include water security and sewage removal in their preparedness plans, and they should build relationships among health departments and local environmental and water agencies. The CDC should include national guidance and metrics for planning for a range of water-related crises.

RECOMMENDATIONS FOR STATE GOVERNMENT:

- **Every state should have a comprehensive climate vulnerability assessment and adaptation plan that incorporates public health.** Public health and environmental agencies should work together to track concerns, coordinate risk-management and communications, and prioritize necessary capabilities to reduce and address threats. States and localities should investigate what additional capacities are necessary and identify vulnerable populations and communities. State and local public health officials should incorporate environmental health into emergency operations planning and incident command.
- **Complete all steps of the CDC's Building Resilience Against Climate Effects, or "BRACE," framework, and continuously work to enhance and refine preparations for climate change.** State agencies must conduct and facilitate rigorous vulnerability assessments at the state and local levels. The assessments should focus especially on populations at highest risk and the health threats most pertinent to them. States must also push ahead to complete all steps of the framework, including identifying and implementing evidence-based interventions to protect residents. Finally, as agencies implement interventions, they should continually evaluate effectiveness and strive for quality improvement.

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Year in Review – 2020 Health Threats Incidents and Actions

This section reviews 2020's major events, research, and policy actions related to global and domestic health security.

Disease Outbreaks

Notable Incidents

- **COVID-19**
  - The novel coronavirus SARS-CoV-2, the virus that causes COVID-19, emerged internationally in late 2019. As of late February 2021, as this report was being prepared for publication, over 28 million cases; and over 500,000 deaths have been reported in the U.S. alone.[160] Globally, there have been over 109 million confirmed cases of COVID-19, and over two million deaths, reported to the World Health Organization (WHO).[161] The number of cases and the number of deaths from COVID-19 is higher in the United States than in any other country.[162] In the United States, slightly more women than men have been infected, but deaths in men are disproportionate (54 percent to 46 percent).[163] Black people account for nearly 16 percent of COVID-19 deaths, where race is known, despite representing 13 percent of the U.S. population.[164] Hispanic or Latino people account for 18 percent of reported COVID-19 cases in the U.S. as of late January 2021, a proportion approximately equal to their percentage of the U.S. population.[165] In addition, research indicates a significant level of asymptomatic cases, so true infection counts are likely higher than confirmed cases.[166] Deaths may also be underreported due to inadequate testing and given that the pandemic response itself may have indirectly caused mortality due to limited access to healthcare during pandemic surges and due to those who avoided seeking care in hospitals.[167,168] The Centers for Disease Control and Prevention (CDC) found that in the 10 weeks following declaration of the COVID-19 national emergency, emergency department visits declined 23 percent for heart attack, 20 percent for stroke, and 10 percent for hyperglycemic crisis.[169]
  - Those at highest risk for severe disease and death are the elderly and people with underlying medical conditions, but COVID-19 has severely sickened and killed many young and otherwise healthy individuals, as well. Researchers are trying to determine if certain genetic characteristics are responsible for severe versus mild disease.[170] The disease in young children is usually mild, but in rare cases it is associated with multisystem inflammatory syndrome in children, in which different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs.[171] National data reported between March and July 2020 showed that MIS-C disproportionately impacted Black and Latino children.[172] The long-term effects of COVID-19 infection aren't fully known, but findings show heart

and lung damage in some patients, and many patients report lingering fatigue, shortness of breath, and confusion.[173]

- In June 2020, the U.S. Department of Health and Human Services (HHS) Office of Minority Health announced Morehouse School of Medicine as the awardee for a new $40 million initiative to fight COVID-19 in racial- and ethnic-minority, rural, and socially vulnerable communities. The initiative—the National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities (NIMIC)—is a three-year project designed to work with community-based organizations nationwide to deliver education and information on resources to help fight the pandemic. Its aim is to strengthen efforts to link communities to COVID-19 testing, healthcare, and social services and to share and implement effective response, recovery, and resilience strategies.[174]
- The United States has undertaken unprecedented efforts to accelerate the development, manufacturing, and distribution of COVID-19 vaccines and therapeutics through significant federal investments and scientific cooperation, while maintaining standards for safety and efficacy.[175] Usually, vaccines take years of research and testing before they are available to the public. As of December 2020, two vaccines, one developed and manufactured by Pfizer-BioNTech, the other by Moderna, received emergency-use authorization (EUA) from the U.S. Food and Drug Administration (FDA).[176] Initial administration of the vaccine to priority groups, including healthcare workers and residents of nursing homes, also began in December 2020.

nycshooter

- The Trump Administration created a centralized system to order, distribute, and track COVID-19 vaccines.[177] States can order vaccine quantities (as supply allows) from the CDC. Airlines worldwide are providing transportation for billions of doses of vaccine that must be stored in frigid temperatures. FedEx and UPS are installing ultracold freezers near their air-cargo hubs, and dry-ice producers are increasing production to support vaccine distribution.[178] The U.S. Department of Defense and HHS coordinated the shipment of the initial doses to states.[179] The CDC released a playbook for state, tribal, territorial, and local jurisdictions on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions.[180] The Advisory Committee on Immunization Practices recommended priority groups to receive the initial doses of the vaccines,[181] but the final decisions on population prioritization and logistics

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are up to the states to determine, with most states prioritizing healthcare providers and long-term care facility residents in the initial phase.[182]

- While shipping of the vaccine began shortly after the FDA issued emergency-use authorizations, the initial administration of the newly approved vaccines fell far short of projected goals. As of December 30, 2020, 12.4 million vaccine doses had been distributed to states, but only 2.6 million had been administered. Experts called on the federal government to provide more coordination and resources to the states to increase their capacity to quickly administer the vaccine to more people.[183] The challenges in initial administration of the vaccine likely occurred for many reasons, including: funding for states to administer the vaccine was not signed into law until December 27, 2020, which hindered planning, communications, hiring, and training; the lack of a centralized planning effort; the lack of federal leadership; the lack of communication between federal, state, and local planners on the number of initial doses available and when; slow engagement with local partners; and the sheer immensity and complexity of the project.[184,185] HHS is partnering with pharmacies, including CVS and Walgreens, to deliver vaccines on-site at nursing homes and assisted-living facilities. Following distribution to the initial critical populations, states are planning for COVID-19 vaccines to be available in a phased approach to the priority groups in the broader population at locations such as retail pharmacies, healthcare facilities, and vaccination sites, but as this report was being finalized, a specific time frame for availability of the vaccine to the general population was unclear and may be different from state to state.[186]

Editor's note: In January 2021, the Biden administration set a goal and put in place a plan to administer 100 million vaccine doses during its first 100 days in office.[187] That goal was later increased to 150 million doses. FEMA and National Guard troops went to work in many states to assist in the vaccination effort. As of March 1, 2021, 96,402,490 vaccine doses had been distributed nationwide and 76,899,987 had been administered.[188] However, based on preliminary data from 17 states, during the first two months of vaccine distribution, Blacks and Hispanics were being vaccinated at a much lower rate than were whites.[189]

- **Seasonal flu.** As TFAH was preparing this report, flu rates for the 2020–2021 flu season were lower than usual for major regions of the country.[190] The 2019–2020 flu season was of "moderate severity"; however, the severity of the season in some age groups was higher: hospitalization rates among children ages 0 to 4 years old and adults ages 18 to 49 years old were higher than observed during the 2009 H1N1 pandemic.[191] The CDC estimates found that the 2019–2020 flu accounted for approximately 38 million illnesses, 405,000 hospitalizations, and 22,000 flu deaths.[192] Seasonal flu vaccine coverage rates increased modestly across all age groups in 2019–2020, with vaccine rates among adults increasing 3.1 percentage points over the previous season and up 1.2 percentage points among children—but that was still far below Healthy People 2020 and 2030 goals.[193] The CDC estimates that influenza vaccination prevented 7.5 million illnesses, 3.7 million medical visits, 105,000 hospitalizations, and 6,300

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deaths due to influenza during the 2019–2020 season.[194] The low 2020–2021 seasonal flu activity was likely a result of the mitigation measures to reduce the spread of COVID-19.[195]

- **Hepatitis A.** In 2020, 27 states experienced outbreaks of the Hepatitis A virus, driven in part by increases among those who reported drug use and homelessness.[196] Hepatitis A is a highly transmissible infection.[197] The Hepatitis A vaccine is recommended for certain populations; in 2019, the Advisory Committee on Immunization Practice updated its recommendations to include people experiencing homelessness in the populations who should receive the vaccine.[198] Hepatitis A infections had been going down between 2000 and 2012 but increased in 2013, 2016, and 2018.[199] As of December 4, 2020, there have been 36,848 reported cases that lead to 22,546 hospitalizations and 348 deaths since the ongoing outbreak began in 2016.[200]

- **Measles outbreaks, United States.** In 2020, U.S. measles cases were low—only 13 confirmed cases in eight jurisdictions, as of November 30, 2020.[201] Conversely, 31 states confirmed 1,282 individual cases of measles in 2019.[202] Measles is a highly contagious disease that predominantly affects young children and can cause hospitalization, and death and serious complications, such as pneumonia, encephalitis.[203] It can cause up to a 90 percent chance of disease contraction in unimmunized individuals.[204] Outbreaks have been linked to the sustained spread of measles among unvaccinated communities.[205]

- **Measles outbreaks, global.** The WHO reported that during 2019, there were more measles cases reported worldwide than in any year since 1996—869,770 confirmed cases and an estimated 207,500 deaths.[206] Fortunately, as of September 2020, the number of confirmed cases worldwide was much lower, though the Democratic Republic of the Congo, Brazil, and Nigeria reported high numbers and there were ongoing outbreaks in other nations.[207] However, COVID-19 is increasing the risk of measles outbreaks, following the suspension of measles vaccination campaigns in 26 countries. On the current trajectory, experts predict more child deaths from measles than from COVID-19 in Africa.[208]

- **The Democratic Republic of Congo Ebola outbreak.** On June 1, 2020, the Democratic Republic of the Congo declared its 11th outbreak of Ebola virus disease.[209] In November 2020, it was declared over, following a total of 130 cases and 55 deaths.[210]

- **Candida auris.** C. auris is an emerging drug-resistant fungus that has led to severe illnesses in hospitalized patients. A majority of reported cases in 2020 were in New Jersey, New York, and Illinois. Infection by this multi-drug-resistant fungus has a mortality rate close to 60 percent and presents a serious global health threat.[211] As of November 30, 2020, in the United States, there were 1,595 reported clinical cases of C. auris and an additional 3,056 patients identified with C. auris. There is transmission in multiple countries, as well.[212] With the increase of patient transfers from long term care facilities to ICUs due to COVID-19, the CDC said that it expects C. auris and other fungal infections to remain an infection control challenge for healthcare facilities in the U.S. and around the world.[213]

- **Cholera.** Cholera, an acute intestinal infection, is rare in the United States, but cases have increased steadily since 2005 globally,[214] and it is a major cause of epidemic diarrhea in the developing world. Regions with humanitarian crises, high rates of poverty, and a lack of water and sanitation infrastructure are at higher risk. In 2020, Yemen and Somalia faced serious outbreaks.[215] Researchers estimate that every year, there are 1.3 to 4.0 million cases and 21,000 to 143,000 deaths worldwide due to cholera.[216]

- **Polio.** In August 2020, the African Continent was certified wild poliovirus free by the World Health Organization, making the world poliovirus free except for Pakistan and Afghanistan.[217] After months of severe disruptions from the COVID-19 pandemic, polio vaccination campaigns have resumed in both countries as of August 2020. UNICEF estimates up to 50 million children missed their vaccinations when efforts were halted in March 2020 to minimize transmission of COVID-19.[218]

- **Foodborne illnesses.** In 2020, multistate foodborne illness outbreaks resulted from mushrooms, peaches, onions, clover sprouts, deli meats, and bagged salads. The pathogens involved include several strains of Salmonella and E. coli, as well as Listeria and Cyclospora.[219] The CDC estimates that 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne illness each year in the United States.[220] The five most common pathogens that cause foodborne illness are: (1) Norovirus, (2) Salmonella, (3) Clostridium perfringens, (4) Campylobacter, and (5) Staphylococcus aureus.[221]

Notable Events and Policy Actions:

COVID RESPONSE

- **Public Health Emergency Declaration and early COVID-19 response.** On January 31, 2020, U.S. Health and Human Services Secretary Alex Azar declared a public health emergency for the United States for the 2019 novel coronavirus.[222] Since then, HHS has renewed the declaration several times. The declaration allowed some flexibilities for states, such as temporary reassignment of personnel to the response. Before the declaration and before the Trump administration requested emergency funding, Secretary Azar tapped $105 million from the Infectious Disease Rapid Response Reserve Fund for the initial response.[223] The WHO issued a public health emergency declaration of international concern in January and labeled the outbreak as a pandemic in March, 2020.[224] [225]

- **COVID Response Legislation.** Congress has enacted several public laws providing funding and authorities to assist in the response to the pandemic:[226,227]

  - **Coronavirus Preparedness and Response Supplemental Appropriations Act (P.L. 116-123).** The President signed the act into law on March 6, 2020, providing $8.3 billion in emergency funding for public health measures, including the development of medical countermeasures and grants for public health agencies.

  - **The Families First Coronavirus Response Act (P.L. 116-127).** The President signed the act into law on March 18, 2020; it included the Second Coronavirus Preparedness and Response Supplemental Appropriations Act. The legislation expanded food and nutrition programs, unemployment benefits, and emergency family and medical leave; it also required certain employers to provide paid sick leave for workers unable to work due to COVID-19, and it provided access to COVID-19 testing with no cost to the individual.

  - **The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136).** The President signed the act into law on March 27, 2020, providing over $2.2 trillion in relief to individuals; businesses; state, local, and federal agencies; and industry sectors affected by the COVID-19 pandemic and the government-led effort to limit its public health impact. It also included a variety of oversight provisions designed to increase the information available to Congress regarding the federal government's implementation of the CARES Act and response to the COVID-19 pandemic.[228]

  - **The Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139).** The President signed the act into law on April 24, 2020; it included Additional Emergency Appropriations for Coronavirus Response. The bill extended the Paycheck Protection Program and small-business loans and allocated funding for healthcare providers and COVID-19 testing.

  - **The Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (P.L. 116-26).** Congress passed and the President signed the act with the fiscal year (FY) 2021 appropriations bills and signed it into law on December 27, 2021. The bill provided $900 billion in emergency appropriations, including $73 billion for HHS, of which $8.75 billion will support the vaccination campaign.

- **Payments to healthcare providers.** The CARES Act, Paycheck Protection Program and Health Care Enhancement Act, and the Coronavirus Response and Relief Supplemental Appropriations Act allocated $178 billion for a provider relief fund for hospitals, clinics, and other healthcare providers to recover some revenue lost due to the pandemic.[229] In addition, changes in HHS telehealth policies were put in place to expand access to telehealth services during the pandemic.[230]

COVID-19 Vaccine

- **COVID-19 Vaccine.** As of December 2020, two vaccines—one developed and manufactured by Pfizer-BioNTech, the other by Moderna—received emergency-use authorization from the FDA (see COVID sidebar, on page 55).

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COVID RESPONSE

Additional COVID-19 Response Actions:

- **Medical supply shortages.** The quantities of medical supplies in the Strategic National Stockpile and through the private-sector supply chain were not sufficient for a pandemic as widespread as COVID-19. Shortages of PPE,[231] ventilators,[232] testing supplies,[233] and other medical supplies and products reached critical levels at different phases of the pandemic. President Trump invoked the Defense Production Act in April 2020 to try to spur private-sector production of these supplies.[234]
- **National Special Pathogen System.** In March 2020, ASPR expanded the Regional Ebola Treatment Network to become the National Special Pathogen System (NSPS) through COVID-19 emergency supplemental funding. The NSPS builds on the Regional Ebola Treatment Network and was originally created to support the urgent preparedness and response needs of hospitals, health systems, and healthcare providers on the front lines of the COVID-19 outbreak. The system is designed to to help prepare hospitals and health systems to identify, isolate, assess, transport, and treat patients with COVID-19 or other special pathogens or persons under investigation for such illnesses. The long-term vision of the NSPS is to create a nationwide systems-based network approach, similar to other national systems (e.g., the national trauma system) for all special pathogens.
- **Crisis standards of care.** Major surges in COVID-19 patients caused hospitals and intensive-care units to exceed capacity. Hospitals canceled admissions and nonemergency procedures and established alternate care sites. In December 2020, 10 national organizations issued a statement outlining urgent action for states, healthcare systems, and health departments to implement crisis standards of care, including legal protections for healthcare workers, statewide information sharing, distribution of patients and resources, and care coordination across jurisdictions.[235]

Vaccines: Earning Trust and Access in Communities of Color and Tribal Nations

The reported hesitance among some populations of color and Tribal Nations toward COVID-19 vaccines[236] has a basis in historic mistreatment and the effect of current-day structural racism. These experiences could have long-term impacts on vaccine confidence and vaccination rates in these groups. In October 2020, TFAH, the National Medical Association, and UnidosUS partnered to host an expert convening on how to earn vaccine trust and increase vaccine access within communities of color and Tribal Nations. The experts concluded that earning such trust will require working with leaders in those communities to use their agency as trusted messengers. Leaders from these communities must have a place at the planning table and be provided the resources needed to engage with and share information with their stakeholders. All vaccine education messaging must be culturally and linguistically appropriate. Messaging campaigns must feature trusted messengers, and education programs should take advantage of existing health communications networks. Read the full policy brief, *Building Trust in and Access to a COVID-19 Vaccine Within Communities of Color and Tribal Nations*, or find it on the TFAH website.[237]

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- **Ending the HIV epidemic.** In FY 2020, the Trump administration awarded funding to its *Ending the HIV Epidemic: A Plan for America Initiative,* which aims to reduce the number of new HIV infections in the United States by 90 percent by 2030. In December 2019, Congress approved the largest increase to domestic HIV/AIDS-prevention programs from multiple federal sources, including the CDC, in decades, bringing federal funding in FY 2020 for HIV/AIDS (across multiple programs) to just over $28 billion.[238,239] In addition, HHS, through the Health Resources and Services Administration (HRSA), awarded more than $2 billion in Ryan White HIV/AIDS Program grants to cities, counties, states, and local community-based organizations. This funding supports a comprehensive program of HIV primary medical care, medication, and essential support services with the goal of improving the health quality of more than half a million people with HIV in the United States.[240]

- **Emerging infectious diseases.** The National Institute of Allergy and Infectious Diseases (NIAID), within NIH, awarded 11 grants totaling approximately $17 million to establish the Centers for Research in Emerging Infectious Diseases. The new global network will involve multidisciplinary investigations into how and where viruses and other pathogens emerge from wildlife and spillover to cause disease in people. NIAID intends to provide approximately $82 million over five years to support the network.[241]

- **Viral hepatitis strategic plan.** HHS released the Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination 2021–2025, which serves as a roadmap to hepatitis elimination. HHS sought input from a broad mix of stakeholders on whether the plan's goals, objectives, and strategies appropriately address the viral hepatitis epidemic and whether there are any critical gaps.[242]

- **National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB).** Antimicrobial resistance, the rise of superbugs that are resistant to existing medicines, is a major threat to health. Originally released in 2015, the 2020–2025 CARB builds on the original by expanding evidence-based activities that have been shown to stop the spread of antibiotic resistance, such as increasing infection prevention and control and improving the way antibiotics are used. Developed by the HHS Office of the Assistant Secretary for Planning and Evaluation and authored by agencies within the CARB Task Force, which is co-chaired by HHS, the U.S. Department of Agriculture, and the U.S. Department of Defense, the plan's purpose is to guide U.S. government activities, as well as action by public health, healthcare, and veterinary partners to address urgent and serious antibiotic-resistant threats that affect people in the United States and globally.[243]

- **United States officially withdraws from the World Health Organization.** In July 2020, President Trump formally announced his intention to withdraw the United States from the WHO, effective July 6, 2021.[244]

Editor's note: on January 21, 2021, the Biden administration restored U.S. membership in the WHO.

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- **Food safety.** In July 2020, the FDA released its *New Era of Smarter Food Safety Blueprint*, which reflects input from a variety of stakeholders and outlines a path forward building on the implementation of the FDA Food Safety Modernization Act.[245] Its four core elements are: (1) tech-enabled traceability and foodborne outbreak response—using technologies, data streams, and approaches that will greatly reduce the time it takes to trace the origin of a contaminated food; (2) smarter tools and approaches for prevention—identifying new tools, processes, and communications to inform prevention efforts; (3) new business models and retail modernization—advancing the safety of both new business models, such as e-commerce and home delivery of food, and traditional business models, such as retail food establishments; and (4) food safety culture—supporting and strengthening cultures that embrace food safety within the FDA, on farms, and in facilities.[246]

Notable Research Findings, Meetings, and Federal Hearings:

- **Malaria treatment and prevention.** In May 2020, the FDA approved artesunate for injection to treat severe malaria in adult and pediatric patients.[247] Treatment of severe malaria with intravenous artesunate should always be followed by a complete treatment course of an appropriate oral antimalarial regimen. According to the CDC, approximately 2,000 cases of malaria are diagnosed in the United States each year, with 300 of those infected having severe disease.[248] In addition, the first phase 1 clinical trial, testing the safety and effectiveness of a monoclonal antibody against malaria, began. If effective, it would prevent malaria infections for several months with a single dose—a benefit to tourists, medical workers, and military personnel.[249]
- **Eastern Equine Encephalitis vaccine.** In June 2020, Bavarian Nordic announced topline results from the first-in-human trial of a prophylactic vaccine candidate against three equine encephalitis viruses (EEEV): western, eastern, and Venezuelan. The study, although small, showed that the vaccine was well tolerated and immunogenic across all dose groups, with injection-site pain as the most common vaccine-related adverse event.[250]
- **Ebola treatment.** In October 2020, the FDA approved Inmazeb, a mixture of three monoclonal antibodies made by Regeneron. This is the first FDA-approved treatment for Ebola virus infection in adult and pediatric patients, following a U.S. government-supported trial and expanded-access protocol in the Democratic Republic of the Congo.[251]
- **Universal flu vaccine study.** A universal influenza vaccine, FLU-v, which could confer long-lasting immunity from multiple influenza subtypes among all age groups, demonstrated immunogenicity and safety in its phase 2b study and will enter a larger phase 3 trial.[252] The FLU-v vaccine is designed to stimulate the production of flu-specific cytotoxic T lymphocytes, which kill and remove influenza-infected cells, by targeting internal viral proteins that are not as variable as the constantly mutating surface proteins currently targeted in seasonal flu vaccines.[253]

Severe Weather and Natural Disasters

Notable Incidents:

- **Tornados.** In early March 2020 in the Nashville area, 24 people were killed by two tornadoes, one of which was an EF-4 traveling at 60 miles per hour (mph)—significantly harder to outrun (or take cover from) than a typical tornado's 10 to 20 mph speed.[254] Also during a two-day period in mid-March, over 100 tornadoes ravaged the South and Southeast,[255] causing over $450 million in damage and 32 fatalities.[256]

- **Extreme heat.** In the United States, extreme heat kills more people than any other weather-related threat.[257] July 2020 nearly tied July 2019's record of the hottest month ever recorded on Earth—coming in just 0.02 degrees shy.[258,259] In August 2020, Death Valley reached 130 degrees Fahrenheit, and on September 6, 2020, Los Angeles County recorded its highest temperature ever, at 121 degrees Fahrenheit.[260] September 2020 was also the hottest September on record.[261]

- **Hurricanes.** The 2020 Atlantic hurricane season was the most active—breaking the record for the most named storms in a season, including six major hurricanes.[262] In the United States, Hurricane Isaias made landfall in North Carolina as a Category 1 and killed nine people as it moved up the coast,[263] causing more than $4 billion in damage.[264] Laura formed in the Caribbean, leaving nine dead, before developing into a Category 4 storm and making landfall in Louisiana, where it killed 27 people[265] and caused an estimated $10 to $12 billion in damage.[266] In September 2020, Hurricane Sally hit Alabama as a Category 2 and caused major flooding but no deaths,[267] though damage is estimated at $8 to $10 billion.[268] Hurricane Delta hit Louisiana in October 2020, killing at least four.[269] Central America was hit hard in 2020 with two back-to-back Category 4 storms: just weeks after Hurricane Eta made landfall and killed over 130 people, Hurricane Iota (a massive Category 5 storm while in the Atlantic) hit the same area. Together, the storms killed over 200 people.[270] In addition, the pandemic made hurricane preparations, evacuations, and sheltering more difficult.

- **Iowa derecho.** A powerful derecho—a fast wind storm associated with strong thunderstorms—tore through central Iowa in August 2020. Winds topped 100 mph and destroyed miles of crops, homes, businesses, and vehicles, and killed four people. The derecho was officially the costliest thunderstorm event in recorded U.S. history—estimated at $7.5 billion in damages.[271]

- **Wildfires in California and other states.** Several states experienced wildfires in 2020, including California, Oregon, and Colorado.[272,273] California experienced another historic fire season in 2020—five of the six largest wildfires since 1932 in California happened in 2020.[274] As of November 29, 2020, over 4 million acres had burned, compared with just under 260,000 acres burned during the same period in 2019.[275] Thirty-three people, including four firefighters, died in California in 2020 due to wildfires.[276] California's average temperature has increased by about 3 degrees Fahrenheit over the past century, which is three times the global temperature increase of 1 degree Fahrenheit.[277] Heavy spring rains promoted extensive vegetation growth, which withered in the heat and became fuel for wildfires to spread quickly through dry land.[278] In addition, the 2020 season was a La Niña cycle—colder than average surface-water temperatures in the Pacific—which often trigger hotter and drier weather in the Southwest.[279] Oregon also experienced an especially destructive wildfire season: 4,009 homes burned down in 2020, compared with 93 homes total from 2015 to 2019.[280] In Colorado, wildfires have consumed 9 percent of Rocky Mountain National Park and destroyed several historic buildings.[281] Exacerbating these fires is an ongoing pine-beetle outbreak, which has increased the number of dead trees for fuel.[282] Across the United States, 9.5 million acres have burned as of December 4, 2020, compared with 4.6 million acres for the same period in 2019.[283]

- **California power outages.** In an attempt to reduce the risk of overloading the power grid during an extreme heatwave, California's Independent System Operator, which manages the state's power supply, ordered utilities to impose temporary blackouts for the first time in 19 years.[284] While these outages only lasted an hour or two,[285] there is potential for unplanned and planned outrages to create health emergencies for some residents, including by presenting significant risks to patients in healthcare and long-term care facilities; people with electrically dependent medical equipment or medicines, such as oxygen, wheelchairs, and insulin; and the safety of food and water.[286]

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Notable Events and Policy Actions:

- **Public health emergency declarations.** In January 2020, HHS Secretary Azar declared a public health emergency for Puerto Rico following the late-December 2019 earthquakes and continuing aftershocks.[287] Azar declared emergencies in Louisiana and Texas due to Hurricane Laura and in Oregon and California due to wildfires. The declarations and related waivers give HHS's Centers for Medicare & Medicaid Services (CMS) beneficiaries and their healthcare providers and suppliers greater flexibility in meeting emergency health needs.[288,289]

- **Health center support.** In September 2020, HHS, through HRSA, awarded more than $79 million in construction and other capital support for 165 HRSA-funded health centers impacted by Hurricanes Florence and Michael, Typhoon Mangkut, and Super Typhoon Yutu, as well as for wildfires and earthquakes that occurred in 2018 and tornadoes and floods that occurred in 2019.[290]

Notable Research Findings, Meetings, and Federal Hearings:

- **Extreme rain.** Research from the National Oceanic and Atmospheric Administration on all Atlantic hurricanes affecting the southeastern and eastern United States during the 20th century found that extreme rain risk is highest after hurricanes weaken into tropical storms. The heaviest rainfall over the largest areas occurs after major hurricanes become tropical storms, not during the hurricanes—even major hurricanes—themselves.[291]

- **National Risk Index.** In November 2020, the Federal Emergency Management Agency (FEMA) released the National Risk Index, an online tool to help illustrate the nation's communities most at risk of natural hazards. It provides a holistic view of community-level risk nationwide by combining 18 hazards with socioeconomic and built-environment factors. The tool determines risk by reviewing a community's expected annual loss, by measuring hazard frequency, exposure, and historic loss rate; social vulnerability, by measuring the susceptibility of impacted social groups; and community resilience, by measuring the ability of a community to recover from the impacts of natural hazards. These data can help in developing a FEMA-approved hazard-mitigation plan to help increase community resilience, which is a prerequisite for applying for FEMA's mitigation grants.[292]

- **Climate reports.** The United Nations' World Meteorological Organization released two reports on climate in 2020. The State of Climate Services (2020) found that between 1970 and 2019, 79 percent of disasters worldwide involved weather-, water-, and climate-related hazards, which accounted for 56 percent of deaths and 75 percent of economic losses from disasters. The report highlights progress made in early warning systems' capacity, and it identifies where and how governments can invest in effective early warning systems to strengthen countries' resilience to multiple weather-, water-, and climate-related hazards. United in Science 2020, a new multi-agency report from leading science organizations, highlights the increasing and irreversible impacts of climate change and documents how COVID-19 has impeded the ability to monitor these changes through the global observing system.[293]

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CLIMATE CHANGE & HEALTH: MEASURING STATES' VULNERABILITY AND PREPAREDNESS

TFAH and JHU Bloomberg School of Public Health study reports on states' vulnerability to and readiness for the health impacts of climate change.

Climate change poses serious, immediate threats to human health. Catastrophic impacts are well-understood, such as death and injury from more frequent and more intense hurricanes and wildfires. Many dangers, however, lack a singular, spectacular event and are therefore more insidious: longer-lasting heatwaves; poorer air quality; chronic flooding; increases in vector-, water-, and food-related infections; and the toll all of this takes on people's mental health and well-being.

The release of greenhouse gases through human activities over the past two centuries has made some level of global warming inevitable. Humans must learn to live with the effects of this change (adaptation), even as they pursue the essential objective of minimizing future warming by reducing greenhouse gas emissions (mitigation).

Climate change, however, does not affect all people and places equally. A person's experience depends, in large part, on where she lives. Many health outcomes are linked to environmental factors and, therefore, sensitive to changes in climate. Social and demographic factors also drive vulnerability, meaning that the health of some communities or people could be more affected than others. In many cases, vulnerability reflects existing health risk factors and disparities, which are in turn tied to structural and systemic racism.

Fortunately, important opportunities to protect people's health from the impacts of climate change exist at the state and local level. Adaptation, which seeks to reduce injuries, illness, death, and suffering, is an extension of public health approaches that emphasize prevention and preparedness. Many of these actions are driven by state-level plans, policies, and programs, which provide a critical foundation and supply of resources to support additional efforts at the community level.

Given the size and diversity of the country, each state and its communities will experience climate change differently. State leaders must understand their particular risks and vulnerabilities in order to plan effectively. In areas of a state where vulnerability is higher, state leaders should invest more in adaptation and preparedness. Likewise, states that are more vulnerable overall should go to greater lengths to adapt to climate-related hazards.

A December 2020 report, *Climate Change & Health: Assessing State Preparedness*, by TFAH and the Johns Hopkins Bloomberg School of Public Health, examined states' readiness to protect residents from the health impacts of climate change in light of the nature and level of risks they face.[294] While every state had engaged in at least some level of planning and preparation, there was significant variation, and, in many places, a great deal of room for improvement. Of greatest concern, states with the highest

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levels of vulnerability—predominantly located in the Southeast—tended to be among the least prepared. (See Table 14.)

Leaders at all levels of government must act with urgency and persistent focus to ensure that their people, particularly those who are most vulnerable, are safe and secure. The report offers federal and state policy and program recommendations, including enacting legislation requiring a national strategic plan, fully funding the CDC's Climate and Health program, bolstering states' core public health preparedness capabilities, and establishing ongoing, dedicated state funding and staff for climate-related preparations.

Table 14. States Grouped by Level of Vulnerability and Preparedness

Vulnerability Group	State	Vulnerability Score Least Vulnerable: 3.4-4.7 More Vulnerable: 4.8-5.3 Most Vulnerable: 5.4-6.3	Preparedness Score Least Prepared: 4.0-5.0 More Prepared: 5.1-5.8 Most Prepared: 5.9-6.6
Least Vulnerable	Utah	3.8	6.6
	Maryland	4.4	6.3
	Vermont	4.3	6.3
	Colorado	4.0	6.2
	Wisconsin	4.4	6.1
	New Hampshire	4.1	6.0
	District of Columbia	4.5	5.9
	Maine	4.5	5.9
	Minnesota	4.4	5.8
	Washington	4.5	5.8
	Michigan	4.7	5.8
	Alaska	3.4	5.4
	North Dakota	4.1	5.2
	Nebraska	4.6	5.1
	Idaho	4.2	5.0
	Montana	4.3	4.8
	Wyoming	4.2	4.5
More Vulnerable	Virginia	4.8	6.3
	Massachusetts	4.9	6.2
	Rhode Island	4.9	6.0
	Illinois	4.9	6.0
	New York	5.3	5.9
	Pennsylvania	5.3	5.9
	Connecticut	4.9	5.9
	Oregon	4.8	5.8
	Delaware	4.9	5.7
	Kansas	5.1	5.3
	Iowa	4.9	5.3
	Indiana	5.0	5.0
	Ohio	5.1	5.0
	New Jersey	5.2	4.9
	Hawaii	5.3	4.8
	Nevada	4.9	4.6
	South Dakota	4.8	4.5
Most Vulnerable	North Carolina	5.5	6.0
	Arizona	5.4	5.9
	Alabama	5.8	5.8
	California	5.5	5.8
	Louisiana	5.9	5.7
	New Mexico	5.8	5.7
	Arkansas	6.1	5.5
	Missouri	5.4	5.5
	Florida	6.3	5.1
	Tennessee	5.5	4.9
	Georgia	5.6	4.9
	Kentucky	5.9	4.8
	South Carolina	5.9	4.8
	Texas	5.5	4.6
	Mississippi	5.9	4.5
	Oklahoma	5.5	4.5
	West Virginia	5.8	4.0

"Most prepared," among states that were "least vulnerable."

"Least prepared," among states that were "least vulnerable."

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All Hazards Events and Policy Actions

Notable Incidents:

- **E-cigarette and vaping injuries and deaths.** According to the CDC, as of February 18, 2020, a total of 2,807 hospitalized e-cigarette or vaping-associated lung injuries (EVALI) or deaths were reported to the CDC from all 50 states, DC, Puerto Rico, and the U.S. Virgin Islands. Sixty-eight deaths have been confirmed in 29 states and DC. Due to continued declines in new EVALI cases since September 2019, and the identification of vitamin E acetate as a likely primary cause of EVALI, the CDC is no longer collecting case reports.[295]

- **Mass shootings.** During 2020, in the United States, there were 611 mass shootings—defined as an incident in which at least four people are shot, excluding the shooter—in 2020.[296] This is a significant increase since 2019, when there were 417 total mass shootings.[297] These events have long-term health effects on communities and survivors, including post-traumatic-stress disorder, substance abuse, anxiety, and depression.[298]

- **Terror attacks.** On Christmas day, a bomb detonated in downtown Nashville, damaging over 40 businesses in the area and injuring three people. Quick evacuations by first-responders likely saved lives in the area.[299] While the motivation for the Christmas Day bombing is not known, the Center for Strategic and International Studies reported that white supremacists and other like-minded extremists conducted two-thirds of terrorist plots and attacks in the United States as of October 2020.[300]

Notable Events and Policy Actions:

- **Animal disease research.** The U.S. Department of Homeland Security is transferring a new facility—the National Bio and Agro-Defense Facility, which will research foreign animal diseases—to the U.S. Department of Agriculture. Foreign animal diseases pose a risk to livestock (and in rare cases, people) and the facility will develop countermeasures for these diseases. A report by the Government Accountability Office (GAO) found that it may not be ready to open in December 2022 as planned, despite both departments following practices for a successful transfer.[301]

- **Radiological detection.** The Defense Advanced Research Projects Agency (DARPA) greenlit an automated, networked radiation detection system known as SIGMA for use by the Port Authority of New York and New Jersey, which is theoretically capable of providing counterterrorism support through constant monitoring for radiological and nuclear threats. DARPA has further developed and tested sensors for SIGMA to add chemical, biological, and explosive threat detection to its list of capabilities. SIGMA is based in worn, portable sensors, vehicular-mounted sensors, and stationary sensors at key transportation nodes, and it can be constantly improved through regular software updates. Officials and first-responders can use SIGMA to track alerts and threats in real time, allowing for enhanced coordination.[302]

- **Next Generation 911.** The U.S. Department of Homeland Security Science and Technology Directorate and the U.S. Department of Transportation have begun systems interoperability and compatibility testing for the Next Generation 911 (NG911) through a contract with the Critical Infrastructure Resilience Institute of the University of Illinois at Urbana-Champaign. NG911 will update the current nationwide emergency response system to an Internet Protocol (IP) platform, which will enable voice, video, photographs, text, and future communications technologies to be transmitted to and by the public and first-responders for assistance.[303] No system launch date has been announced.

- **HHS/ASPR Strategic Plan.** In April 2020, the U.S. Office of the Assistant Secretary for Preparedness and Response (ASPR) released the ASPR Strategic Plan for FY 2020-23, which organizes and identifies how ASPR will fulfill its mission of saving lives and protecting Americans from 21st-century health security threats and achieve its strategic vision: "the nation's health care and response systems and the communities they serve are prepared, responsive, and resilient, thereby limiting the adverse health impacts of emergencies and disasters." The plan builds on the successful foundation established by the ASPR strategic plans issued in 2011 and 2014, and aligns with the HHS Strategic Plan FY 2018-2022 and other relevant national strategies and legislation. It is also informed by experience and lessons from real-world incidents, exercises, and training activities occurring over more than a decade. The plan organizes ASPR's efforts under four priority goals: (1) foster strong leadership; (2) sustain robust and reliable public health security capabilities; (3) advance an innovative medical countermeasures enterprise; and (4) build a regional disaster health response system.[304]

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Notable Research Findings, Meetings, and Federal Hearings:

- **Retention of the public health workforce.** As of November 2020, at least 70 top public health officials had been fired, resigned, or planned to leave their posts since the beginning of the pandemic.[305] The alarming trend often resulted from threats, both in-person and via social media, scapegoating, or political retribution. Even before the pandemic and related recession, state health agencies had lost nearly 10 percent of their full-time equivalent (FTE) workforce from 2012 to 2019,[306] while local health departments lost about 16 percent of their FTE staff from 2008 to 2019.[307]

- **Recruitment and retention of scientists.** A May 2020 GAO report found that HHS has had trouble recruiting and retaining medical, engineering, and other science and technology professionals to support activities like biomedical and clinical research. The 21st Century Cures Act provides additional hiring and retention authority—allowing HHS to hire up to 2,000 scientists with certain specialized graduate degrees and to increase the top pay to hire and retain an expert staff.[308]

- **Rebuilding the Public Health Workforce.** State and local revenue losses due to the COVID-19 economic crisis is likely to lead to budget cuts at the state and local level and is expected to worsen the public health workforce staffing shortfall. COVID response funding did allow for short-term staffing increases but not for the hiring of the permanent public health professionals necessary to meet 21st-century challenges.[309]

- **Antibiotic resistance.** Two novel investigative drugs that target antibiotic-resistant infections began advanced development through the Biomedical Advanced Research and Development Authority to begin phase 2 and 3 clinical trials. One drug tackles Clostridioides difficile (C. difficile) infections, which causes an estimated12,800 deaths per year.[310] The second uses CRISPR technology to kill Escherichia coli (E. coli) bacteria that cause recurring or drug-resistant urinary tract infections. If successful, it would be the first CRISPR-engineered bacteriophage therapy to be FDA-approved.[311] Bacteriophages are viruses that infect and replicate only in bacterial cells. They cannot infect human cells, and because each type of bacteriophage only kills a specific set of bacteria, it's less likely to disturb the beneficial bacteria in the human body.[312] In addition, the FDA approved cefiderocol for hospital-acquired, ventilator-associated bacterial pneumonia due to multidrug-resistant gram-negative bacteria.[313]

- **Legislative pandemic preparation blueprint.** In July 2020, then–Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander released "Preparing for the Next Pandemic," a legislative blueprint with five recommendations for legislators to address future pandemics based on lessons learned from COVID-19 and the past 20 years of pandemic planning. The five recommendations involve: (1) accelerated research and development for tests, treatments, and vaccines; (2) expanded disease surveillance; (3) improved stockpile capacity and distribution process; (4) improved state and local response capacity; and (5) improved federal coordination.[314] Leading public health experts sent the committee over 350 recommendations of short-term and long-term proposals to address future pandemics on a range of topics, including sustaining onshore manufacturing, creating and sustaining state stockpiles, and improving the federal stockpile.[315]

- **Preparedness Summit.** In August 2020, more than 1,300 attendees—who work in all levels of government, emergency management, volunteer organizations, healthcare coalitions, and academia—participated in the first ever virtual Preparedness Summit, "Fixing Our Fault Lines: Addressing Systemic Vulnerabilities." Attendees participated in more than 115 demonstrations, workshops, and educational sessions, and heard from expert-led panels, which provided an opportunity to prepare for, respond to, and recover from the waves of the COVID-19 pandemic and the many other threats to public health and health security.[316]

- **COVID-19 and Achieving Health Equity Report.** In September 2020, then–Senate HELP Committee Ranking Member Patty Murray also released a report, "COVID-19 & Achieving Health Equity: Congressional Action is Necessary to Address Racism and Inequality in the U.S. Health Care System." The report included 30 recommendations to Congress, including dedicated funding for COVID-19 relief for communities of color, requiring an equitable vaccine distribution plan, and a federal right to paid sick days and family and medical leave.[317]

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Appendix B: Methodology

Trust for America's Health (TFAH) made major refinements to its methodology for Ready or Not in 2018. For more information, see the 2019 edition of the series, Appendix A: Methodology.[318]

To meet TFAH's criteria, each indicator must be:

- **Significant.** The indicator needed to be a meaningful measure of states' public health emergency preparedness. The NHSPI first measured significance by using a multistage Delphi process with a panel of experts and then again by TFAH through interviews with additional experts.
- **Broadly relevant and accessible.** The indicator needed to be relevant—and timely data needed to be accessible—for every state and the District of Columbia.
- **Timely.** Data for the indicator needed to be updated regularly.
- **Scientifically valid.** Data supporting the indicator needed to be credible and rigorously constructed.
- **Nonpartisan.** The indicator, and data supporting the indicator, could not be rooted in or seen as rooted in any political goals.

Using these criteria, TFAH aims to select a broad set of actionable indicators with which it—and other stakeholders, including states themselves—can continue to track states' progress. (Complete data were not available for U.S. territories.) TFAH will strive to retain all or most of these indicators for multiple years to assist states in tracking their progress against each measure.

TFAH seeks measures that are incorporated in the NHSPI and that most closely meet TFAH's criteria. There is one exception: a measure of state public health funding-level trends that the NHSPI does not track.

Indicator Data Collection

The NHSPI provided TFAH with data for every indicator except five (those data tied to the NLC, public health funding, flu vaccination, hospital patient safety, and laboratory surge capacity). In cases where newer data were available than those modeled in the 2020 edition of the NHSPI, TFAH collected and verified figures from their original sources.

Public Health Funding Data Collection and Verification

To collect public health funding data for this report, TFAH examined states' publicly available funding documents and surveyed state officials. Informed by the Public Health Activities and Services Tracking project at the University of Washington, TFAH defines public health programming and services as inclusive of communicable disease control; chronic disease prevention; injury prevention; environmental public health; maternal, child, and family health; and access to and linkage with clinical care. Specifically, this definition includes:

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- **Communicable disease control.** Public health services related to communicable disease epidemiology, hepatitis, HIV/AIDS, immunization, sexually transmitted diseases, tuberculosis, etc.
- **Chronic disease prevention.** Public health services related to asthma, cancer, cardiovascular disease, diabetes, obesity, tobacco, etc.
- **Injury prevention.** Public health services related to firearms, motor vehicles, occupational injuries, senior falls prevention, substance-use disorder, other intentional and unintentional injuries, etc.
- **Environmental public health.** Public health services related to air and water quality, fish and shellfish, food safety, hazardous substances and sites, lead, onsite wastewater, solid and hazardous waste, zoonotic diseases, etc.
- **Maternal, child, and family health.** Public health services related to the coordination of services; direct service; family planning; newborn screening; population-based maternal, child, and family health; supplemental nutrition; etc.
- **Access to and linkage with clinical care.** Public health services related to beneficiary eligibility determination, provider or facility licensing, etc.

TFAH excludes from its definition insurance coverage programs, such as Medicaid or the Children's Health Insurance Program, as well as inpatient clinical facilities.

TFAH, under the guidance of state respondents, revised data for the base year. (In this report, that was FY 2019.) For some states, this was necessary to improve comparability between the two years when a reorganization of departmental responsibilities had occurred over the period.

All states and the District of Columbia verified their funding data.

Scoring and Tier Placements

TFAH grouped states based on their performances across the 10 indicators, and TFAH gave partial credit for some indicators to draw finer distinctions among states and within states over time. TFAH placed states into three tiers—high tier, middle tier, and low tier—based on their relative performance across the indicators.

Specifically, TFAH scored each indicator as follows:

- Adoption of the NLC: 0.5 point. No adoption: 0 points.
- Percent of hospitals participating in healthcare coalitions: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - Within one standard deviation above the mean (and states with universal participation): 1 point.
  - Within one standard deviation below the mean: 0.75 point.
  - Between one and two standard deviations below the mean: 0.5 point.
  - Between two and three standard deviations below the mean: 0.25 point.
  - More than three standard deviations below the mean: 0 points.
- Accreditation by the PHAB: 0.5 point. Not accredited: 0 points.
- Accreditation by the EMAP: 0.5 point. Not accredited: 0 points.
- Size of state public health budget compared with the past year (nominally, not inflation-adjusted).
  - No change or funding increase: 0.5 point.
  - Funding decrease: 0 points.
- Percent of population who used a community water system that failed to meet all applicable health-based standards: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - Within one standard deviation above the mean (and states with 0 percent of residents who used a noncompliant community system): 1 point.
  - Within one standard deviation below the mean: 0.75 point.
  - Between one and two standard deviations below the mean: 0.5 point.
  - Between two and three standard deviations below the mean: 0.25 point.
  - More than three standard deviations below the mean: 0 points.
- Percent of employed population with paid time off: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - Between one and two standard deviations below the mean: 0.25 point.
  - More than two standard deviations below the mean: 0 points.

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- Percent of people ages 6 months or older who received a seasonal flu vaccination: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - Between one and two standard deviations below the mean: 0.25 point.
  - More than two standard deviations below the mean: 0 points.
- Percent of hospitals with a top-quality ranking ("A" grade) on the Leapfrog Hospital Safety Grade. TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - Positive number, more than one standard deviation below the mean: 0.25 point.
  - No hospitals with a top-quality ranking ("A" grade): 0 points.
- Public health laboratory has a plan for a six- to eight-week surge in testing capacity: 0.5 point. Did not report having a plan: 0 points.

The highest possible score a state could receive was 7.5 points.

TFAH placed states whose scores ranked among the top 17 in the high-performance tier. TFAH placed states whose scores ranked between the 18th-highest and 34th-highest in the middle tier. TFAH placed states with scores ranked between the 35th-highest and 51st-highest in the low-performance tier. (Ties in states' scores can prevent an even distribution across the tiers.)

This year, states in the high tier had scores ranging from 6 to 7; states in the middle tier had scores ranging from 5.25 to 5.75; and states in the low tier had scores ranking from 4 to 5.

Assuring data quality

TFAH conducted several rigorous phases of quality assurance to strengthen the integrity of the data and to improve and deepen TFAH's understanding of states' performance, especially that of outliers on specific indicators. During collection of state public health funding data, researchers systematically inspected every verified data file to identify incomplete responses, inconsistencies, and apparent data entry errors. Following this inspection, TFAH contacted respondents and gave them the opportunity to complete or correct their funding data.

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From: The Forum at the Harvard T.H. Chan School of Public Health
To: Hancock, Breanne
Subject: Today/The Coronavirus Pandemic: The Mental Health Impacts of Reopening Society
Date: Tuesday, June 29, 2021 7:35:25 AM

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Tuesday, June 29, 2021

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After more than a year of measures such as mask mandates and social distancing, Americans are adjusting to a reopening society. But with ongoing concerns about the pandemic's spread, disparate vaccine acceptance rates, and an uncertain future, the coronavirus pandemic continues to cast a long shadow on our mental health. In this live online Q&A, Karestan Koenen, Professor of Psychiatric Epidemiology at the Harvard T.H. Chan School of Public Health, talks with The World's Elana Gordon about well-being and mental health during this transition.

EXPERT PARTICIPANT

Karestan Koenen, Professor of Psychiatric Epidemiology, Harvard T.H. Chan School of Public Health

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From: The Forum at the Harvard T.H. Chan School of Public Health
To: Dobbs, Thomas E
Subject: Today/The Coronavirus Pandemic: The Mental Health Impacts of Reopening Society
Date: Tuesday, June 29, 2021 7:35:41 AM

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MISSISSIPPI STATE DEPARTMENT OF HEALTH

March 23, 2022

Hart Wood
1030 15th Street NW
Suite B255
Washington, DC 20005
records@americanoversight.org

Re: Public Records Request

Ms. Wood:

With this letter you will find emails and attachments produced by the Mississippi State Department of Health (MSDH) in response to your public records request originally submitted on January 4, 2022. Public records requests at MSDH are governed by Mississippi's Public Records Act (Miss. Code. Ann. § 25-61-1, et seq.) as well as any laws providing exemptions to this Act.

A chart of redactions made in the produced emails and/or their attachments is provided. Note that over 120 emails from the National Biosurveillance Integration Center (NBIC) were completely redacted in alignment with the direction of the U.S. Department of Homeland Security which oversees the NBIC.

Should you have any questions, please reach out to the following agency staff member who helped conduct the review of your documents:

David Trewolla, JD
Director, Data Governance
David.Trewolla@msdh.ms.gov

Sincerely,

DocuSigned by:
Walter, Cassandra 3/23/2022 | 3:05 PM CDT
1D6CE85904314A6...

Cassandra Walter, Esq.
General Counsel
Mississippi State Department of Health

DocuSign

Certificate Of Completion

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Trewolla, David
570 East Woodrow Wilson Drive
Jackson, MS 39216
david.trewolla@msdh.ms.gov
IP Address: 69.60.36.32

Record Tracking

Status: Original
3/23/2022 3:00:56 PM

Holder: Trewolla, David
david.trewolla@msdh.ms.gov

Location: DocuSign

Signer Events	Signature	Timestamp
Walter, Cassandra cassandra.walter@msdh.ms.gov Special Assistant Attorney General Mississippi State Department of Health Security Level: Email, Account Authentication (None)	DocuSigned by: Walter, Cassandra 1D6CE85904314A6... Signature Adoption: Pre-selected Style Using IP Address: 75.65.213.119 Signed using mobile	Sent: 3/23/2022 3:01:48 PM Viewed: 3/23/2022 3:05:34 PM Signed: 3/23/2022 3:05:42 PM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/23/2022 3:01:48 PM
Certified Delivered	Security Checked	3/23/2022 3:05:34 PM
Signing Complete	Security Checked	3/23/2022 3:05:42 PM
Completed	Security Checked	3/23/2022 3:05:42 PM

Payment Events	Status	Timestamps

	A	B	C	D	E
1		MSDH PUBLIC RECORDS REDACTIONS LIST			
2		Type of Document	Description or File Name	Corresponding Email Subject Line	Email Date
3		Email	National Biosurveillance Integration Center (NBIC) Monitoring List 19 May 2021 (x2)	National Biosurveillance Integration Center (NBIC) Monitoring List - FEDERAL - 20210519	5/19/2021
4		Email	National Biosurveillance Integration Center (NBIC) Monitoring List (x120)	National Biosurveillance Integration Center (NBIC) Monitoring List - SLTT - [insert date]	6/30/2020 - 10/28/2021
5		Email	National Biosurveillance Integration Center (NBIC) Monitoring List 22 July 2021 (x2)	*CORRECTION* National Biosurveillance Integration Center (NBIC) Monitoring List - SLTT - 20210722	7/22/2021
6		Attachment	MS COVID-19 Joint Operational Summary (Sunday, November 08, 2020) (MS COVID-19 Joint OPSUM #248-FOR OFFICIAL USE ONLY.pdf)	ICC COVID 19	11/9/2020
7		Attachment	MS COVID-19 Joint Operational Summary (Monday, November 09, 2020) (MS COVID-19 Joint OPSUM #249-FOR OFFICIAL USE ONLY.pdf)	ICC COVID 19	11/10/2020
8		Attachment	MS COVID-19 Joint Operational Summary (Wednesday, October 07, 2020) (MS COVID-19 Joint OPSUM #216-FOR OFFICIAL USE ONLY.pdf)	ICC COVID 19 and weather update	10/8/2020
9		Email	Just got this from CDC.pdf	Just got this from CDC	12/8/2021
10		Email	CSTE COVID-19 Response	Digest for Apr. 9 (incl. CDC Info on Vaccine Breakthrough Infections, MH Survey Extension, CDC Webinar on Public Use Data, MMWR Early Release, and more)	CSTE COVID-19 Response | Digest for Apr. 9 (incl. CDC Info on Vaccine Breakthrough Infections, MH Survey Extension, CDC Webinar on Public Use Data, MMWR Early Release, and more)	4/9/2021
11		Attachment	COVID vaccine breakthrough Key messages (4-9-2021).pdf	CSTE COVID-19 Response | Digest for Apr. 9 (incl. CDC Info on Vaccine Breakthrough Infections, MH Survey Extension, CDC Webinar on Public Use Data, MMWR Early Release, and more)	4/9/2021

	F	G	H	I
1				
2	Partial or Complete Redaction	Reason for Redaction		
3	Complete	Security (at direction of U.S. Department of Homeland Security)		
4	Complete	Security (at direction of U.S. Department of Homeland Security to State, Local and Tribal Territories (SLTT) partners)		
5	Complete	Security (at direction of U.S. Department of Homeland Security to State, Local and Tribal Territories (SLTT) partners)		
6	Complete	Security (for Official Use Only)		
7	Complete	Security (for Official Use Only)		
8	Complete	Security (for Official Use Only)		
9	Partial	Personal information, see - 2015 WL 1744886, (Miss. A.G.), March 27, 2015		
10	Partial	Security (at direction of CDC)		
11	Complete	Security (at direction of CDC)		

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Oct. 6 (incl. Abbott BinaxNOW Training, MMWR Early Release, CDC Partner Call)
Date:	Tuesday, October 6, 2020 3:38:53 PM
Attachments:	image001.png image002.png MMWR ER COVID-19 Incidence After Mitigation Measures - October 6, 2020.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, Surveillance/Informatics Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of recent Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

- Webinars: Abbott BinaxNOW Training [Links]
  - This week, Abbott Laboratories will hold two educational webinars in support of their BinaxNOW COVID-19 tests. These webinars are designed to reinforce the Training Toolkit and highlight key points that should be kept in mind during BinaxNOW COVID-19 and NAVICA implementation. To register for either training, please use the links below:
    - **Wednesday, October 7** at **4:00 pm EDT**: [Link]
    - **Friday, October 9** at **4:00 pm EDT**: [Link]
  - For additional training videos and documents, visit Abbott's website here.
- MMWR Early Release: "Trends in COVID-19 Incidence After Implementation of Mitigation Measures — Arizona, January 22–August 7, 2020" [Attachment, Link]
  - From the summary: *"The number of COVID-19 cases in Arizona stabilized and then decreased after sustained implementation and enforcement of statewide and locally enhanced mitigation measures, beginning approximately 2 weeks after implementation and enforcement of mask mandates and enhanced sanitations practices began on June 17; further decreases were observed during July 13–August 7, after statewide limitations and closures of certain services and businesses."*
- CDC Partner Update Call: Campus Guidebook – Slowing the Spread at US Colleges and Universities [Link]
  - CDC will host a webinar **Monday, October 19** at **3:00 pm EDT**, focusing on COVID-19 at colleges and universities. Dr. Cliff McDonald will share updates on CDC's COVID-19 response, including the latest scientific information available. Additionally, Drs. Greta

Massetti and Lisa Barrios will review CDC COVID-19 guidance for institutes of higher education.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 10/19" in the subject line. The call will be recorded and posted to CDC's website here.
- Reminder: Request for CSTE COVID-19 Call Topics [Link]
    - To ensure timely and relevant information is provided to our members, CSTE has developed a topic submission form, available here. Please submit suggestions for topics (or speakers) to be discussed on future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations.

--

Council of State and Territorial Epidemiologists
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Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 69
October 6, 2020

Trends in COVID-19 Incidence After Implementation of Mitigation Measures — Arizona, January 22–August 7, 2020

M. Shayne Gallaway, PhD[1,2]; Jessica Rigler, MPH[1]; Susan Robinson, MPH[1]; Kristen Herrick, MPH[1]; Eugene Livar, MD[1]; Kenneth K. Komatsu, MPH[1]; Shane Brady, MPH[1]; Jennifer Cunico[1]; Cara M. Christ, MD[1]

Mitigating the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), requires individual, community, and state public health actions to prevent person-to-person transmission. Community mitigation measures can help slow the spread of COVID-19; these measures include wearing masks, social distancing, reducing the number and size of large gatherings, pausing operation of businesses where maintaining social distancing is challenging, working from or staying at home, and implementing certain workplace and educational institution controls (*1*–*4*). The Arizona Department of Health Services' (ADHS) recommendations for mitigating exposure to SARS-CoV-2 were informed by continual monitoring of patient demographics, SARS-CoV-2 community spread, and the pandemic's impacts on hospitals. To assess the effect of mitigation strategies in Arizona, the numbers of daily COVID-19 cases and 7-day moving averages during January 22–August 7, 2020, relative to implementation of enhanced community mitigation measures, were examined. The average number of daily cases increased approximately 151%, from 808 on June 1, 2020 to 2,026 on June 15, 2020 (after stay-at-home order lifted), necessitating increased preventive measures. On June 17, local officials began implementing and enforcing mask wearing (via county and city mandates),* affecting approximately 85% of the state population. Statewide mitigation measures included limitation of public events; closures of bars, gyms, movie theaters, and water parks; reduced restaurant dine-in capacity; and voluntary resident action to stay at home and wear masks (when and where not mandated). The number of COVID-19 cases in Arizona peaked during June 29–July 2, stabilized during July 3–July 12, and further declined by approximately 75% during July 13–August 7. Widespread implementation and enforcement of sustained community mitigation measures informed by state and local officials' continual data monitoring and collaboration can help prevent transmission of SARS-CoV-2 and decrease the numbers of COVID-19 cases.

ADHS supports surveillance and investigation efforts of local public health departments, compiles surveillance and investigation information across counties, and provides infrastructure statewide to support infectious disease surveillance. Data on laboratory-confirmed and probable (*5*) COVID-19 cases (based on the Council of State and Territorial Epidemiologists case definitions)† were collected in the centralized Medical Electronic Disease Surveillance Intelligence System (MEDSIS),§ which is used by state, tribal, and county public health agencies to report human-based diseases in Arizona. Information was submitted to or entered into MEDSIS by health care providers, laboratories, local health departments, tribal entities, and ADHS. Multiple laboratory tests submitted for a single patient were combined into a single record. Specimen collection date was used for confirmed cases, and symptom onset date was used for probable cases.

Temporal trends were examined by comparing the number of daily COVID-19 cases (as of September 1)¶ and 7-day moving averages before, during, and after implementation of enhanced community mitigation measures, defined as the following: limitations on persons' time away from their place of residence

*Mandates and ordinances varied and were county- and city-specific. Enforcement types included educating persons on the dangers of COVID-19 spread, issuing fines to persons and businesses who refused to comply with mandates, and loss of licenses for businesses not enforcing rules or mandates.

†https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/positionstatement2020/Interim-20-ID-02_COVID-19.pdf.

§https://azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-services/index.php#medsis-faqs.

¶https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/covid-19/dashboards/index.php.

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Centers for Disease Control and Prevention

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except for essential activities; certain business closures and service limitations (e.g., occupancy limitations, curbside pickup, and delivery of goods); enhanced sanitation practices**; social distancing, employee mask wearing, and symptom screenings for all businesses operating a physical location; limitations on the occurrence and size of public events; and local mandates enforcing mask use. The 7-day moving average was calculated after the cumulative case count exceeded 20 cases and is presented to describe COVID-19 trends.

On March 11, 2020, Arizona declared a public health state of emergency to prepare for, prevent, respond to, and mitigate the spread of SARS-CoV-2. Additional guidance was provided to local officials, businesses, communities, and individual persons to implement social distancing and close schools statewide (March 15); postpone and limit large gatherings to fewer than 50 persons; recommend telework options; restrict access to congregate settings; require restaurants to provide dine-out options only; and close all bars, gyms, and movie theaters in counties with confirmed COVID-19 cases (March 19) (Table). Based on Arizona data and CDC guidance (*1*,*2*), ADHS also recommended limiting persons' time away from their place of residence except for essential activities (i.e., stay-at-home order, "Stay Home, Stay Healthy, Stay Connected")†† (March 31).

During April 1–May 15, the 7-day moving average of daily cases ranged from 154 to 443 (Figure). During April 29–May 11, Arizona initiated a phased approach for retail shops and stores, cosmetologists, and barbers to reopen and operate, and for restaurants to resume dine-in services; the stay-at-home order ended May 15.

Average daily cases increased 151% from June 1 (808) to June 15 (2,026), necessitating an increased focus on preventive measures by businesses, communities, and individual persons. Updated guidance from state officials provided local governments the authority to implement mask policies (June 17) and enforcement measures tailored to local public health needs (local policies were applicable to approximately 85% of the total Arizona population). Before June 17, mask wearing had not been widely mandated or enforced. Arizona limited organized public events to fewer than 50 persons (with some exceptions); closed bars, gyms, movie theaters, and water parks and recreational tubing facilities (June 29); and limited restaurants' indoor dining to <50% capacity, with at least 6 feet of separation between patrons (July 9). The 7-day moving average of daily cases peaked during

** Based on guidance from ADHS, CDC, and the Department of Labor, and Occupational Safety and Health Administration to limit and mitigate the spread of COVID-19, including promoting healthy hygiene practices; and intensifying cleaning, disinfection and ventilation practices.

†† https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-admin-orders; https://azgovernor.gov/executive-orders.

TABLE. Public policies to implement and enforce COVID-19 community mitigation measures and dates of issue/reissue* — Arizona, March 11–August 7, 2020

Mitigation measure	Date of issue/reissue
Declaration of emergency	Mar 11
School closure (on-site learning)	Mar 15
Limits on senior living facilities visitation	Mar 19
Expanded availability and coverage for telemedicine for persons, pets, and animals	Mar 25, Apr 1
Deferred requirements to renew driver license	Mar 20
Stay-at-home order	Mar 30–May 15
Business/Service closures	
Bars	Mar 19, Jun 29, Jul 23
Movie theaters	Mar 19, Jun 29, Jul 23
Indoor gyms and fitness clubs	Mar 19, Jun 29, Jul 23
Restaurants, on-site dining	Mar 19
Pools	Mar 19
Water parks and recreational tubing facilities	Jun 29, Jul 23
Business/Service limits (requirements)	
All businesses operating a physical location (enhanced sanitation,† social distancing, employee mask wearing, symptom screenings)	Jun 17
Retail (limited capacity, social distancing, enhanced sanitation)	Apr 29
Barbers and cosmetologists (employee mask wearing, spaced appointments, enhanced sanitation)	May 4
Restaurants (social distancing, limited capacity, employee mask wearing, patron mask wearing [when not eating or drinking], employee screening, enhanced sanitation)	May 4, Jul 9
Public pools (e.g., at hotels; limited capacity)	Jun 29, Jul 23
Private pools in public areas (e.g., multihousing complexes; limited capacity)	Jun 29, Jul 23
Public events (<50 persons)	Mar 15, Jun 29, Jul 23
Wearing masks (mandatory)	
Local officials able to mandate and enforce wearing masks	Jun 17
Yuma County	Jun 18
Maricopa County	Jun 19
Pima County	Jun 19
Santa Cruz County	Jun 19
Coconino County	Jun 20
>40 other cities/tribal communities	Jun 17–25§

Abbreviation: COVID-19 = coronavirus disease 2019.

* Issue dates are the dates the issuing official signed the order implementing the mandatory mitigation measure. In some instances, mitigation measures were effective either immediately or within 1 to 3 days of issue. https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-admin-orders; https://azgovernor.gov/executive-orders.

† Based on guidance from the Arizona Department of Health Services, CDC, Department of Labor, and Occupational Safety and Health Administration (OSHA) to limit and mitigate the spread of COVID-19 including promoting healthy hygiene practices; and intensifying cleaning, disinfection and ventilation practices.

§ Other tribal communities with mask mandates (issued June 18–23) included Fort McDowell Yavapai Nation, Gila River Indian Community, Navajo Nation, Salt-River Pima-Maricopa Indian Community, Tohono O'Odham Nation. Other cities with mask mandates (issued June 17–25) included Avondale, Bisbee, Buckeye, Carefree, Casa Grande, Chandler, Clarkdale, Clifton, Coolidge, Cottonwood, Douglas, Flagstaff, Fountain Hills, Gila Bend, Gilbert, Glendale, Globe, Goodyear, Guadalupe, Jerome, Kingman, Litchfield Park, Mammoth, Mesa, Miami, Nogales, Oro Valley, Paradise Valley, Payson, Peoria, Phoenix, San Luis, Sedona, Scottsdale, Somerton, Superior, Surprise, Tempe, Tolleson, Tucson, Youngtown, Yuma. Several other tribal communities and cities encouraged but did not mandate wearing masks.

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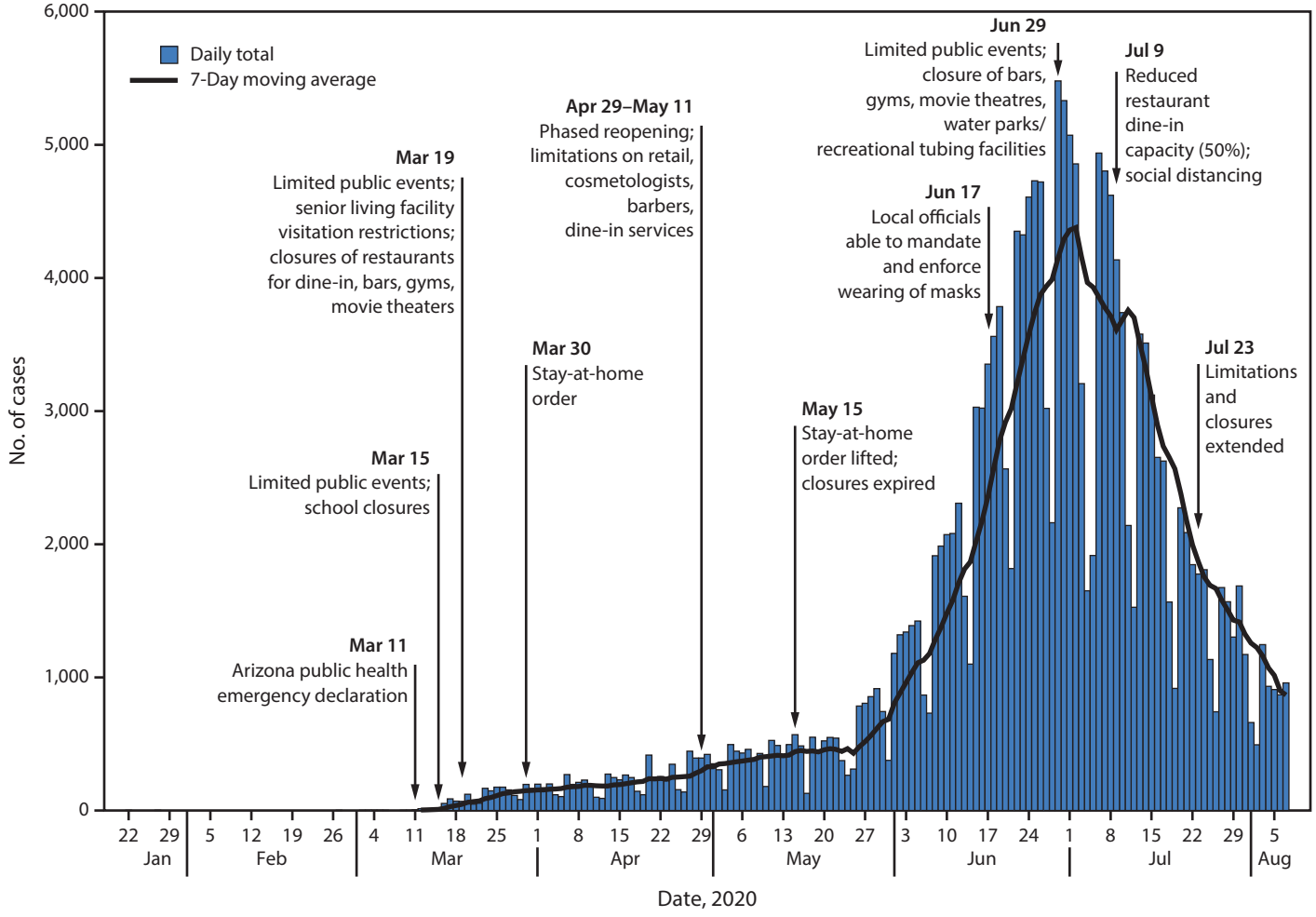
FIGURE. Selected community mitigation measures* and COVID-19 case counts† and 7-day moving averages§ — Arizona, January 22–August 7, 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

* Issue dates are the dates the issuing official signed the order implementing the mandatory mitigation measure. In some instances, mitigation measures were effective either immediately or within 1 to 3 days of issue. https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-admin-orders; https://azgovernor.gov/executive-orders.

† As of September 1, 2020. Specimen collection date was used for confirmed cases, and symptom onset date was used for probable cases.

§ Plotting of 7-day moving average began when cumulative case count exceeded 20 cases.

June 29–July 2 (range = 4,148–4,377), stabilized during July 3–12 (range = 3,609–4,160), and subsequently decreased 75% from July 13 (3,506) to August 7 (867). Mitigation measures put in place in June were extended through August to further limit transmission.

Discussion

Quantitative data on the effectiveness of community mitigation measures at suppressing the spread of COVID-19 are limited. The primary goal of implementing widespread enhanced mitigation measures in Arizona was to protect and save lives and maintain capacity in the health care system. A combination of voluntary and enforceable measures is more effective than any single measure (*6*). Mitigation measures mandated through public policy can effectively increase social distancing (*7*), and wearing masks has prevented transmission of SARS-CoV-2 (*8*). In Arizona, decreases in daily COVID-19 cases were observed after widespread sustained community mitigation measures that promoted social distancing, limited large gatherings, paused operations of businesses where mask use and social distancing were difficult to maintain, mandated and enforced mask wearing, and promoted voluntary resident actions to stay at home and wear masks (when and where not mandated). The number of COVID-19 cases stabilized and began to decrease approximately 2 weeks after local officials began mandating mask wearing (throughout several counties

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and cities) and enhanced sanitation practices. Additional declines in case counts were associated with implementation of statewide limitations and closures sustained throughout July and extended into August.

The findings in this report are subject to at least four limitations. First, the relationship between mitigation measures and changes in case counts are temporal correlations and should not be interpreted to infer causality. Other factors that might have influenced the rate of change (e.g., travel restrictions, neighboring state mitigation measures, and individual choices to reduce movement before implementation of mandates) cannot be ruled out. Second, health centers run by tribal entities and federal health facilities (i.e., Indian Health Service, Veteran's Administration, and Department of Defense) in the state are requested but not required to comply with state reporting rules. Many of these health centers and federal health facilities complied with reporting, but the completeness of reporting by these entities is unknown. Third, adherence to mitigation measures was not assessed, nor could the extent to which each individual measure affected the number of incident COVID-19 cases be established. Finally, Arizona might not be representative of other U.S. states, and community mitigation measures might have a different impact in more populous or densely populated states; thus, these findings are not necessarily generalizable to other settings.

Enhanced mitigation measures should be implemented by communities and persons to slow COVID-19 spread, particularly before a vaccine or therapeutic treatment becomes widely available. State, local, and tribal officials are best positioned to continually monitor data and collaborate to determine the level and types of enhanced mitigation required. Mitigation measures, including mask mandates, that are implemented and enforced statewide appear to have been effective in decreasing the spread of COVID-19 in Arizona.

Acknowledgments

Arizona Department of Health Services COVID-19 Response teams; county, local and tribal local health departments; CDC COVID-19 Health Department Section; CDC AZ-1 COVID-19 Response Team.

Corresponding author: Cara M. Christ, pio@azdhs.gov.

[1]Arizona Department of State Health Services; [2]CDC COVID-19 Response Team.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

Summary

What is already known about this topic?

Community mitigation measures can help slow the spread of COVID-19.

What is added by this report?

The number of COVID-19 cases in Arizona stabilized and then decreased after sustained implementation and enforcement of statewide and locally enhanced mitigation measures, beginning approximately 2 weeks after implementation and enforcement of mask mandates and enhanced sanitations practices began on June 17; further decreases were observed during July 13–August 7, after statewide limitations and closures of certain services and businesses.

What are the implications for public health practice?

Widespread implementation and enforcement of sustained community mitigation measures, including mask wearing, informed by state and local officials' continual data monitoring and collaboration can help prevent transmission of SARS-CoV-2 and decrease the numbers of COVID-19 cases.

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From: CSTE Emergency Response
To: CSTE Emergency Response
Cc: CSTE Novel Coronavirus 2019
Subject: CSTE COVID-19 Response | Materials from Ad Hoc All State Epi Call (Oct. 19)
Date: Wednesday, October 21, 2020 5:52:38 PM
Attachments: image001.png
image002.png
image003.png
Science Agenda Development and Update.pdf
Mask Effectiveness References.zip
20201016_Science Update.pdf
20200925_Science Update.pdf
20200521_Science Update.pdf

Sent to State Epidemiologists, CLUE, and the CSTE Executive Board

Thank you for joining this week's CSTE COVID-19 Response Ad Hoc Weekly All State Epi Call. The following call materials have been gathered for your awareness:

- Slides: "Science Agenda Development and Update" [Attachment]
  - Presented by Dr. Chris Braden, CDC
- Resources: Effectiveness of Community Mask Use [Links, Attachments]
  - In response to a request for additional scientific evidence regarding effectiveness of community mask use to support local mandates, please find the attached articles shared with us by Dr. McDonald and Dr. John Brooks. Dr. Brooks also recommended the October 3–9 Weekly Science Review from *Resolve to Save Lives*, available here.
  - Additionally, Dr. McDonald recommended the new *CDC COVID-19 Science Update* publication series, available on CDC's website here. Three of these updates feature either summaries or informative briefs on articles related to masks, and are attached to this email for your convenience.
- Announcement 1: NIOSH Funding Opportunity Announcement for State Occupational Safety and Health Surveillance Programs [Links]
  - The National Institute for Occupational Safety and Health (NIOSH) recently published the funding announcement for the State Occupational Safety and Health Surveillance Program. NIOSH intends to commit $40 million in total costs (direct and indirect) over a five-year period to fund about 30 applications. The letter of intent deadline is **October 30**, and the deadline to apply for this cooperative agreement is **December 16**. Full funding details can be found at grants.gov; for more information, please contact NIOSH Scientific Program Official, CAPT Linda West, at lkw0@cdc.gov.
    - You can find more information about the State Occupational Safety and Health Surveillance Program on NIOSH's website here. For more information on the

grant process, visit the NIOSH Extramural Research and Training Programs website here.

- Announcement 2: NHSN Webinars - "Reporting Results of Point of Care Testing for COVID-19 – A New NHSN Pathway" [Links]
  - CDC's National Healthcare Safety Network (NHSN) team will host two webinars this week to train attendees on its new Long Term Care Facility COVID-19 Pathway laboratory data reporting option. This option will enable nursing homes to enter point of care (POC) SARS-CoV-2 laboratory test data into the NHSN application. NHSN, in turn, will report the nursing home POC laboratory test data electronically to the public health agency—state or local—that has jurisdictional authority and responsibility to receive and use the nursing home's data. Webinar information is below:
    - **Thursday, October 22** at **11:00 am EDT**
      Weblink: https://cdc.zoomgov.com/j/1613111399?pwd=NjNCR0svMFk3N1JtUWhZVUxOT3YxUT09
      Passcode: 6x+*.8bx
      - One-Tap Mobile:
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        Telephone: (669) 254-5252 *or* (646) 828-7666
        Meeting ID: 161 311 1399
        Passcode: 73848065
    - **Friday, October 23** at **2:00 pm EDT**
      Registration link: https://cdc.zoomgov.com/meeting/register/vJIsd-2orzooHuSyPRJ5icjmzTkwOlSrC1k
      - After registering, you will receive a confirmation email containing call information
      - This will be a rebroadcast of the 10/22 training, followed by a live Q&A session

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As a reminder, the next CSTE Ad Hoc Weekly All State Epi Call is **Monday, October 26** at 4:00 pm EDT.

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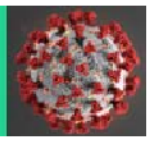
COVID-19 Science Update



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SPECIAL TOPIC: Cloth Face Coverings to Prevent Exhaled SARS-CoV-2

EXECUTIVE SUMMARY

CDC recommends community use of cloth face coverings as one measure to reduce the risk of COVID-19 spread. Infected persons can spread infection before they develop symptoms, and cloth face coverings provide "source control" to reduce spread from the wearer's coughs or exhaled breath. Data are limited on the effectiveness of cloth face coverings in this respect and come primarily from laboratory studies. Future studies are needed that measure the filtering efficiency and extent to which face coverings reduce SARS-CoV-2 transmission from infected persons, especially among persons infected with SARS-CoV-2 who are asymptomatic or pre-symptomatic.

Erratum

An earlier version of this Special Topic Science Update cited an article, 'Effectiveness of Surgical and Cotton Masks in Blocking SARS-CoV-2: A Controlled Comparison in 4 Patients' published in Annals of Internal Medicine on April 6, 2020. This article was retracted June 1, 2020 due the authors' misinterpretation of values below the limit of detection (LOD) by their in-house PCR assay. The LOD is a statistical measure of the lowest quantity of the analyte that can be distinguished from the absence of that analyte. The authors initially concluded that neither surgical nor cotton masks effectively filtered SARS-CoV-2 during coughs from infected patients. However, this conclusion is not valid given the reporting of values below the LOD.

BACKGROUND

A significant proportion of individuals infected with SARS-CoV-2 are asymptomatic or pre-symptomatic, and thus can unknowingly transmit the virus to others. In response, cloth face coverings have been recommended as source control to help prevent transmission, especially in settings where people are in close proximity and social distancing is difficult to maintain.[1] This recommendation excludes surgical masks and N95 respirators so as to not reduce the supply of these devices for first responders and other health care personnel. Face coverings may help prevent acquisition of respiratory viruses by wearers;[2] however, it is unclear if they can protect against SARS-CoV-2 infection, and if so, which materials are most effective.

CAN FACE COVERINGS PREVENT SARS-CoV-2 TRANSMISSION FROM A COUGH OR EXHALED BREATH?

Transmission of SARS-CoV-2 is thought to occur primarily through exposure to respiratory droplets or to fomites on environmental surfaces. Based on data from other human coronaviruses, it's possible that an infected person's normal exhaled breath could also be responsible for transmission by releasing aerosolized viral particles.[3] The evidence for face coverings to provide source control of SARS-CoV-2 is limited; however, studies of source control and community protection from influenza support using face coverings in combination with other preventive measures, such as hand hygiene and social distancing.

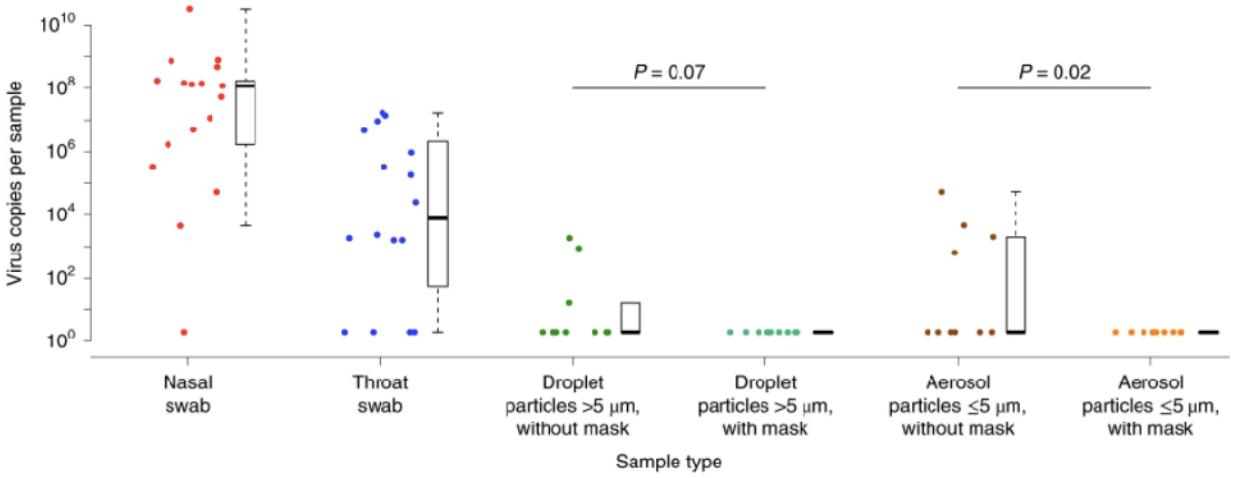
Other Coronaviruses

A study aimed to quantify source control from respiratory viral shedding (viral copies/sample) from a 30-minute exhaled breath sample from patients with seasonal coronaviruses (N=17), influenza virus (N=43), or rhinovirus (N=54).[5]

- In patients with seasonal coronavirus infection documented by viral RNA in nasal and throat swabs, viral RNA was detected in respiratory droplets (3/10 samples) or aerosols (4/10 samples) from patients without surgical face masks. However, viral RNA was not detected in any respiratory or droplet samples from patients wearing surgical face masks (**Figure 3**).
- Surgical face masks significantly reduced influenza virus shedding in droplet particles, but not aerosols. Significant reduction of rhinovirus shedding was not observed.

Limitations: Only surgical masks were tested. Patients were symptomatic, and those with coronaviruses coughed an average 17 times during the exhaled breath collection. RNA, not viral transmissibility, was measured.

Figure 3. Efficacy of surgical face masks in reducing seasonal coronavirus shedding in exhaled respiratory droplets and aerosols of symptomatic patients.



Note: Adapted from Leung *et al.*[5] Viral load from nasal and throat swabs were measured prior to cough (red and blue, respectively). Virus was undetectable in droplets and aerosols (green and orange, respectively) after mask use.

Influenza and Influenza-Like-Illness

In a pre-print update to a previously published Cochrane systematic review,[6] the effect of face mask use as source control was investigated in 14 randomized trials.[7] Nine trials compared masks with no masks: seven included people living in the community and two included healthcare workers. Only one of the nine studies compared cloth masks to other types of masks, and in health care workers only. All studies were in non-pandemic settings.

- Comparing mask use alone with no mask, there were no significant reductions in influenza-like illness (RR 0.93; 95% CI 0.83 to 1.05) or influenza infection (RR 0.84; 95% CI 0.61 to 1.17) in the pooled analysis.
- *Limitations*. Nearly all studies compared surgical face masks, not cloth face coverings. The authors indicated that the studies reviewed were limited by poor design and reporting and had few events. In some studies, the impact of measures like hand hygiene could not be distinguished from the impact of source control from mask use alone.

A pre-print review cited several studies from the influenza literature supporting use of cloth face coverings, in combination with other preventive measures, that are likely translatable to the current COVID-19 pandemic.[8]

- Three randomized controlled trials and one intervention trial found that use of face masks by infected persons, along with other non-pharmaceutical interventions such as intensified hand hygiene, could reduce transmission of influenza and influenza-like illnesses.[9-12]
- One observational study in Hong Kong reported that SARS-CoV cases were less likely to have worn face masks frequently in public venues compared to negative controls.[13] The contribution of masks as source control versus protection from exposure was not examined.

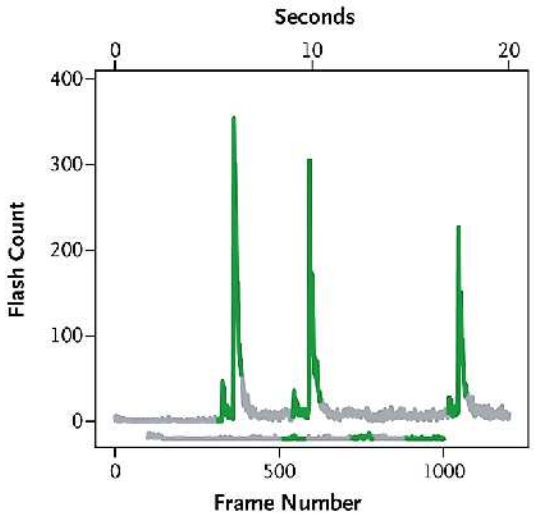
HOW WELL DO DIFFERENT MATERIALS FILTER DROPLETS AND AEROSOLS?

The ability of different types of material to effectively filter viral particles (whether as source control for exhaled virus or as protection against inhaled virus) has been simulated and measured under various laboratory conditions. In addition to types of materials used, many factors can contribute to the potential for reducing exhalation of virus, including design, fit, quality, and particle size. At this time, evidence demonstrating a reduction in viral transmissibility is inadequate.

A study to quantify speech-generated droplet emission in a laser light-scattering experiment measured exhaled droplets as a person verbalized a phrase three times. The investigator counted the flashes produced by droplets as they passed through a laser light sheet.[8]

- When the speaker used a damp[14] or dry[15] cloth mask and repeated the phrase, droplet emission was reduced to baseline (**Figure 4**).

Figure 4. Flash count corresponding to the number of droplets produced when speaking with and without wearing a damp cloth.



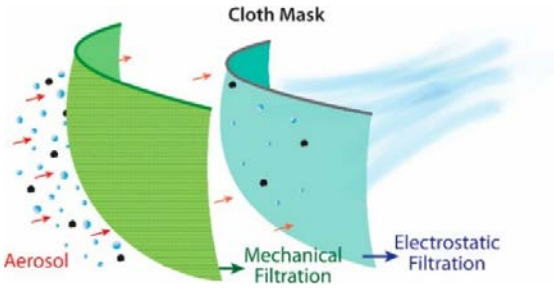
Note: Adapted from Anfinrud *et al.* Three green peaks reflect when person said "stay healthy" three times without a cloth mask. When spoken holding a damp cloth over the speaker's mouth, emission of droplets was substantially reduced (lower plot).[14]

Another study measured filtration of NaCl-based aerosols with particle sizes from 0.01 to 6 μm, a technique widely used for testing respirators.[16,17] Filtration efficiencies varied based on materials, layers of the same material, layers of different materials (hybrids) and particle size (< 0.3 μm and > 0.3 μm) (**Figure 5**).

- Most of these experiments were conducted under gapless conditions, simulating a fit-tested mask. The following are descending order of performance:
  - 2 layers consisting of cotton (80 twists per inch [TPI]) and chiffon, flannel, or silk
  - 2 layers of 80 TPI cotton
  - 1 layer of 80 TPI cotton

- When a gap was introduced (to simulate a non-fit-tested, loose mask) for the cotton/silk hybrid, the filtration efficiency dropped ~60%. However, some filtration was retained at both particle sizes (37% and 32% respectively).
- A gap was introduced only for the cotton/silk hybrid, limiting interpretation of filtration efficiencies of other materials and hybrids.
    - Filtration improved with multiple layers of the same materials and hybrids of different materials. Hybrid material layering likely increased filtration via both mechanical and electrostatic filtration.[17]

Figure 5. Filtration efficiencies were measured for both like and different materials and different particle sizes under laboratory conditions.



Note: Adapted from Konda *et al.*[17]

Another laboratory study used an aerosolized low pathogenic avian influenza strain to assess the percentage blocked by a homemade mask/covering (four layers of kitchen paper towels and one layer of polyester) compared to N95 and medical (surgical) masks under simulated breathing conditions.

- The homemade mask performed favorably compared with the N95 and medical masks (**Table 1**), and the authors noted it was more breathable than the N95.[18]

Table 1. Percentage of avian influenza virus blocked by masks under laboratory conditions.

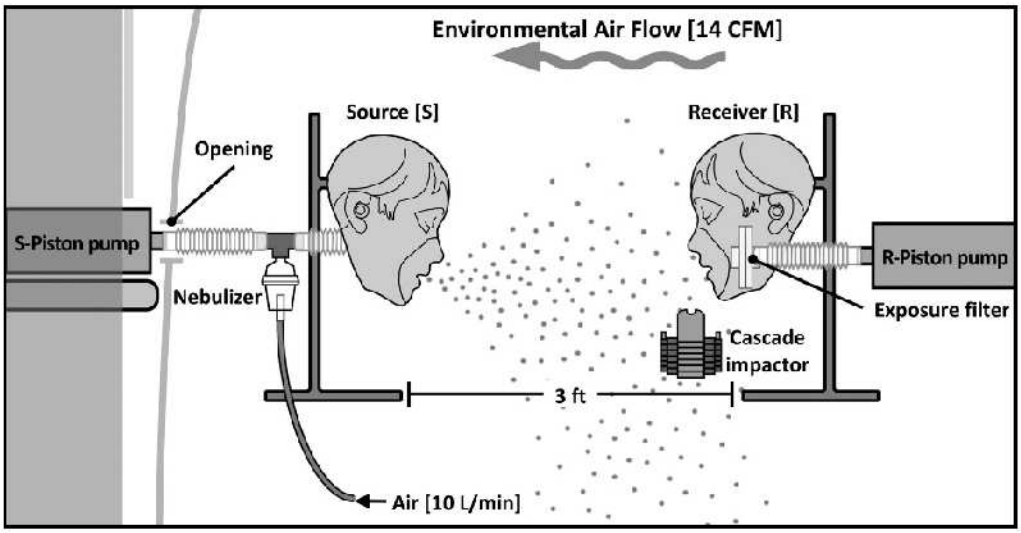
	C_t increase ($\bar{X} \pm SD$)	Percentage blocked (95% CI)
N95 mask	12.49 ± 0.33	99.98% (99.98%-99.99%)
Medical mask	5.13 ± 0.98	97.14% (94.36%-98.55%)
Homemade mask	4.37 ± 0.90	95.15% (90.97%-97.39%)

Note: Adapted from Ma *et al.* [18] Homemade mask was constructed of four layers of kitchen paper towels and one layer of polyester. Abbreviations: C_t, threshold cycle= increasing threshold cycle is inversely related to viral RNA detection by RT-PCR. SD=standard deviation; CI=confidence interval.

Another laboratory study created a chamber that simulated exhalation of contaminated aerosols during normal breathing from a source with and without a surgical mask or N95, and measured exposure to a receiver (**Figure 6**).[19] The exhaled particles were similar in size to exhaled droplets *in vivo* and exhaled into an environment with 6 air changes per hour to simulate flows typically found in public environments. The source and receiver were setup 3 feet apart to mimic 2 individuals in a room.

- A mask placed on the *source* resulted in a significant reduction in exposure to the receiver.
- A mask placed on the *receiver* did not significantly reduce exposure from the source when compared to no mask.

Figure 6. Schematic representation of experimental setup.

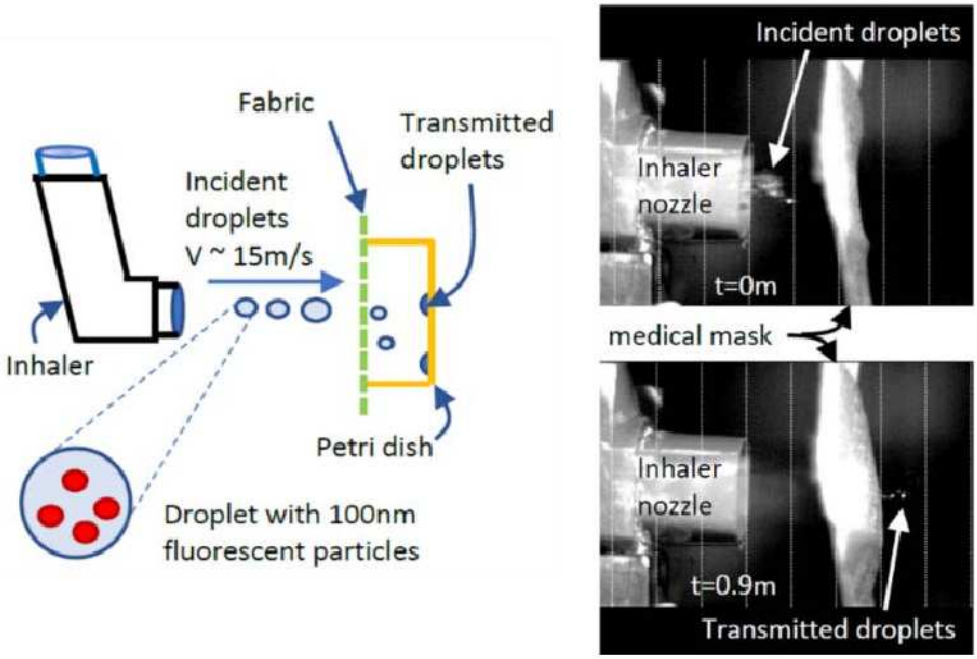


Note: Adapted from Diaz *et. al.* [19] Breathing pattern of both source and receiver: tidal volume 500 mL, rate 15 breaths/min.[19]

Lastly, in a pre-peer-reviewed manuscript, investigators described experiments to measure the ability of various fabrics that can be used to fashion homemade masks to filter a suspension of 0.10 µm fluorescent beads in distilled water to mimic SARS-CoV-2.[20] The suspension was loaded and dispersed by a metered-dose inhaler through various fabrics into a petri dish (**Figure 7**). Particle velocity was measured with a high-speed camera and quantified using a confocal laser scanning microscope.

- Cotton and cotton blend t-shirts' 'blocking ability' ranged from 43% to >90% (comparable to surgical masks); however, it's uncertain whether these results would be consistent in a clinical setting.

Figure 7. High speed camera snapshots of droplets hitting and penetrating mask materials.



Note: Adapted from Aydin *et al.*[20] A metered-dose asthma inhaler is loaded with the test solution and used to expel the solution into the fabric. The figure depicts the experimental set-up. The upper photograph shows expelled particles hitting the surgical mask. The lower photograph shows expelled particles penetrating the surgical mask.

IMPLICATIONS AND FUTURE RESEARCH

Limited evidence exists that quantifies the effectiveness of face coverings (cloth or other materials) for source control to reduce SARS-CoV-2 transmission via coughing or exhaled breath from COVID-19 patients. However, studies on source control from influenza and influenza-like illnesses support the use of cloth face coverings in combination with other preventive measures.

- Face coverings for source control and community protection from SARS-CoV-2 should be used in combination with other preventive measures, such as hand hygiene and social distancing.
- Studies of SARS-CoV-2 transmission among patients using different face covering materials are needed outside of laboratory settings and in the context of coughing, sneezing, and normal breathing.

A limited report that described deposition of SARS-CoV-2 on the outside of masks worn by infected persons who were asked to cough requires confirmation**.**

SARS-CoV-2 is widely thought to spread via respiratory droplets, but may also be spread by smaller aerosol particles. These smaller particles may be found in a normal exhaled breath, and thus have relevance to asymptomatic and pre-symptomatic spread.

- Studies are needed to better understand the fraction and particle size variability of exhaled SARS-CoV-2, and their potential infectivity and contribution to transmission, especially smaller aerosol particles.

Did you know?

French surgeon Paul Berger is credited with being the first to use a surgical mask during an operation in 1897.

> *"For several years I have been worried as to the part that drops of liquid projected from the mouth of the operator or his assistants may exercise on the outbreaks of infection which one still sees from time to time under conditions of surgical asepsis which are apparently satisfactory."*

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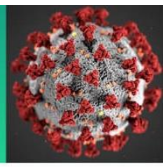

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Epidemiology

PEER-REVIEWED

Association of daily wear of eyeglasses with susceptibility to coronavirus disease 2019 infection. Zeng *et al.* JAMA Ophthalmology (September 16, 2020).

Key findings:

- A review of 276 COVID-19 patients found 16 (5.8%; 95% CI, 3.04% – 8.55%) wore glasses.
- The prevalence of SARS-CoV-2 infection for people who wear glasses (5.8%) was lower than the population prevalence described in a previous study (31.5%).
- Underlying diseases as well as COVID-19 symptoms and severity were not significantly different between patients who did and did not wear eyeglasses.

Methods: Cross-sectional evaluation of 276 hospitalized patients with SARS-CoV-2 infection in Suizhou, China between January 27 and March 13, 2020. The proportion of hospitalized persons who wore eyeglasses for more than 8 hours a day (wearing glasses for an extended period) were compared with the regional proportion of people with myopia from a 1985 study of 7 to 22-year-old students who by 2020 comprised an age-matched comparison cohort. *Limitations*: Single center study with small sample size; comparison to previous study of youth rather than a contemporary age-matched comparison group.

Implications: Whether SARS-CoV-2 is transmitted through the ocular route and what protective measures are needed remain a source of debate. This study suggests eyeglasses may provide some protection, however, as noted in an accompanying editorial, caution is needed as association may not imply causation, and additional data are needed to confirm this finding.

Case-control study of use of personal protective measures and risk for severe acute respiratory syndrome coronavirus 2 infection, Thailand. Doung-ngern *et al.* Emerging Infectious Diseases (September 14, 2020).

Key findings:

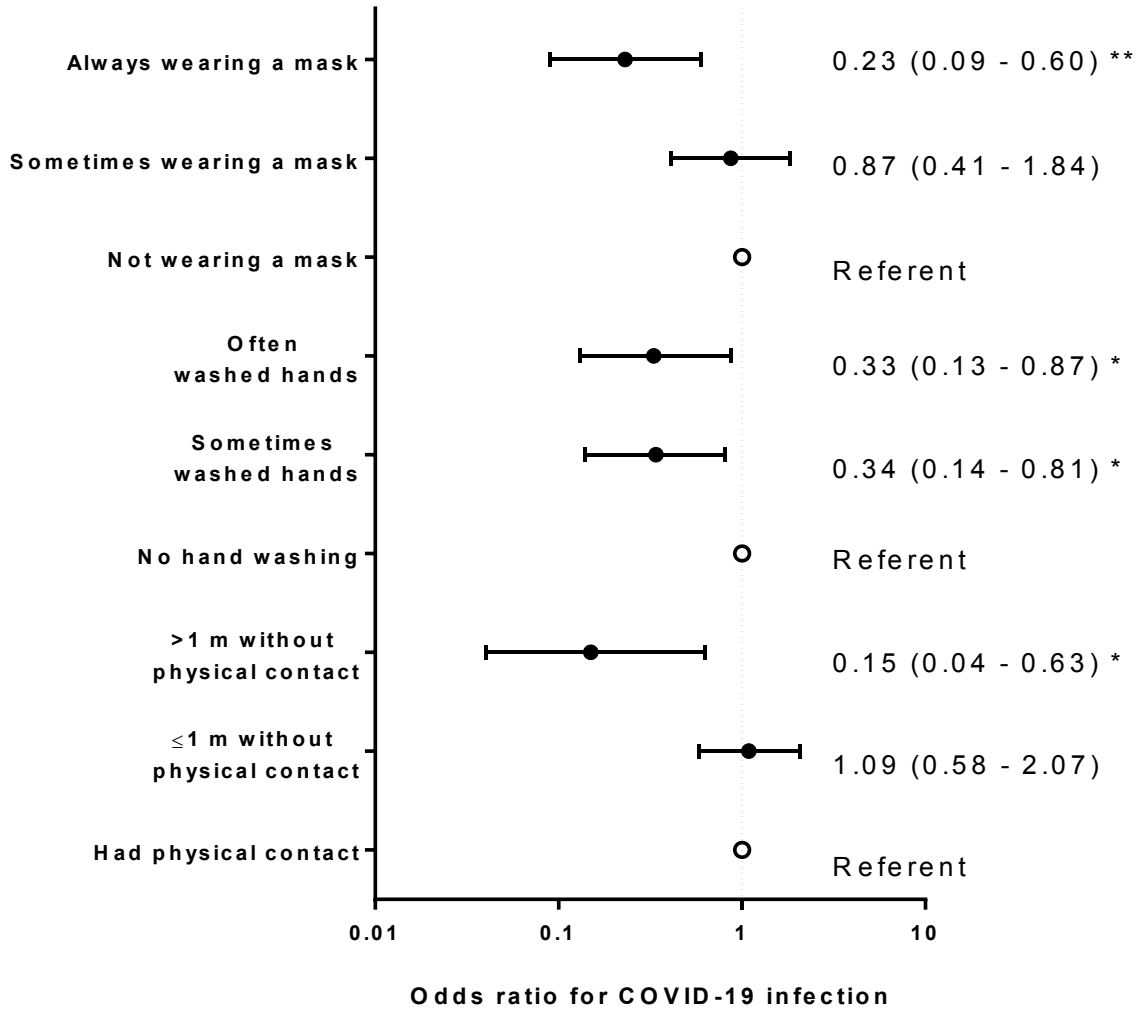
- Among 1,050 persons in three clusters, 211 (20.1%) tested positive for SARS-CoV-2 and were classified as cases, while 839 (79.9%) never tested positive and were classified as controls (Figure).
- Multivariate analysis showed low odds ratios for developing COVID-19 among those who maintained ≥1m distance from a contact (adjusted OR 0.15, 95% CI 0.04 – 0.63) and who frequently washed their hands (aOR 0.33, 95% CI 0.13 – 0.87) (Figure).
    - Always wearing a mask was more protective than sometimes wearing a mask (aOR 0.23, 95% CI 0.09 – 0.60 vs aOR 0.78, 95% CI 0.41 – 1.84, respectively).

MS-DOH-21-1816-A-000276

Methods: A retrospective case-control study of 1,050 asymptomatic people in 3 large COVID-19 clusters in Thailand between March and April 2020. People who had contact with COVID-19 index patients were questioned on mask wearing, social distancing, and hand hygiene. *Limitations*: Analysis from three settings might not be generalizable; estimated odds ratios were based on reported contact with the primary index case and did not evaluate the probability of having contact with other infected individuals; only 89% of defined controls were tested and the remainder could have been positive and confounded results.

Implications: This analysis supports recommendations for consistent and correct mask-wearing, proper social distancing and hand washing to lower risk of SARS-CoV-2 infection.

Figure:



Note: Adapted from Doung-ngern *et al*. Adjusted odds ratios for factors associated with SARS-CoV-2 infection among persons identified through contact tracing in Thailand, March – April 2020. ** p-value <0.01, * p-value<0.05. Open access journal; all content freely available.

Epidemiological and clinical findings of short-term recurrence of SARS-CoV-2 RNA PCR positivity in 1282 discharged COVID-19 cases: A multi-center, retrospective, observational study. Chen *et al.* Open Forum Infectious Diseases (September 13, 2020).

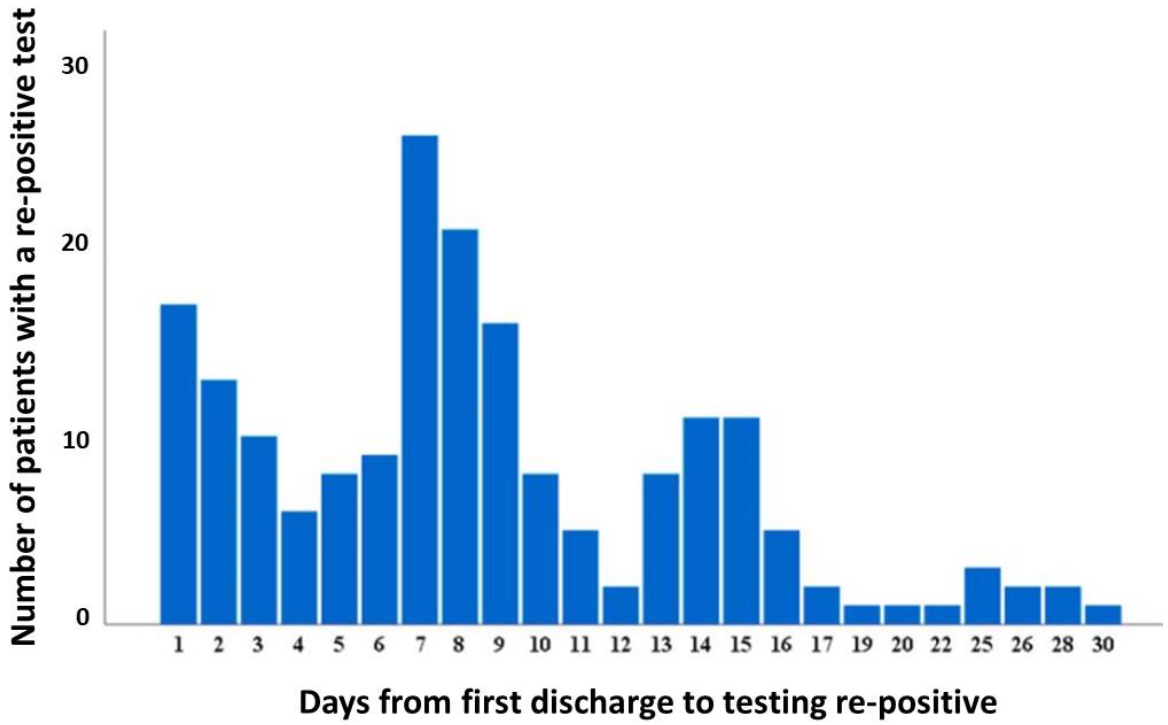
Key findings:

- 189 (14.7%) discharged patients re-tested positive for SARS-CoV-2 RNA.
  - 90.5% tested re-positive within 15 days of discharge (Figure 1).
  - Compared with patients who did not test re-positive, re-positive patients were more likely to be <40 years (63.5% vs 40.4%), had more moderate symptoms initially (95.8% vs 84.4%, p <0.001), were less likely to report comorbidities (11.1% vs 22.7%, p <0.001), and had shorter median length of primary hospitalization (17 days vs 19 days, p = 0.013).
- Most patients (80.4%) were readmitted only because of a positive test and had no symptoms.
  - 87.8% of re-positive patients had a negative test following the re-positive test within 20 days of hospital readmission (median 8 days) (Figure 2).
- No close contacts of re-positive patients developed symptoms and all tested negative for SARS-CoV-2.

Methods: Retrospective observational study of 1,282 COVID-19 patients discharged from 32 hospitals in China between January 14 and March 10, 2020 and followed for 28 days. All COVID-19 patients were discharged after 2 consecutive negative RT-PCR tests and thereafter tested at least weekly and reported symptoms daily, per provincial policy. *Limitations*: Viral genotyping was not conducted; the small number of close contacts may not be enough to look at risk of transmission from re-positive patients.

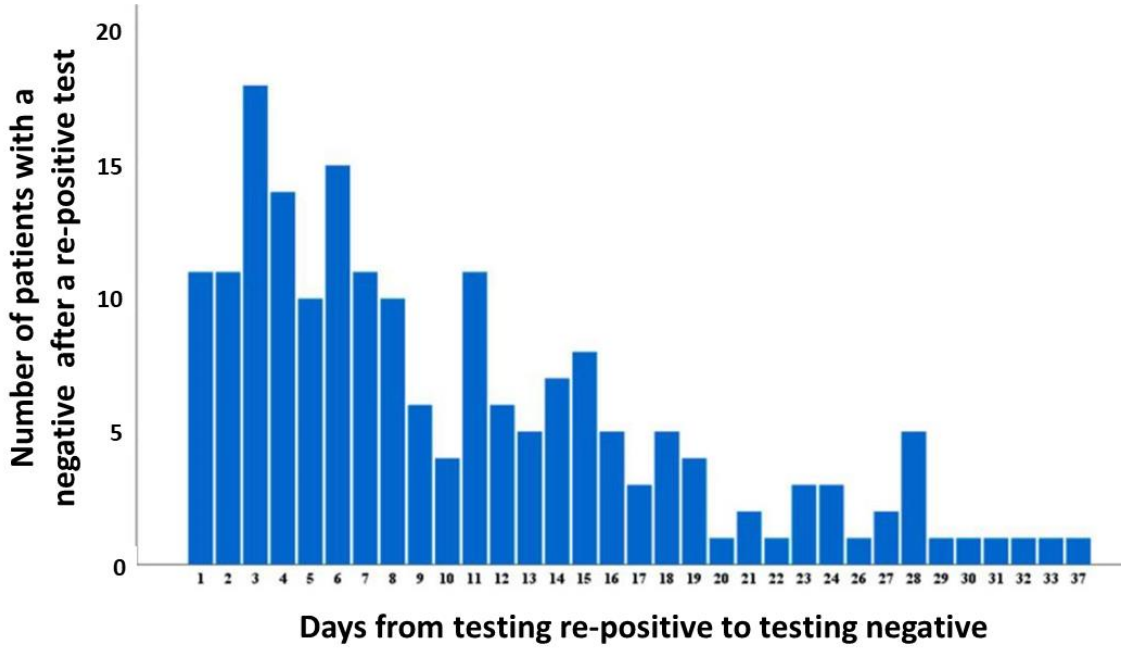
Implications: This study suggests that short-term recurrence of detectable SARS-CoV-2 RNA in discharged patients is not a relapse of COVID-19 and risk of ongoing transmission was not demonstrated.

Figure 1



Note: Adapted from Chen *et al*. Number of patients with a re-positive test for SARS-CoV-2 by the number of days after hospital discharge (n = 189). Licensed under CC BY-NC-ND.

Figure 2



Note: Adapted from Chen *et al*. Number of patients who had a negative test after a re-positive test in days (n = 188). Licensed under CC BY-NC-ND.

Modeling & Transmission

PEER-REVIEWED

Projected health-care resource needs for an effective response to COVID-19 in 73 low-income and middle-income countries: A modelling study. Tan-Torres Edejer *et al*. Lancet Global Health (September 9, 2020).

Key findings:

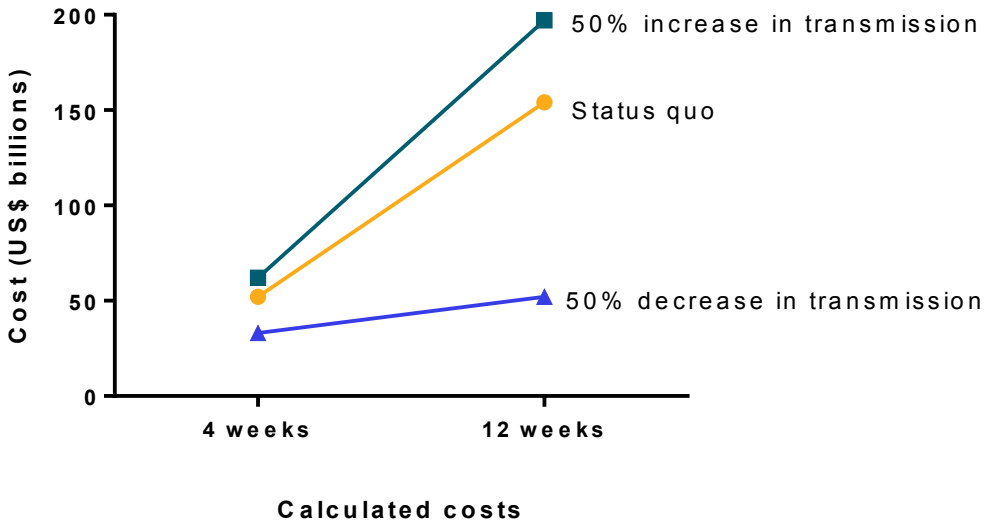
- In a modelling exercise, investigators found the main cost drivers for an effective COVID-19 response were case management (52%), maintaining essential services (21%), rapid response and case investigation (14%), and infection prevention and control (9%).
- Total healthcare cost estimates at baseline for 4 weeks was $52 billion (US$) for the status quo scenario, $33 billion for 50% decrease in transmission scenario, and $62 billion for the 50% increase in transmission scenario (Figure).
- At 12 weeks, under the 50% reduction in transmission scenario, costs were projected to be equivalent to the 4-week status quo scenario costs.
    - Under the status quo or increasing transmission scenarios, costs were projected to triple the 4-week costs (Figure).

Methods: Cost analysis model of COVID-19 strategic preparedness and response costs in 73 low and middle-income countries at two time periods: baseline for 4 weeks (June, 2020 to July, 2020) and 12 weeks (July, 2020 to September, 2020) under 3 scenarios regarding transmission (status quo, 50% increase, 50% decrease). Costs included costs for laboratories and health facilities, personal protective equipment, diagnostic supplies, pharmaceuticals, and labor costs. *Limitations:* Only costs borne by healthcare sector were included; costs for

quarantine and isolation for mild to moderate COVID-19 cases not included; sensitivity analyses were limited to 50% changes in transmission.

Implications: COVID-19 response costs quickly escalate if public health measures are relaxed and transmission increases. Public health measures to reduce transmission can reduce these future costs to sustain the response. Costs for case management services were the biggest drivers of COVID-19 response costs in low- and middle-income countries.

Figure:



Note: Adapted from Tan-Torres Edejer *et al*. Calculated cost estimates for a COVID-19 response in billions of US dollars for low- and middle-income countries. Costs were estimated for three scenarios: **status quo**, **+50% transmission**, and **-50% transmission** at 4 and 12 weeks. Licensed under CC-BY-NC-ND.

Diabetes-related COVID-19 Mortality

Early in the pandemic diabetes was recognized as a risk for poor COVID-19 outcomes. Below we present two studies that describe COVID-19-related mortality rates stratified by type of diabetes in England.

PEER-REVIEWED

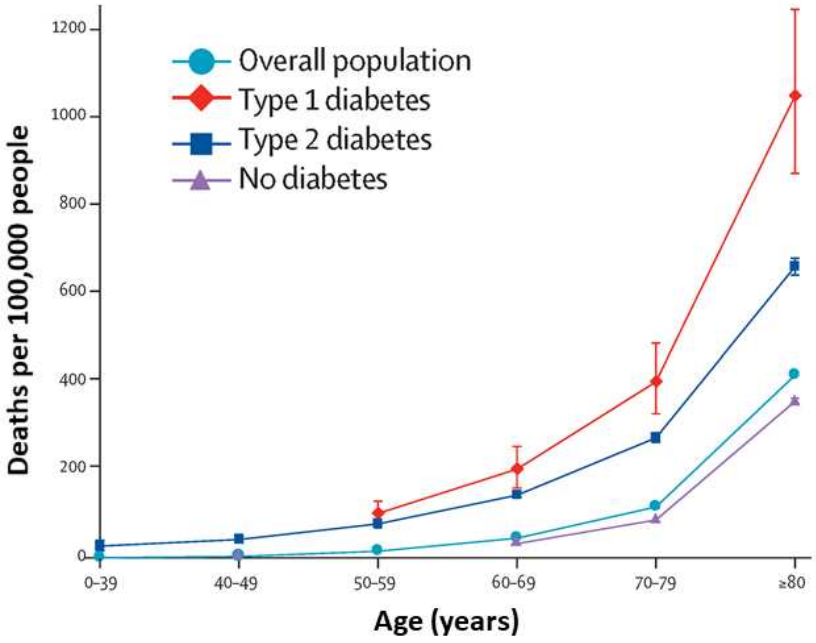
A. **Associations of type 1 and type 2 diabetes with COVID-19 related mortality in England: A whole-population study.** Barron *et al.* Lancet Diabetes & Endocrinology (August 13, 2020).

Key findings:

- Persons with diabetes comprise 5.2% of the population in England but comprised 33.6% (7,867/23,698) of all COVID-19 deaths.
- Both type 1 and type 2 diabetes were independently associated with increased odds of COVID-19 death after adjusting for age, sex, ethnicity, socioeconomic status, and region: type 1 diabetes adjusted OR 3.51 (95% CI 3.16 – 3.90), type 2 diabetes aOR 2.03 (95% CI 1.97 – 2.09).
- There was a strong association between death and age; this effect was more pronounced among those with type 1 diabetes compared with type 2 diabetes (Figure).

Methods: Whole-population study looking at risk of COVID-19-related in-hospital death associated with diabetes status in the England from March 1 to May 11, 2020 in all individuals registered with a general practice. *Limitations*: Because the outcome was in-hospital death, the association of diabetes with COVID-19 mortality was likely underestimated.

Figure:



Note: Adapted from Barron *et al*. Unadjusted in-hospital COVID-19 mortality rates, March 1 to May 11, 2020, for the **Overall population**, **Type 1 diabetes**, **Type 2 diabetes**, and **No diabetes**. Whisker bars show 95% CIs. Data for age groups 0 – 39 years and 40 – 49 years for type 1 diabetes and 0 – 39 years and 50 – 59 years for no diabetes were excluded because of small numbers of events (one to four), to comply with data protection regulations. Permission request in process.

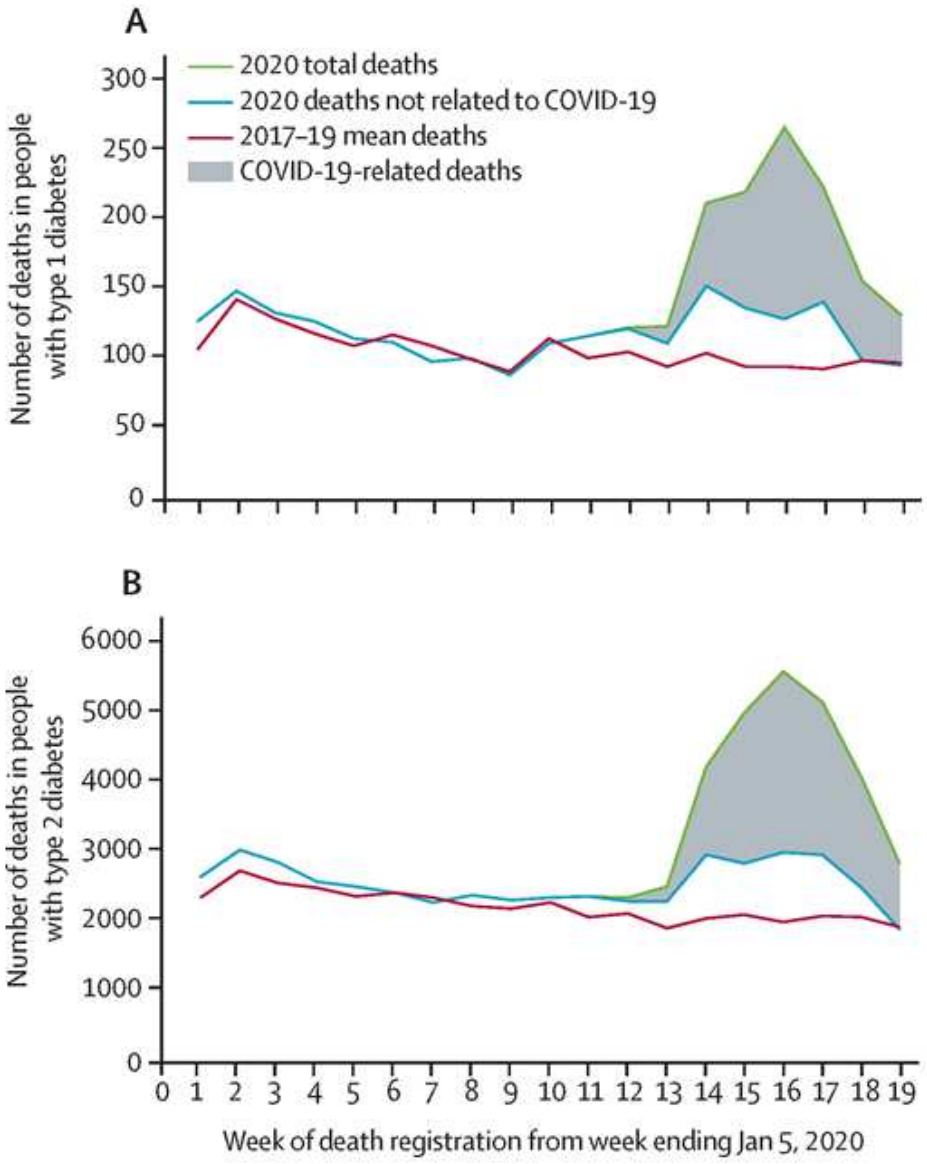
B. Risk factors for COVID-19-related mortality in people with type 1 and type 2 diabetes in England: A population-based cohort study. Holman *et al.* Lancet Diabetes & Endocrinology (August 13, 2020).

Key findings:

- During early 2020, the number of deaths among persons with type 1 and type 2 diabetes increased by 50.9% and 64.3% respectively, compared with the mean number of deaths during the previous three years for that period (Figure 1).
    - There were 464 (69%) additional deaths in persons with type 1 diabetes and 10,525 (65.5%) additional deaths in persons with type 2 diabetes listed as COVID-19-related.
- Factors identified that increased risk for mortality included BMI, renal function, and blood sugar control.

Methods: Population-based cohort study and survival analysis among people with diabetes registered in 6,774 general practices, from January 2, 2017, to May 11, 2020. The weekly number of deaths among persons with diabetes was calculated for the first 19 weeks of 2020 and compared to the same time period in 2017, 2018, and 2019. During the 2020 study period, potential risk factors for COVID-19-related deaths were examined. *Limitations*: Possible under-recognition of COVID-19-related mortality; cohort in this study may be part of Barron *et al*. study, summarized above.

Figure 1



Note: From Holman *et al.* Weekly numbers of deaths registered from week 1 to week 19 in people with type 1 (**A**) and type 2 (**B**) diabetes in England, **mean deaths from 2017–19** and 2020. Deaths in 2020 are stratified into **deaths not related to COVID-19** and **total deaths**. Note different scale on y axes for the 2 graphs. Permission request in process.

Implications for 2 studies (Barron *et al*. & Holman *et al*.): During the COVID-19 pandemic, diabetes has been associated with increased risk for death with mortality largely attributable to COVID-19. However, rates of non-COVID-19 mortality for diabetics have also increased, possibly due to avoidance of care, other demographic and social factors in diabetic patients or under-recognition of contribution of COVID-19 as a cause of death. As discussed in COVID-19 and diabetes: a co-conspiracy, poor blood sugar control impairs host immunity and has been associated with infections in general and worse outcomes with COVID-19. Supporting people with diabetes in effective self-management during the pandemic is an important measure to aid in mitigating the effects of SARS-CoV-2 infection.

Clinical Treatment & Management

PEER-REVIEWED

Pediatric lung imaging features of COVID-19: A systematic review and meta-analysis. Nino *et al*. Pediatric Pulmonology (September 14, 2020).

Key findings:

- 35.7% of pediatric COVID-19 patients had normal chest CT scans.
- Most common chest CT findings in pediatric COVID-19 patients were ground-glass opacities 37.2%, (95% CI 29.3% – 45%), pneumonic infiltrates or consolidations 22.3%, (95% CI 17.8% – 26.9%), and bilateral involvement 27.7% (95% CI 19.9% – 35.6%) (Table).
- Typical lung imaging features of viral infections in the pediatric population, such as perihilar markings and hyperinflation, were not present in pediatric COVID-19 patients.

Methods: A meta-analysis of 29 studies including 1,026 children 0-18 years with RT-PCR-confirmed SARS-CoV-2 to obtain the pooled chest CT scan features. *Limitations*: Variation in CT reporting practices could have influenced results; only one database was included in the systematic search limiting the inclusion of international studies; a risk-of-bias assessment was not done; authors did not describe methods for data transformation or synthesis.

Implications: CT scan abnormalities in the pediatric COVID-19 population are distinct from typical lung images of viral respiratory infections. When compared with adults, children with COVID-19 had greater variability in CT findings and more commonly had normal chest CT scans.

Table:

	Children with COVID-19 (n = 1,026)	Adults with COVID-19 (n = 4,121)	Adults with COVID-19 (n = 2,738)
Normal lung imaging (%)	35.7	8.4	10.24
Bilateral compromise (%)	27.7	73.8	78.2
Ground-glass opacities (%)	37.2	68.1	83.3
Consolidation, infiltrates (%)	22.3	32	44

Note: Adapted from Nino *et al*. Comparison between most common pediatric and adult CT findings. Permission request in process.

Convalescent plasma treatment of severe COVID-19: A propensity score–matched control study. Liu *et al.* Nature Medicine (September 15, 2020).

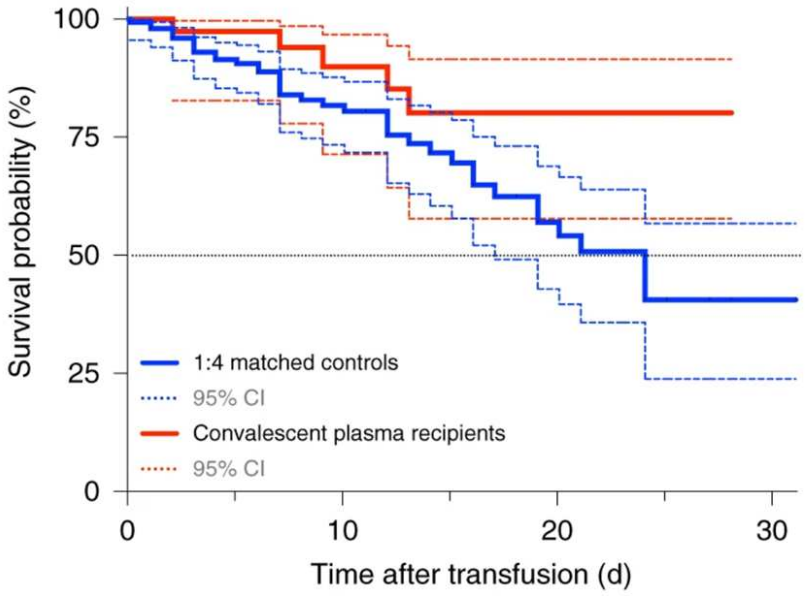
Key findings:

- Fewer patients who received convalescent plasma (CP) died (5/39, 12.8%) than matched controls (38/156, 24.4%).
- CP was associated with improved survival in patients who were not intubated (HR 0.23; 95% CI 0.05 – 0.98, p = 0.046), had symptoms for less than 1 week (HR 0.33; 95% CI 0.11 – 0.93, p = 0.035), or received anticoagulation (HR 0.28; 95% CI 0.10 – 0.80, p = 0.018).
    - Patients who were intubated showed no improved survival (HR 0.79; 95% CI 0.22 – 2.79, p = 0.716).
- Survival rates improved in CP recipients compared with the control patients (HR 0.34; 95% CI 0.13 – 0.89, p = 0.027).

Methods: Retrospective case-control study analyzing the effectiveness of CP treatment in patients hospitalized at Mount Sinai Hospital with severe COVID-19 between March 24 and April 8, 2020. Propensity-score matched analysis was performed on data from baseline, up to the day of CP transfusion and from the day of CP transfusion forward while in care. *Limitations*: Cannot exclude the possibility that CP recipients benefitted from more assertive clinical management.

Implications: Results from nonrandomized case series such as this one suggest a benefit of CP in selected patients; high quality data from randomized controlled trials are needed to confirm these findings.

Figure:



Note: Modified from Liu *et al*. Survival probability of patients **receiving CP transfusion** vs **control arm**. Solid lines represent the survival curve, dashed lines represent 95% CI. Reprinted by permission from Springer Nature Customer Service Centre GmbH: Springer Nature, Nature Medicine. Liu *et al*. Convalescent plasma treatment of severe COVID-19: a propensity score–matched control study. https://doi.org/10.1038/s41591-020-1088-9, COPYRIGHT 2020.

Laboratory Science

PEER-REVIEWED

Detection and infectivity potential of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) environmental contamination in isolation units and quarantine facilities. Ben-Shmuel *et al.* Clinical Microbiology and Infection (September 9, 2020).

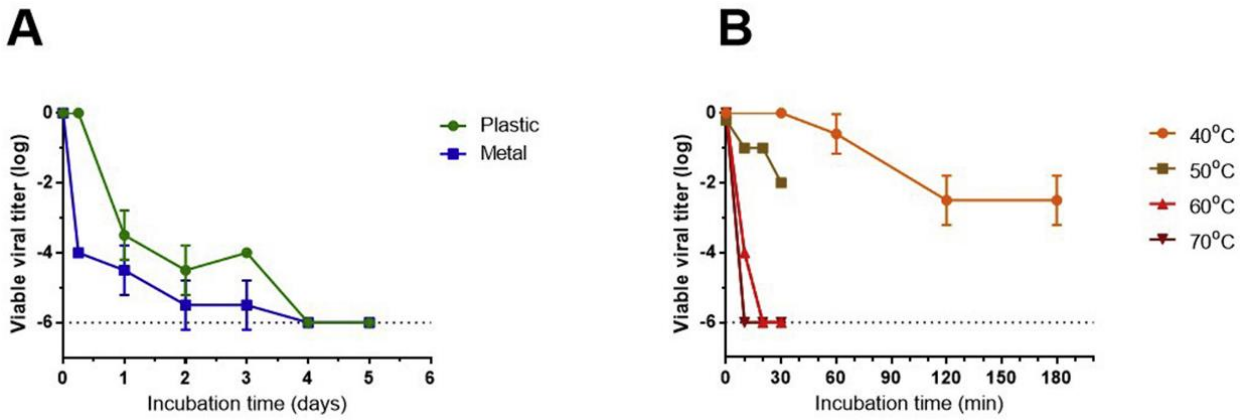
Key findings:

- At room temperature, SARS-CoV-2 lost infectivity on inoculated non-porous surfaces by day 4, and the rate of viral decay increased at higher temperatures (Figure).
- Viral RNA was detected in 46% (45/97) of environmental surface and air samples from three facilities housing COVID-19 patients; none of the samples contained infectious SARS-CoV-2.

Methods: Plastic and metal surfaces were inoculated with virus and infectivity was assessed at varying times and temperatures. Air and surface samples were collected from two hospital COVID-19 isolation wards and one hotel quarantine facility in Israel. RT-PCR identified viral RNA, and Vero E6 cytopathic assay assessed infectivity. *Limitations*: When rooms were being sampled, some patients may not have been shedding viable virus; very low levels of viable virus may not have been detected; remnants of surface cleaning materials and disinfectants may have inactivated virus; small sample size.

Implications: The lack of infectious SARS-CoV-2 detected from environmental samples in healthcare facilities suggests environmental contamination plays a minor role in the spread of infection in this setting. Staff should prioritize strengthening prevention measures interrupting direct person-to-person and droplet transmission.

Figure:



Note: From Ben-Shmuel et al. **A:** Reduction in SARS-CoV-2 titers over time (days) at 22°C (room temperature) following inoculation on **plastic** and **metal**. **B:** Reduction in SARS-CoV-2 titers over time (minutes) at (**40°C**, **50°C**, **60°C**, **70°C**) following inoculation on plastic. Licensed under CC-BY-NC-ND.

In Brief

- Marshall M. **The lasting misery of coronavirus long-haulers.** Nature. Describes the long-term effects of COVID-19 and the researchers trying to identify symptoms and prevalence.
- Chang *et al*. **Host tolerance contributes to persistent viral shedding in COVID-19.** EClinicalMedicine. Brief report describing characteristics of three patients with persistent viral shedding for at least 50 days.
- Guglielmi G. **'We didn't model that people would go to a party if they tested positive'.** Nature. The University of Illinois spent months preparing for students to return. Their ability to test up to 10,000 students per day drew praise in national press. There was still a spike as students with positive tests failed to isolate.
- Cahan E. **Ethical or exploitative — Should prisoners participate in COVID-19 vaccine trials?** Science News. Incarcerated populations are typically excluded from clinical trials over ethical concerns. A bioethicist and sociologist/epidemiologist discuss the benefits and risks of enrolling incarcerated persons in COVID-19 vaccine trials.
- Callaway E. **The coronavirus is mutating — Does it matter?** Nature. News feature that discusses the rate and role of mutations in SARS-CoV-2 and how mutations could impact future vaccines.
- Raahman *et al*. **Neurological manifestations in COVID-19: A narrative review.** Sage Open Medicine. A review of reported neurological manifestations of COVID-19, possible mechanisms and treatment strategies.

Disclaimer: The purpose of the CDC COVID-19 Science Update is to share public health articles with public health agencies and departments for informational and educational purposes. Materials listed in this Science Update are selected to provide awareness of relevant public health literature. A material's inclusion and the material itself provided here in full or in part, does not necessarily represent the views of the U.S. Department of Health and Human Services or the CDC, nor does it necessarily imply endorsement of methods or findings. While much of the COVID-19 literature is open access or otherwise freely available, it is the responsibility of the third-party user to determine whether any intellectual property rights govern the use of materials in this Science Update prior to use or distribution. Findings are based on research available at the time of this publication and may be subject to change.

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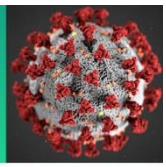
COVID-19 Science Update



From the Office of the Chief Medical Officer, CDC COVID-19 Response, and the CDC Library, Atlanta, GA.
Intended for use by public health professionals responding to the COVID-19 pandemic.

***** Available on-line at https://www.cdc.gov/library/covid19 *****

Epidemiology

PEER-REVIEWED

COVID-19 and psychologic distress—changes in internet searches for mental health issues in New York during the pandemic. Stijelja *et al.* JAMA Internal Medicine (October 5, 2020).

Key findings:

- Internet searches were higher than expected based on historical search data for the topics *anxiety*, 18% (95% prediction interval [PI] 5%-29%), *panic attack,* 56% (95% PI 37%-97%), and *insomnia,* 21% (95% PI 1%-55%) after March 22, 2020, and remained high for up to 5 weeks (Figure).
- Searches for the topics *suicide* and *depression* did not increase above expected.
    - Searches for *suicide* increased during the week of April 25 to May 2, matching the time frame of a publicized suicide of a New York physician.

Methods: Google Trend was used to examine relative search volumes (RSV) and forecasts between March 23 and May 14, 2020 for internet search terms including *suicide, anxiety, panic attack, insomnia*, and *depression* in New York State. Weekly RSV forecasts were computed with 95% PIs. *Limitations*: Does not estimate the number of individuals experiencing symptoms; many people with mental health issues may not have access the internet.

Implications: There is the potential to monitor the mental health of a population during emergencies using internet search trends to identify areas needing targeted resources for mental health support.

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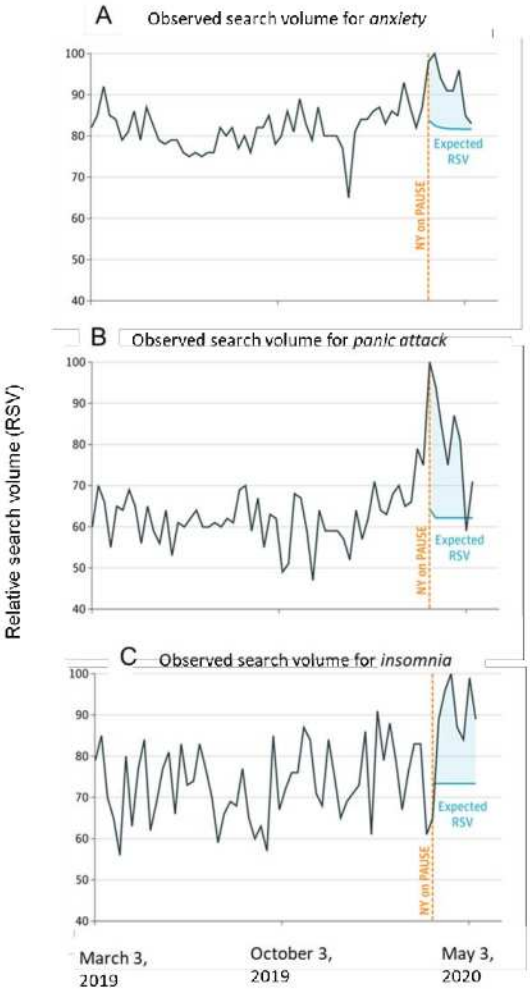
Figure:



Note: Adapted from Stijelja *et al.* Observed search volume and **excess search volume** for the terms *anxiety* **(A)**, *panic attack* **(B)**, or *insomnia* **(C)**. **Orange dotted line** indicates start of New York State lockdown. Reproduced with permission from JAMA Internal Medicine. Stijelja *et al.*, COVID-19 and psychologic distress—changes in internet searches for mental health issues in New York during the pandemic. DOI: 10.1001/jamainternmed.2020.3271. October 5, 2020. Copyright©2020 American Medical Association. All rights reserved.

The impact of the COVID-19 pandemic on healthcare acquired infections with multidrug resistant organisms. Cole *et al.* American Journal of Infection Control (October 1, 2020).

Key findings:

- 25% increase in hand sanitizer and hand soap use among health care personnel in the second quarter (Q2) of 2020 compared to the first quarter (Q1).
- 35% decrease in hospital-acquired multidrug resistant infection rates from 0.3/1,000 person-days in Q1 to 0.2/1,000 person-days in Q2, (p = 0.03); specifically:
    - 80% decrease in vancomycin-resistant *Enterococcus*.
    - 41% decrease in methicillin-resistant *Staphylococcus aureus*.
    - 21% decrease in extended-spectrum beta-lactamase *Enterobacteriaceae* infections.

Methods: Analysis of multidrug resistant infections diagnosed in hospital patients ≥4 days following admission based on isolates from urine, blood, wound, and sputum specimens in four hospitals in Los Angeles County during the first six months of 2020. *Limitations*: demographics of patients and frequencies of type of specimens not included.

Implications: Increased awareness and use of basic infection control practices by health care providers, including effective hand hygiene, can reduce hospital-acquired and other healthcare-associated infections.

PEER-REVIEWED

SARS-CoV-2 outbreak investigation in a German meat processing plant. Günther *et al.* EMBO Molecular Medicine (October 4, 2020).

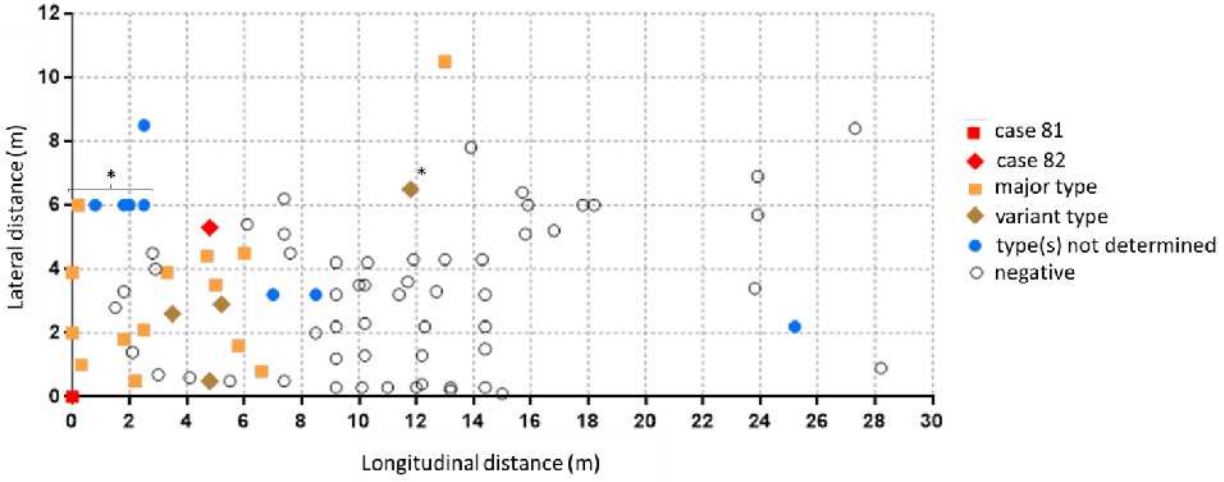
Key findings:

- Based on viral genome relatedness, a cluster of 29 infections among 147 workers from a single shift was attributable to a single index case (Figure).
    - Follow-up screening and testing identified ongoing transmission with more than 1,400 cases identified through June.
- Workers within an 8-meter radius of the index case were at highest risk for infection ($p < 0.001$).
- Infection was associated with working at fixed stations at which air conditioners recirculated air above workers, fans recirculating the air did not have filters and fresh-air exchange rates were low (<1 exchange per hour).
- Sharing a bedroom ($p = 0.039$) and sharing both an apartment and transportation ($p = 0.048$), were associated with infection.

Methods: Report of a large outbreak in a meat processing plant in Germany between May and June 2020, with genome sequencing of virus from cases. *Limitations*: All data on workers, including workplace location, sharing of housing, or transportation, were provided by the employer with no independent verification; genome type was not determined for all cases.

Implications: SARS-CoV-2 super spreading events have occurred in meat processing plants. In the absence of good ventilation, physical distance of 2 meters (6 feet) did not prevent transmission of SARS-CoV-2.

Figure:



Note: Adapted from Günther *et al.* Distance (in meters) of co-workers from the suspected **index case 81**. For workers without fixed position in the beef processing plant (marked with an asterisk) coordinates indicate estimated average location. Squares and diamonds denote major or variant SARS-CoV-2 genotypes, respectively. **Filled blue circles** denote cases for which viral genomes were not sequenced. Case 82 tested positive at the same time as case 81, but genome sequencing did not link this case to the outbreak. Licensed under CC-BY-4.0.

Clinical Treatment & Management

PEER-REVIEWED

Follow-up of adults with non-critical COVID-19 two months after symptoms' onset. Carvalho-Schneider *et al.* Clinical Microbiology and Infection (October 5, 2020).

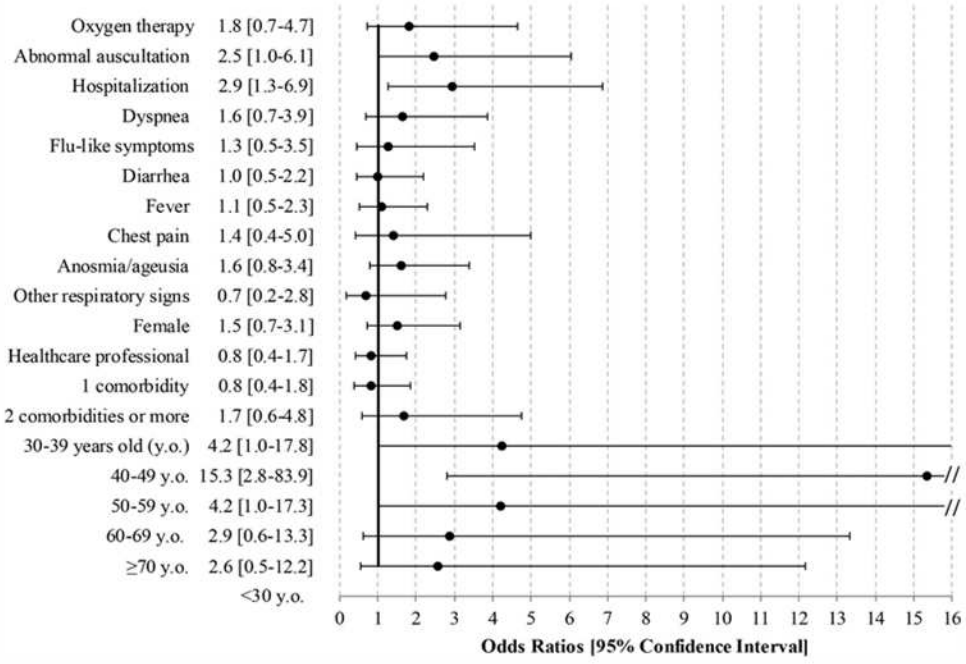
Key findings:

- Two-thirds of non-critical COVID-19 patients experienced prolonged symptoms, and some felt worse later in the disease course than at symptom onset.
    - Loss of smell and taste were the most frequent persistent symptoms at day 60 (22.7%).
- Persisting clinical symptoms were significantly associated with being admitted to the hospital, having an abnormal chest exam (auscultation), and being 40–60 years old at time of symptom onset (Figure).

Methods: Follow-up of 150 patients with non-critical RT-PCR-confirmed COVID-19 admitted to hospitals or seen as outpatients up to 60 days after symptom onset in France, between March 17 and June 3, 2020. Demographic, clinical, and laboratory data were collected from medical records and phone interviews. ***Limitations***: Baseline characteristics partially collected retrospectively; some data for contributing factors were missing limiting analysis; smoking status was not available.

Implications: Clinicians and patients should be aware of the potential need for prolonged medical follow-up even among those with mild initial clinical courses.

Figure:



Note: Adapted from Carvalho-Schneider *et al.* Odds Ratios and 95% CIs of acute-infection and demographic related factors associated with persisting symptoms at day 60 after symptom onset. This article was published in Clinical Microbiology and Infection, Carvalho-Schneider *et al.*, Follow-up of adults with non-critical COVID-19 two months after symptoms' onset. DOI: https://doi.org/10.1016/j.cmi.2020.09.052. October 5, 2020. Copyright European Society of Clinical Microbiology and Infectious Diseases 2020. This article is currently available at the Elsevier COVID-19 resource centre: https://www.elsevier.com/connect/coronavirus-information-center.

Neuropathology of patients with COVID-19 in Germany: A post-mortem case series. Matschke *et al.* Lancet Neurology (October 5, 2020).

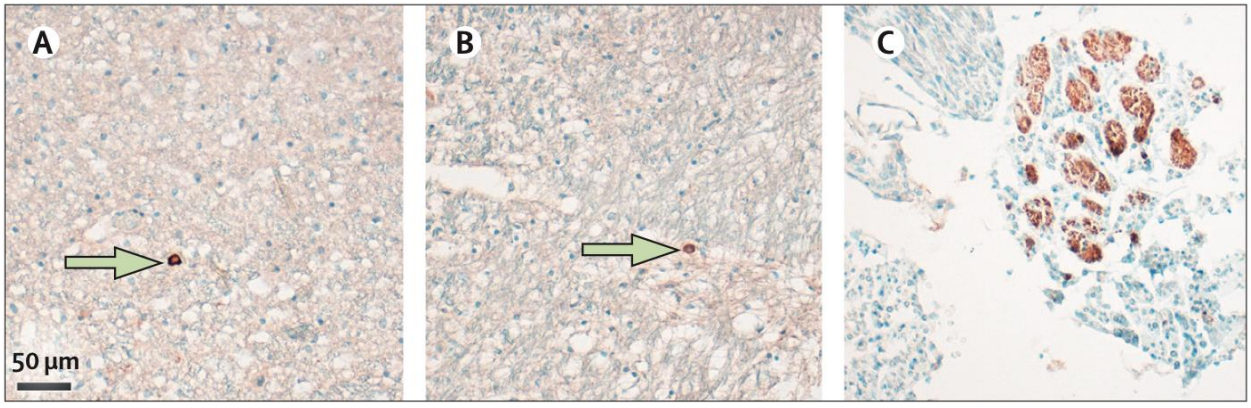
Key findings:

- There was substantial evidence of destruction of neurons (astrogliosis) in all autopsied patients.
  - 86% had astrogliosis in all brain regions tested.
- Infiltration by cytotoxic T lymphocytes and microglia (cells that act as immune defense for the brain and spinal cord) were most prominent in the brainstem and cerebellum.
  - Mild (n = 28) and moderate (n = 6) infiltration of meningeal compartments by cytotoxic T lymphocytes was identified in 79% of patients.
- SARS-CoV-2 RNA or proteins were detected in the brain tissues of 53% of patients tested (21/40), (Figure).
  - Both SARS-CoV-2 RNA and protein were detectable in 20% of patients.
  - SARS-CoV-2 presence did not correlate with the severity of neuropathological alterations.

Methods: Post-mortem case series of neural autopsies of 43 SARS-CoV-2-confirmed patients performed between March 13 and April 24, 2020 in Hamburg, Germany. Neural tissue from six brain regions were evaluated for pathology and for the presence and distribution of SARS-CoV-2 mRNA and protein. *Limitations*: 93% of patients had relevant pre-existing chronic medical conditions, and 30% had pre-existing neurological disease; no controls; small sample.

Implications: These data show that SARS-CoV-2 can infiltrate the central nervous system. Frank *et al.,* discuss the importance of understanding if neuropathological alterations with COVID-19 are from viral-induced cell destruction or from sequelae of an overstimulated systemic immune response, since these different causes would require different treatments.

Figure:



Note: From Matschke *et al.* Viral protein-positive cells (**green arrows**) in the medulla oblongata detected by anti-nucleocapsid protein antibody **(A)** or anti-spike protein antibody **(B)**. **(C)** SARS-CoV-2 nucleoprotein (**brown staining**) in cranial nerves. This article was published in Lancet Neurology, Matschke *et al.*, Neuropathology of patients with COVID-19 in Germany: A post-mortem case series. DOI: https://doi.org/10.1016/ S1474-4422(20)30308-2. October 5, 2020. Copyright Elsevier 2020. This article is currently available at the Elsevier COVID-19 resource centre: https://www.elsevier.com/connect/coronavirus-information-center.

PREPRINTS (NOT PEER-REVIEWED)

Temporal analysis of COVID-19 convalescent plasma donations reveals significant decrease in neutralizing capacity over time. Girardin *et al.* medRxiv (October 6, 2020).

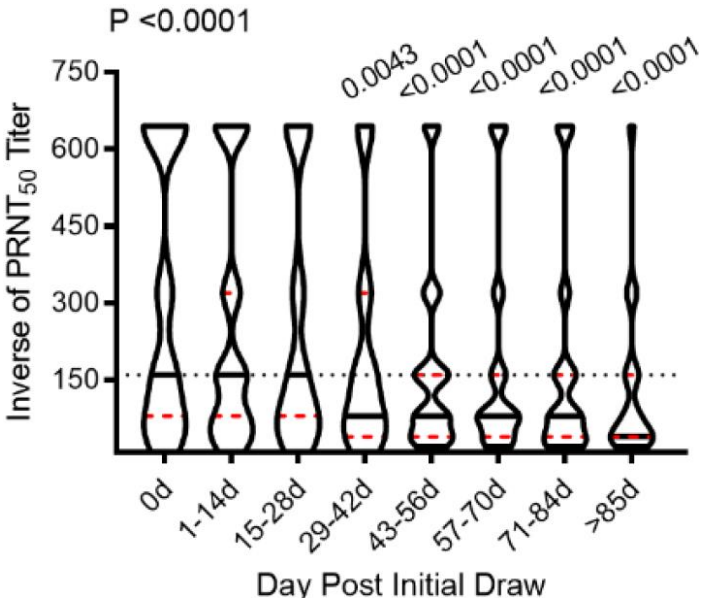
Key findings:

- Of the initial donations of plasma from COVID-19 convalescent patients,79.5% of specimens that neutralized 50% of virus in a plaque reduction neutralization test ($PRNT_{50}$) did so at a plasma IgG titer of at least 1:80, the US Food and Drug Administration (FDA) *minimum titer* for convalescent plasma (CP).
    - 51.4% of specimens with a $PRNT_{50}$ met the FDA *recommended* plasma titer of at least 1:160.
- At 85 days after the initial donation, only 48.8% of specimens with $PRNT_{50}$ met the minimum plasma titer cutoff (Figure 1).
    - The most significant decreases in $PRNT_{50}$ titer occurred at ≥43 days after initial donation.
- When using an FDA-approved IgG test that is a suggested surrogate for virus neutralization, 100% of samples with an IgG signal-to-noise ratio ≥12 (the qualifying cutoff for CP) neutralized virus at a titer ≥1:80 (Figure 2).

Methods: A total of 196 specimens meeting the FDA standard of a minimum $PRNT_{50}$ titer of 1:80 or more were selected at random from CP pools from the Wadsworth Center, New York. Neutralizing capacity of donated CP was measured by PRNT assay. IgG antibodies were detected using the Ortho VITROS SARS-CoV-2. *Limitations*: Information is based on time since initial donation rather than time since infection

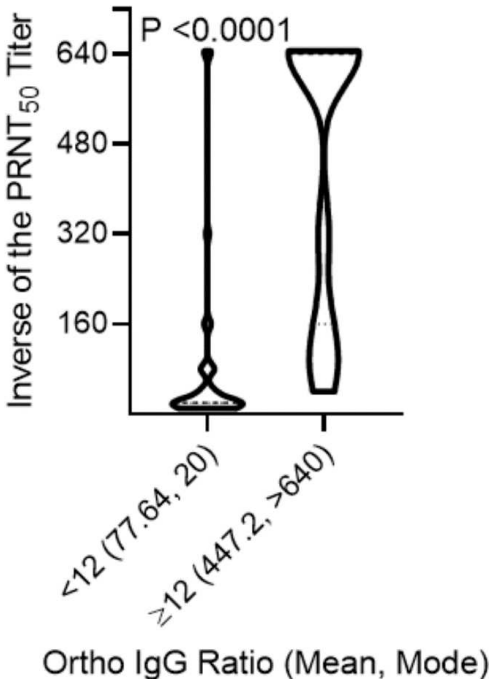
Implications: The decrease in virus neutralization potential in donor CP suggests a limited time frame for CP donation because of potential loss of immunity over time. This also suggests that the donors themselves have waning immunity in this time frame. As assays to measure neutralization are cumbersome and require biosafety level-3 facilities, an antibody test that can be used as a surrogate will facilitate more laboratories to provide rapid turnaround of CP neutralization results. The Ortho IgG ELISA used here is the only FDA-approved surrogate for viral neutralization, and these data confirm the correlation between this test and live SARS-CoV-2 neutralization.

Figure 1



Note: From Girardin *et al*. Change in $PRNT_{50}$ titers over time within two-week strata. Data are presented as inverse titers (i.e. a titer of 1:640 is graphed as 640, so that samples with more neutralizing antibody are higher on the y-axis). Dotted horizontal line represents the FDA recommended titer of 1:160 for use as convalescent plasma. Solid black lines represent median titers, dashed red lines represent 95% CI. Licensed under CC-BY-NC-ND 4.0.

Figure 2



Note: From Girardin *et al*. Distribution of $PRNT_{50}$ titers in groups versus IgG ratios (signal to noise) using the FDA cut-off for CP. Licensed under CC-BY-NC-ND 4.0.

Laboratory Science

PEER-REVIEWED

Upper respiratory tract levels of SARS-CoV-2 RNA and duration of viral RNA shedding do not differ between patients with mild and severe/critical COVID-19. Yilmaz *et al.* Journal of Infectious Diseases (October 6, 2020).

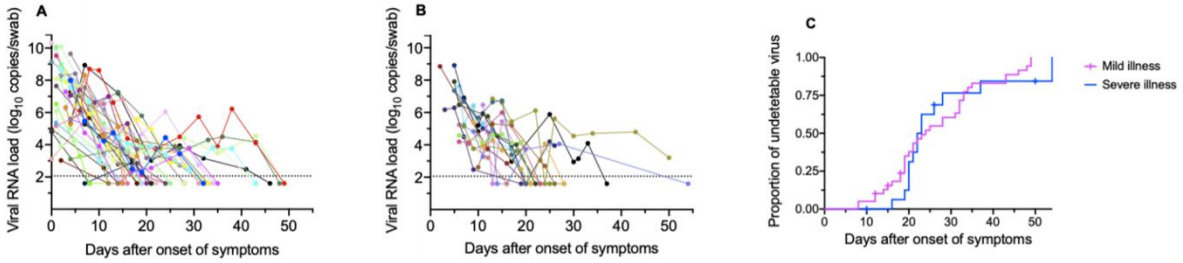
Key findings:

- Highest viral loads were observed early after symptom onset in persons with mild and severe COVID-19 and decreased over time (Figure).
- Median duration of viral shedding in individuals with mild and severe COVID-19 was similar, 24 vs 22.5 days, respectively (Figure).
- Most mild symptomatic cases (26/34) continued to be PCR-positive for 2 to 14 days after resolution of symptoms.

Methods: Retrospective cohort study of 59 individuals diagnosed with either mild or severe COVID-19 between February 25 and April 23, 2020, in Gothenburg, Sweden. Serial NP and throat swabs were collected, relative viral load was calculated, and statistical analysis was performed. *Limitations*: Small sample size from only one location; may not be generalizable.

Implications: Viral shedding was not associated with the severity of disease, indicating the potential for equal transmissibility of virus regardless of disease severity. However, further studies would have to be performed to determine if this is the case.

Figure:



Note: From Yilmaz *et al*. Viral load in nasopharyngeal and throat swabs in patients with COVID-19. Longitudinal viral loads for 39 patients with mild disease **(A)**, and 17 with severe/critical disease **(B)**. Horizontal dotted line in **(A)** and **(B)** mark detection limit of PCR assay. **C:** Time to viral RNA clearance for those with **mild** and **severe/critical** COVID-19. Permission request in process.

Vaccine Development

An effective vaccine will be key in controlling the COVID-19 pandemic, and multiple clinical trials are underway testing SARS-CoV-2 vaccine candidates. Some of these candidates have been given Fast-Track status by the US Food and Drug Administration (FDA) to accelerate licensing. While Fast-Track is an existing systematic approach to accelerate evaluation of vaccines and therapeutics, there is public concern about "rushing" a SARS-CoV-2 vaccine through this process. These two articles document public attitudes towards potential SARS-CoV-2 vaccines.

PEER-REVIEWED

Caregivers' willingness to accept expedited vaccine research during the COVID-19 pandemic–A cross sectional survey. Goldman *et al*. Clinical Therapeutics (October 3, 2020).

Key findings:

- Less than half (43%) of caregivers reported they were willing to accept a COVID-19 vaccine that is approved via Fast-Track status by the US Food and Drug Administration.
- Independent factors associated with willingness to accept expedited vaccine research included:
  - Children up to date on their vaccination schedule (OR 1.72, 95% CI 1.29-2.31, p <0.001).
  - Being worried that the caregivers themselves were sick with COVID-19 (OR 1.1, 95% CI 1.05-1.15, p <0.001).
- Mothers were less likely to accept expedited vaccine development than fathers (OR 0.64, 95% CI 0.53-0.78).

Methods: A cross-sectional survey of 2,557 caregivers arriving with their children (0–18 years of age) to 17 pediatric Emergency Departments in 6 countries between March 26 and June 30, 2020 to determine caregivers' level of support of abridged COVID-19 vaccine testing. *Limitations*: Caregivers completed the survey before the approval of any COVID-19 vaccine; levels of acceptability may change as new information on candidate vaccines becomes available.

Influences on attitudes regarding potential COVID-19 vaccination in the United States. Pogue *et al.* Vaccines. (October 3, 2020).

Key findings:

- 69% of respondents indicated they were open to receiving a COVID-19 vaccine.
    - Positive attitudes towards a COVID-19 vaccine were higher if the vaccine spent longer in clinical testing, had high efficacy, and was developed in the US.
    - Respondents who are current on vaccines recommended by their physician, whose children are current on vaccines, and who perceive that COVID-19 is an important problem in the US were more likely to indicate that they would take a COVID-19 vaccine.
- COVID-19 vaccine attitudes were unrelated to understanding of vaccines, demographics, COVID-19 knowledge, and number of people known with COVID-19 diagnosis.

Methods: Anonymous online survey on attitudes and behaviors related to potential COVID-19 vaccine in 316 respondents selected by age, race, and sex to reflect US population. Factor analysis and structural equation modeling were used. *Limitations*: Survey questions were not piloted or tested for understandability; vaccine history was self-reported; attitudes and beliefs are likely to evolve as more information about investigational vaccines emerge.

Implications for 2 studies (Pogue *et al.* & Goldman *et al*.): In both surveys, people already willing to vaccinate themselves or their child were more accepting of an accelerated SARS-CoV-2 vaccine, suggesting that motivation for COVID-19 vaccines may be driven by attitudes about vaccines in general more than control of the pandemic. Public health messaging around what "Fast Track" means may help quell some fears, but overall vaccine messaging will be needed to reap the full benefits of a COVID-19 vaccine, fast-tracked or not.

In Brief

Face masks:

- Peeples, L. **Face masks: What the data say.** Nature. Reviews anecdotal and experimental evidence supporting a role for masks in decreasing SARS-CoV-2 transmission and debates the need for a randomized controlled trial.
- Singh *et al*. **Bearded individuals can use an under-mask beard cover 'Singh Thattha' for donning respirator masks in Covid-19 patient care.** Journal of Hospital Infection, The *Singh Thattha* technique, covering the beard with a cloth that ties atop the head, was used by 27 male bearded dentists with an N95 respirator and 25/27 (92.6%) passed a fit test.

Note: From Singh *et al.* The *Singh Thattha* technique to secure respirators over a beard. This article was published in Journal of Hospital Infection. Singh et al., Bearded individuals can use an under-mask beard cover 'Singh Thattha' for donning respirator masks in Covid-19 patient care. DOI: https://doi.org/10.1016/j.jhin.2020.09.034. October 3, 2020. Copyright Elsevier 2020 on

behalf of The Healthcare Infection Society. This article is currently available at the Elsevier COVID-19 resource centre: https://www.elsevier.com/connect/coronavirus-information-center.

Clinical complications and sequelae:

- Rajdev *et al*. **Acute ischemic and hemorrhagic stroke in COVID-19: Mounting evidence.** Cureus. Three case reports describing stroke in SARS-CoV-2-positive patients.
- Bazuaye-Ekwuyasi *et al*. **Intussusception in a child with COVID-19 in the USA.** Emergency Radiology. The fourth case overall and first seen in the US of a child with COVID-19-related intestinal obstruction.
- Schwartz, M. **MIS-C: post-infectious syndrome or persistent infection?** Lancet Infectious Diseases. Letter discussing the possibility that COVID-19-related multisystem inflammatory syndrome in children (MIS-C) is more consistent with a subacute infection than a post-infectious syndrome.

Other:

- Pombal *et al*. **Risk of COVID-19 during air travel.** JAMA. Air flow patterns and filtration of recirculated air in modern aircraft decreases the risk of SARS-CoV-2 transmission, with only 42 known flight-based cases; passengers can take additional steps to decrease their risks.
- Hojyo *et al*. **How COVID-19 induces cytokine storm with high mortality.** Inflammation and Regeneration. Describes a potential pathway in which initiation of an IL-6 amplification loop in non-immune cells drives immune hyperreactivity in COVID-19 patients.
- Sallard *et al*. **Clinical trial protocols of repurposed prophylaxis for COVID-19: A review.** Médecine et Maladies Infectieuses. Lists the known clinical trials, with rationales, to use existing drugs for COVID-19 treatment, including chloroquine derivatives, tuberculosis and measles vaccines, lopinavir, interferons, azithromycin, ivermectin, passive immunotherapies, and others.
- Lipsitch *et al*. **Cross-reactive memory T cells and herd immunity to SARS-CoV-2.** Nature Reviews Immunology. Reviews current knowledge of T-cell responses to SARS-CoV-2 and describes scenarios in which pre-existing CD4+ T-cell immunity may provide cross-protection against SARS-CoV-2 infection.
- Hosangadi *et al*. **Current state of mass vaccination preparedness and operational challenges in the United States, 2018–2019.** Health Security. Summary of 37 interviews through March 2019 highlighting the unique operational needs of mass vaccination campaigns and the significant level of advanced planning that will be required for rollout of a SARS-CoV-2 vaccine.
- Wang *et al.* **Inference of person-to-person transmission of COVID-19 reveals hidden super-spreading events during the early outbreak phase.** Nature Communications. Phylogenetic analysis of early transmission in Wuhan, China, with identification of super spreader events.

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Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 69
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Trends in COVID-19 Incidence After Implementation of Mitigation Measures — Arizona, January 22–August 7, 2020

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Mitigating the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), requires individual, community, and state public health actions to prevent person-to-person transmission. Community mitigation measures can help slow the spread of COVID-19; these measures include wearing masks, social distancing, reducing the number and size of large gatherings, pausing operation of businesses where maintaining social distancing is challenging, working from or staying at home, and implementing certain workplace and educational institution controls (*1*–*4*). The Arizona Department of Health Services' (ADHS) recommendations for mitigating exposure to SARS-CoV-2 were informed by continual monitoring of patient demographics, SARS-CoV-2 community spread, and the pandemic's impacts on hospitals. To assess the effect of mitigation strategies in Arizona, the numbers of daily COVID-19 cases and 7-day moving averages during January 22–August 7, 2020, relative to implementation of enhanced community mitigation measures, were examined. The average number of daily cases increased approximately 151%, from 808 on June 1, 2020 to 2,026 on June 15, 2020 (after stay-at-home order lifted), necessitating increased preventive measures. On June 17, local officials began implementing and enforcing mask wearing (via county and city mandates),* affecting approximately 85% of the state population. Statewide mitigation measures included limitation of public events; closures of bars, gyms, movie theaters, and water parks; reduced restaurant dine-in capacity; and voluntary resident action to stay at home and wear masks (when and where not mandated). The number of COVID-19 cases in Arizona peaked during June 29–July 2, stabilized during July 3–July 12, and further declined by approximately 75% during July 13–August 7. Widespread implementation and enforcement of sustained community mitigation measures informed by state and local officials' continual data monitoring and collaboration can help prevent transmission of SARS-CoV-2 and decrease the numbers of COVID-19 cases.

ADHS supports surveillance and investigation efforts of local public health departments, compiles surveillance and investigation information across counties, and provides infrastructure statewide to support infectious disease surveillance. Data on laboratory-confirmed and probable (*5*) COVID-19 cases (based on the Council of State and Territorial Epidemiologists case definitions)† were collected in the centralized Medical Electronic Disease Surveillance Intelligence System (MEDSIS),§ which is used by state, tribal, and county public health agencies to report human-based diseases in Arizona. Information was submitted to or entered into MEDSIS by health care providers, laboratories, local health departments, tribal entities, and ADHS. Multiple laboratory tests submitted for a single patient were combined into a single record. Specimen collection date was used for confirmed cases, and symptom onset date was used for probable cases.

Temporal trends were examined by comparing the number of daily COVID-19 cases (as of September 1)¶ and 7-day moving averages before, during, and after implementation of enhanced community mitigation measures, defined as the following: limitations on persons' time away from their place of residence

*Mandates and ordinances varied and were county- and city-specific. Enforcement types included educating persons on the dangers of COVID-19 spread, issuing fines to persons and businesses who refused to comply with mandates, and loss of licenses for businesses not enforcing rules or mandates.

†https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/positionstatement2020/Interim-20-ID-02_COVID-19.pdf.

§https://azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-services/index.php#medsis-faqs.

¶https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/covid-19/dashboards/index.php.

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except for essential activities; certain business closures and service limitations (e.g., occupancy limitations, curbside pickup, and delivery of goods); enhanced sanitation practices**; social distancing, employee mask wearing, and symptom screenings for all businesses operating a physical location; limitations on the occurrence and size of public events; and local mandates enforcing mask use. The 7-day moving average was calculated after the cumulative case count exceeded 20 cases and is presented to describe COVID-19 trends.

On March 11, 2020, Arizona declared a public health state of emergency to prepare for, prevent, respond to, and mitigate the spread of SARS-CoV-2. Additional guidance was provided to local officials, businesses, communities, and individual persons to implement social distancing and close schools statewide (March 15); postpone and limit large gatherings to fewer than 50 persons; recommend telework options; restrict access to congregate settings; require restaurants to provide dine-out options only; and close all bars, gyms, and movie theaters in counties with confirmed COVID-19 cases (March 19) (Table). Based on Arizona data and CDC guidance (*1*,*2*), ADHS also recommended limiting persons' time away from their place of residence except for essential activities (i.e., stay-at-home order, "Stay Home, Stay Healthy, Stay Connected")†† (March 31).

During April 1–May 15, the 7-day moving average of daily cases ranged from 154 to 443 (Figure). During April 29–May 11, Arizona initiated a phased approach for retail shops and stores, cosmetologists, and barbers to reopen and operate, and for restaurants to resume dine-in services; the stay-at-home order ended May 15.

Average daily cases increased 151% from June 1 (808) to June 15 (2,026), necessitating an increased focus on preventive measures by businesses, communities, and individual persons. Updated guidance from state officials provided local governments the authority to implement mask policies (June 17) and enforcement measures tailored to local public health needs (local policies were applicable to approximately 85% of the total Arizona population). Before June 17, mask wearing had not been widely mandated or enforced. Arizona limited organized public events to fewer than 50 persons (with some exceptions); closed bars, gyms, movie theaters, and water parks and recreational tubing facilities (June 29); and limited restaurants' indoor dining to <50% capacity, with at least 6 feet of separation between patrons (July 9). The 7-day moving average of daily cases peaked during

** Based on guidance from ADHS, CDC, and the Department of Labor, and Occupational Safety and Health Administration to limit and mitigate the spread of COVID-19, including promoting healthy hygiene practices; and intensifying cleaning, disinfection and ventilation practices.

†† https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-admin-orders; https://azgovernor.gov/executive-orders.

TABLE. Public policies to implement and enforce COVID-19 community mitigation measures and dates of issue/reissue* — Arizona, March 11–August 7, 2020

Mitigation measure	Date of issue/reissue
Declaration of emergency	Mar 11
School closure (on-site learning)	Mar 15
Limits on senior living facilities visitation	Mar 19
Expanded availability and coverage for telemedicine for persons, pets, and animals	Mar 25, Apr 1
Deferred requirements to renew driver license	Mar 20
Stay-at-home order	Mar 30–May 15
Business/Service closures	
Bars	Mar 19, Jun 29, Jul 23
Movie theaters	Mar 19, Jun 29, Jul 23
Indoor gyms and fitness clubs	Mar 19, Jun 29, Jul 23
Restaurants, on-site dining	Mar 19
Pools	Mar 19
Water parks and recreational tubing facilities	Jun 29, Jul 23
Business/Service limits (requirements)	
All businesses operating a physical location (enhanced sanitation,† social distancing, employee mask wearing, symptom screenings)	Jun 17
Retail (limited capacity, social distancing, enhanced sanitation)	Apr 29
Barbers and cosmetologists (employee mask wearing, spaced appointments, enhanced sanitation)	May 4
Restaurants (social distancing, limited capacity, employee mask wearing, patron mask wearing [when not eating or drinking], employee screening, enhanced sanitation)	May 4, Jul 9
Public pools (e.g., at hotels; limited capacity)	Jun 29, Jul 23
Private pools in public areas (e.g., multihousing complexes; limited capacity)	Jun 29, Jul 23
Public events (<50 persons)	Mar 15, Jun 29, Jul 23
Wearing masks (mandatory)	
Local officials able to mandate and enforce wearing masks	Jun 17
Yuma County	Jun 18
Maricopa County	Jun 19
Pima County	Jun 19
Santa Cruz County	Jun 19
Coconino County	Jun 20
>40 other cities/tribal communities	Jun 17–25§

Abbreviation: COVID-19 = coronavirus disease 2019.

* Issue dates are the dates the issuing official signed the order implementing the mandatory mitigation measure. In some instances, mitigation measures were effective either immediately or within 1 to 3 days of issue. https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-admin-orders; https://azgovernor.gov/executive-orders.

† Based on guidance from the Arizona Department of Health Services, CDC, Department of Labor, and Occupational Safety and Health Administration (OSHA) to limit and mitigate the spread of COVID-19 including promoting healthy hygiene practices; and intensifying cleaning, disinfection and ventilation practices.

§ Other tribal communities with mask mandates (issued June 18–23) included Fort McDowell Yavapai Nation, Gila River Indian Community, Navajo Nation, Salt-River Pima-Maricopa Indian Community, Tohono O'Odham Nation. Other cities with mask mandates (issued June 17–25) included Avondale, Bisbee, Buckeye, Carefree, Casa Grande, Chandler, Clarkdale, Clifton, Coolidge, Cottonwood, Douglas, Flagstaff, Fountain Hills, Gila Bend, Gilbert, Glendale, Globe, Goodyear, Guadalupe, Jerome, Kingman, Litchfield Park, Mammoth, Mesa, Miami, Nogales, Oro Valley, Paradise Valley, Payson, Peoria, Phoenix, San Luis, Sedona, Scottsdale, Somerton, Superior, Surprise, Tempe, Tolleson, Tucson, Youngtown, Yuma. Several other tribal communities and cities encouraged but did not mandate wearing masks.

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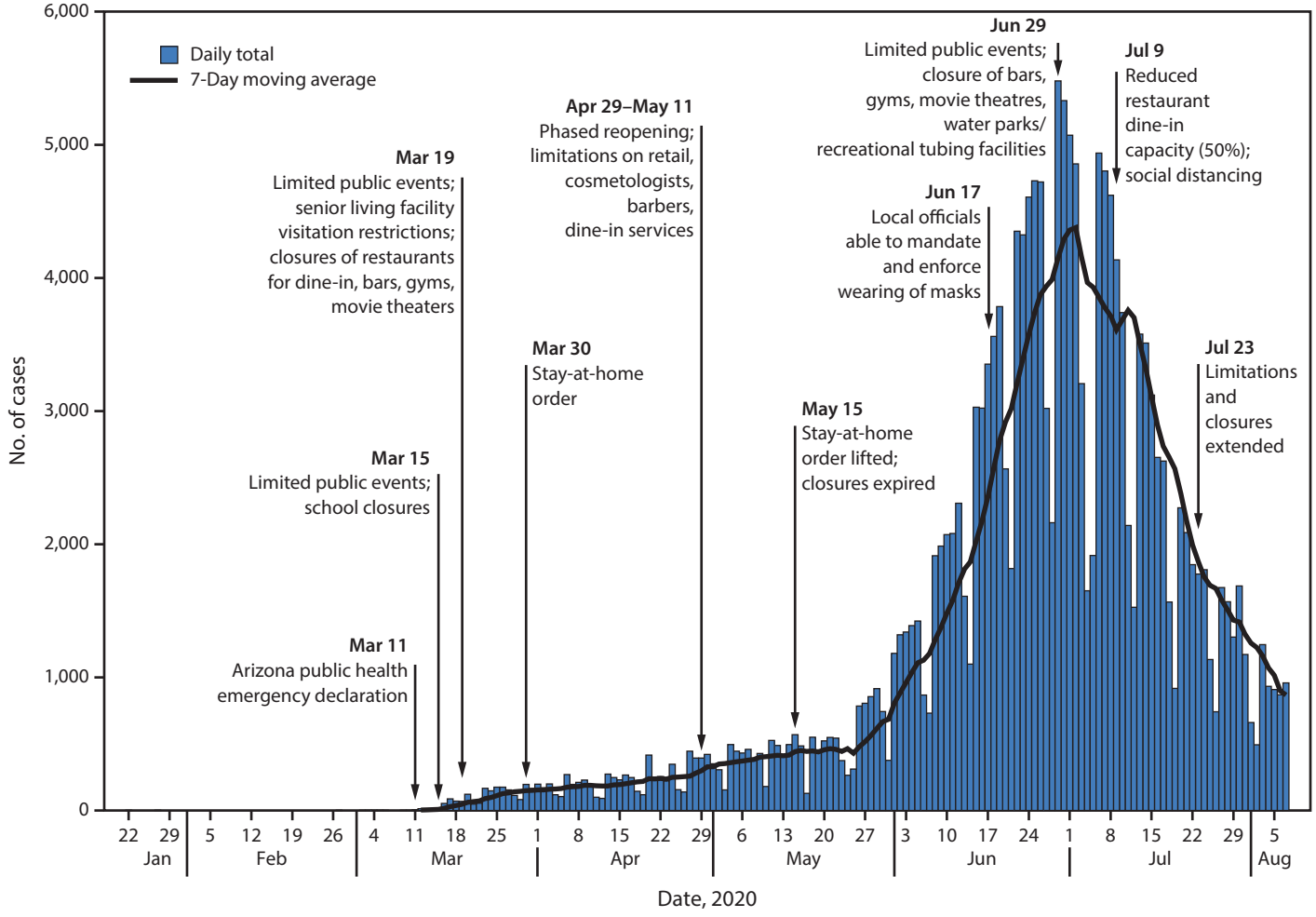
FIGURE. Selected community mitigation measures* and COVID-19 case counts† and 7-day moving averages§ — Arizona, January 22–August 7, 2020



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† As of September 1, 2020. Specimen collection date was used for confirmed cases, and symptom onset date was used for probable cases.

§ Plotting of 7-day moving average began when cumulative case count exceeded 20 cases.

June 29–July 2 (range = 4,148–4,377), stabilized during July 3–12 (range = 3,609–4,160), and subsequently decreased 75% from July 13 (3,506) to August 7 (867). Mitigation measures put in place in June were extended through August to further limit transmission.

Discussion

Quantitative data on the effectiveness of community mitigation measures at suppressing the spread of COVID-19 are limited. The primary goal of implementing widespread enhanced mitigation measures in Arizona was to protect and save lives and maintain capacity in the health care system. A combination of voluntary and enforceable measures is more effective than any single measure (*6*). Mitigation measures mandated through public policy can effectively increase social distancing (*7*), and wearing masks has prevented transmission of SARS-CoV-2 (*8*). In Arizona, decreases in daily COVID-19 cases were observed after widespread sustained community mitigation measures that promoted social distancing, limited large gatherings, paused operations of businesses where mask use and social distancing were difficult to maintain, mandated and enforced mask wearing, and promoted voluntary resident actions to stay at home and wear masks (when and where not mandated). The number of COVID-19 cases stabilized and began to decrease approximately 2 weeks after local officials began mandating mask wearing (throughout several counties

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and cities) and enhanced sanitation practices. Additional declines in case counts were associated with implementation of statewide limitations and closures sustained throughout July and extended into August.

The findings in this report are subject to at least four limitations. First, the relationship between mitigation measures and changes in case counts are temporal correlations and should not be interpreted to infer causality. Other factors that might have influenced the rate of change (e.g., travel restrictions, neighboring state mitigation measures, and individual choices to reduce movement before implementation of mandates) cannot be ruled out. Second, health centers run by tribal entities and federal health facilities (i.e., Indian Health Service, Veteran's Administration, and Department of Defense) in the state are requested but not required to comply with state reporting rules. Many of these health centers and federal health facilities complied with reporting, but the completeness of reporting by these entities is unknown. Third, adherence to mitigation measures was not assessed, nor could the extent to which each individual measure affected the number of incident COVID-19 cases be established. Finally, Arizona might not be representative of other U.S. states, and community mitigation measures might have a different impact in more populous or densely populated states; thus, these findings are not necessarily generalizable to other settings.

Enhanced mitigation measures should be implemented by communities and persons to slow COVID-19 spread, particularly before a vaccine or therapeutic treatment becomes widely available. State, local, and tribal officials are best positioned to continually monitor data and collaborate to determine the level and types of enhanced mitigation required. Mitigation measures, including mask mandates, that are implemented and enforced statewide appear to have been effective in decreasing the spread of COVID-19 in Arizona.

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Arizona Department of Health Services COVID-19 Response teams; county, local and tribal local health departments; CDC COVID-19 Health Department Section; CDC AZ-1 COVID-19 Response Team.

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[1]Arizona Department of State Health Services; [2]CDC COVID-19 Response Team.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

Summary

What is already known about this topic?

Community mitigation measures can help slow the spread of COVID-19.

What is added by this report?

The number of COVID-19 cases in Arizona stabilized and then decreased after sustained implementation and enforcement of statewide and locally enhanced mitigation measures, beginning approximately 2 weeks after implementation and enforcement of mask mandates and enhanced sanitations practices began on June 17; further decreases were observed during July 13–August 7, after statewide limitations and closures of certain services and businesses.

What are the implications for public health practice?

Widespread implementation and enforcement of sustained community mitigation measures, including mask wearing, informed by state and local officials' continual data monitoring and collaboration can help prevent transmission of SARS-CoV-2 and decrease the numbers of COVID-19 cases.

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Face Masks and GDP

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- The sharp increase in confirmed coronavirus cases in the US Sun Belt has led investors to worry about renewed broad lockdowns with large negative effects on GDP. But there are also other ways to reduce infections, including stringent bans on large gatherings and greater use of face masks.
- In particular, we argue that a national face mask mandate could partially substitute for renewed lockdowns. We start by showing that a national mandate would likely increase face mask usage meaningfully, especially in states such as Florida and Texas where masks remain largely voluntary to date.
- We then investigate the link between face masks and coronavirus outcomes. Our analysis includes 1) a US regional panel in which we relate the growth rate of infections and fatalities to the introduction of state face mask mandates, 2) a large country-level cross section in which we relate cumulative infections and fatalities to the lag between the onset of spread and the introduction of a face mask mandate, and 3) a smaller country-level panel in which we relate the growth rate of infections and fatalities to lagged mask usage.
- We find that face masks are associated with significantly better coronavirus outcomes. Since this is true across all three of our models and the results are robust to the inclusion of a number of control variables, it seems to reflect a largely causal impact of masks rather than correlation with other factors (such as reduced mobility or avoidance of large gatherings). Our baseline estimate is that a national mandate could raise the percentage of people who wear masks by 15pp and cut the daily growth rate of confirmed cases by 1.0pp to 0.6%.
- Finally, we translate our results into GDP terms by asking how much our Effective Lockdown Index (ELI) would need to increase in order to cut infections by as much as a national mask mandate, and then converting the ELI impact into a GDP impact using the estimated cross-country relationship between the two. These calculations imply that a face mask mandate could potentially substitute for lockdowns that would otherwise subtract nearly 5% from GDP.

Investors should consider this report as only a single factor in making their investment decision. For Reg AC certification and other important disclosures, see the Disclosure Appendix, or go to www.gs.com/research/hedge.html.

Face Masks and GDP[1]

New US coronavirus cases have risen sharply in recent weeks, with most of the deterioration concentrated in the "Sun Belt," including Florida, Texas, Arizona, and California. This has led investors to worry that renewed lockdowns will again depress economic activity. By our estimates, the increase in our Effective Lockdown Index (ELI)—a combination of official restrictions and actual social distancing data—subtracted 17% from US GDP between January and April, and other countries with even more aggressive restrictions saw even larger economic effects.

Since the first infection wave in March and April, however, it has become clear that broad lockdowns are not the only way to lower virus transmission significantly. For one thing, public health experts have long believed that bans on large gatherings can bring disproportionate benefits. This belief has only grown with a multitude of studies documenting the importance of "super spreader" events, such as those associated with the Shinjeonji Church in South Korea, the Austrian ski resort Ischgl, various European soccer matches, and the celebrations in New Orleans for Mardi Gras.

A more abrupt shift has occurred in the official view on face masks. As late as March 30, the World Health Organization advised that there was "no specific evidence to suggest that the wearing of masks by the mass population has any potential benefit."[2] Since then, however, the public health community's thinking has changed dramatically and many governments have started to require the wearing of face masks.

Should the United States follow these countries and adopt a national face mask mandate? This is inherently a political decision, but we can use our analytical tools to answer three questions that are relevant to it. First, how effective is a face mask mandate in increasing face mask usage? Second, does increased face mask usage lower virus transmission, and if so by how much? And third, how economically valuable is a face mask mandate in terms of reducing the need for broad lockdowns with their well-documented negative effects on GDP?

Face Mask Mandates and Usage

At present, the United States is among the less restrictive countries with respect to face mask mandates. The federal government did issue a national "recommendation" to wear masks in public settings in April, and many state and local governments have taken more stringent measures. However, a recommendation is not a mandate and the governors of both Florida and Texas—the two most heavily affected large states—recently reiterated their opposition to a statewide mask mandate. By contrast, many European countries now have national mask mandates in place, as shown in Exhibit 1, and much of East Asia has strong social norms of mask wearing when sick and during pandemics.

[1] We thank Sid Bhushan and Dan Milo for valuable help with this report.

[2] See Jaqueline Howard, "WHO stands by recommendation to not wear masks if you are not sick," CNN, March 30, 2020.

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Exhibit 1: The US Is Among the Less Restrictive Economies with Respect to Face Mask Mandates

Economy	Region	Mask Policy*	Policy Details*	Date Implemented*
China	East Asia	National Norm/Universal Mask Usage		
Hong Kong	East Asia	National Norm/Universal Mask Usage		
South Korea	East Asia	National Norm/Universal Mask Usage		
Japan	East Asia	National Norm/Universal Mask Usage		
Singapore	Southeast Asia	National Mandate	Everywhere in Public	14-Apr-20
Germany	Europe	National Mandate	Public Transport & Stores	27-Apr-20
India	South Asia	National Mandate	Everywhere in Public	1-May-20
Italy	Europe	National Mandate	Public Transport & Stores	4-May-20
France	Europe	National Mandate	Public Transport & Schools & Stores	11-May-20
Mexico	Americas	National Mandate	Public Transport	20-May-20
UK	Europe	National Mandate	Public Transport	15-Jun-20
Spain	Europe	National Mandate	Public Transport & Stores	21-Jun-20
Brazil	Americas	Regional Mandate	Belo Horizonte, Federal District, Rio Grande do Sul, Rio de Janeiro, Salvador***	
Russia	Central Asia	Regional Mandate	Moscow, St. Petersburg***	
US	Americas	Regional Mandate	CA, CT, DE, DC, HI, IL, KY, ME, MD, MA, MI, NV, NJ, NM, NY, NC, PA, RI, UT, VA, WA	
Switzerland	Europe	National Recommendation	Public Transport & Stores	22-Apr-20
Canada	Americas	National Recommendation	Public Settings**	20-May-20
Australia	Oceania	None		
New Zealand	Oceania	None		
Norway	Scandinavia	None		
Sweden	Scandinavia	None		

* Based on information on MASKS4ALL Website (https://masks4all.co) and Leffler et al. (2020) study.
** Where social distancing is not possible.
*** List not exhaustive.

Source: masks4all.co, Leffler et al. 2020, Goldman Sachs Global Investment Research

What about actual mask usage? In this respect, the US scores somewhat better than one might expect, at least when looking at the national self-reported average. As shown in Exhibit 2, the share of respondents saying that they wear a face mask in public is nearly 90% in East Asia, 80% in Southern Europe, just below 70% in the US and Germany, 30% in the UK, and as low as 10% in Scandinavia. Most countries, including the US, have seen large increases in self-reported mask usage since the start of the pandemic.

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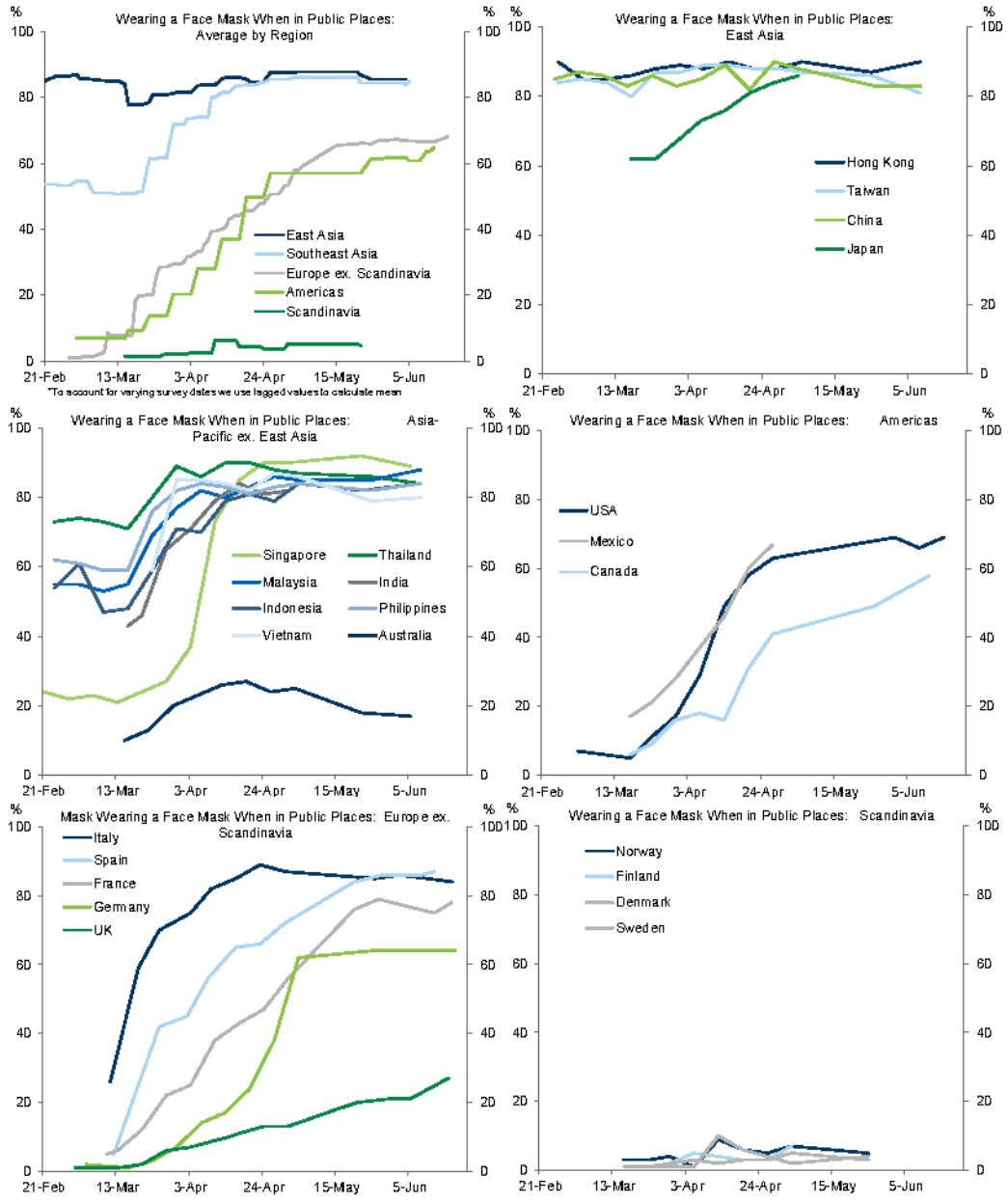
Exhibit 2: The Percentage of People Saying That They Wear a Face Mask in Public Ranges from Less than 10% in Scandinavia to Nearly 90% in East Asia



Source: YouGov, Goldman Sachs Global Investment Research

However, the national data don't tell the full story. As shown in Exhibit 3, face mask usage is highest in the Northeast, where the virus situation has improved dramatically in recent months, and generally lower in the South, where the numbers have deteriorated.[3] For example, only about 40% of respondents in Arizona say that they "always" wear face masks in public, compared with nearly 80% in Massachusetts.

[3] As an aside, note that Minnesota has the lowest self-reported rate of mask usage among larger states in the US. This is interesting because the state is home to a large population of Scandinavian-Americans and Scandinavia has some of the lowest rates of face mask usage in the world.

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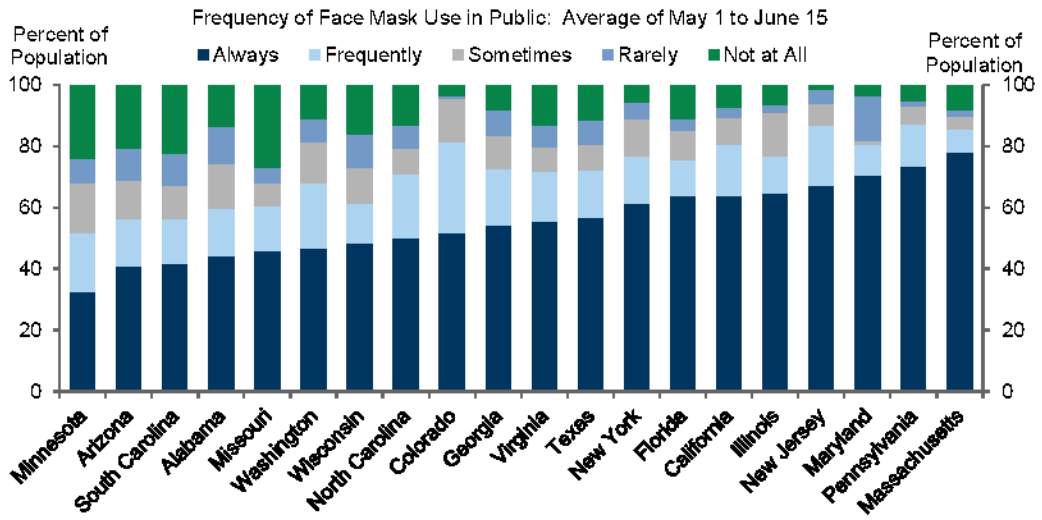
Exhibit 3: The Share "Always" Wearing a Face Mask in Public Ranges from Around 40% in Minnesota and Arizona to 80% in Massachusetts



Source: YouGov, Goldman Sachs Global Investment Research

How effective would a national mask mandate be in pushing mask usage to Southern European or East Asian levels? To investigate this, we turn to a statistical event study that relates the adoption of mask mandates across US states to subsequent changes in self-reported mask usage.

We analyze the impact of face mask mandates issued by 20 US states plus DC between April 8 and June 24 in a state panel. We collect the announcement dates of mask mandates from a study in Health Affairs by Wei Lyu and George Wehby and construct statewide time series of face mask usage outside the home using YouGov Covid-19 Behaviour Tracker respondent-level data. We regress state-level mask usage on various event time dummies around the announcement and include state fixed effects and time fixed effects.[4]

Exhibit 4 shows our estimates of a large and highly significant impact of mandates on mask usage. We estimate that statewide mask mandates gradually raise the percentage of people who "always" or "frequently" wear masks by around 25pp in the 30+ days after signing (left panel). The percent of respondents who "always" wear masks rises by nearly 40pp 30+ days after, reflecting some people switching from "frequently" and other categories to "always" (right panel).

[4] Our mask usage regressions are weighted by state population, focus on states with more than 4 million people (given the small samples in the respondent-level data) and use robust standard errors at the state level. Our sample starts on April 2nd when respondent-level data become available. We also control for cumulative cases per million and cumulative deaths per million.

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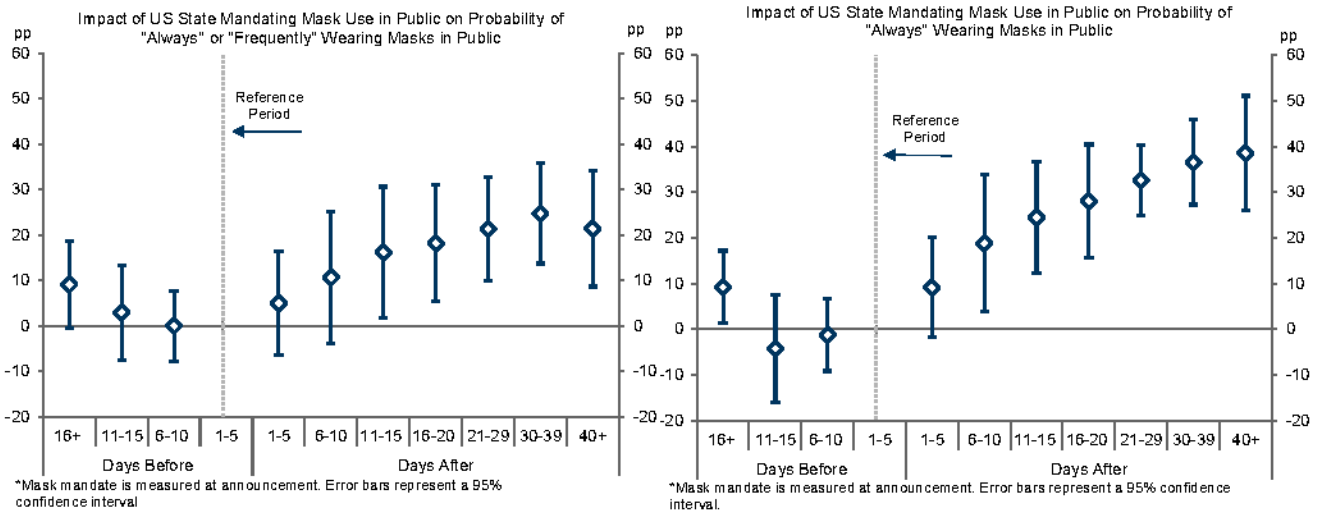
Exhibit 4: Mask Mandates Raise the Percentage of People Who "Always" or "Frequently" Wear Masks by Around 25pp in the 30+ Days After Signing



Source: YouGov, Goldman Sachs Global Investment Research

Exhibit 4 suggests that a national mask mandate could increase US face mask usage by statistically significant and economically large amounts, especially in states such as Florida and Texas that currently don't have a comprehensive mandate and are seeing some of the worst outbreaks. Specifically, we estimate that a national mandate would increase the national average share of people who "always" or "frequently" wear masks by 15pp. This estimate is based on two assumptions. First, we assume that states that currently don't have a mandate—which account for 50% of the population—experience a 25pp rise in mask usage in line with the average response to statewide mandates. Second, we assume that states which already have a state mandate see a 5pp increase in mask usage because of increased focus on the issue.

Face Masks and Virus Outcomes

Approach 1: US County Panel

Does increased face mask usage lower virus transmission, and if so by how much? To investigate this, we turn to three statistical approaches relating face mask usage and mandates to virus spread and fatalities.

Our first approach extends our event study analysis of US state-level mandates to the impact on the growth rate of infections and fatalities. Specifically, we regress county-level growth rates of infections and fatalities on event time dummies around the announcement and control for state fixed effects, time fixed effects, and a rich set of county-level controls.[5]

As shown in Exhibit 5, we estimate that face mask mandates have large and highly

[5] The county-level controls are population density, median house value, median household income, homeownership, pollution, maximum summer temperature, and maximum winter temperature, educational attainment, mean Body Mass Index, and the share of population over 65. We use county population weights and cluster robust standard errors at the state level. Our sample covers 2,373 counties and extends from March 31 to June 24. See Lyu and Wehby (2020).

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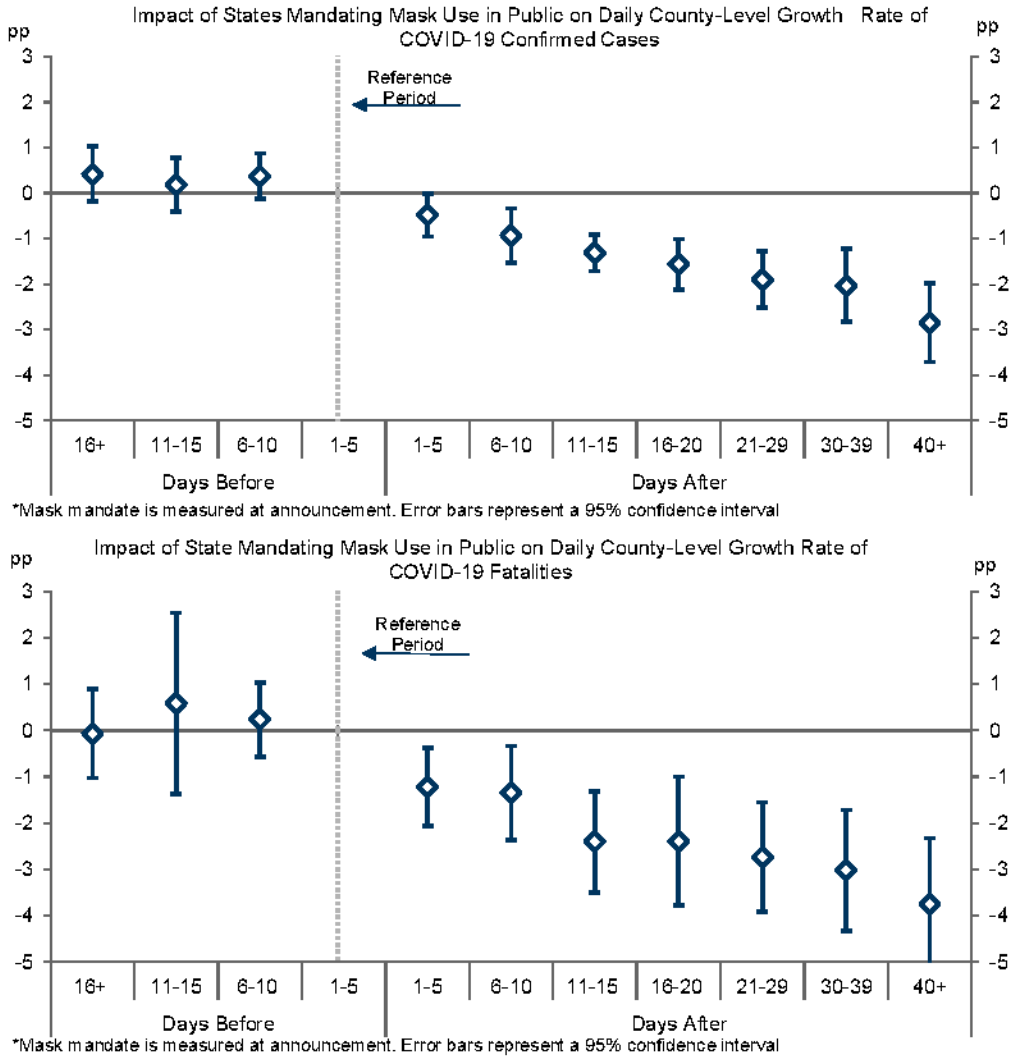
statistically significant effects on health outcomes. Our estimates imply that mask mandates lower the infection growth rate by 1.3pp in the 11-15 days after announcement. Relative to the 5.4% average infection growth rate prior to announcement, the growth rate of infections is cut by 25%. We also estimate significant and somewhat larger declines in the growth rate of COVID-19 fatalities of 2.4pp in the 11-15 days after announcement and of 3.7pp in the 21-29 days after.

Exhibit 5: Mask Mandates Are Associated with Large Declines in COVID-19 Case and Fatality Growth



Source: YouGov, Goldman Sachs Global Investment Research

Approach 2: Large Country Cross-Section

Our second approach is a large country cross section in which we relate cumulative case counts and fatalities to the lag between the onset of spread and the introduction of a face mask mandate, building on a study by Christopher Leffler and co-authors.

Exhibit 6 presents the descriptive relationships graphically by plotting the length of the outbreak before masks were widely adopted against cumulative cases per capita (left panel) and cumulative fatalities per capita (right panel). We measure the start of the outbreak as the day of the first fatality. Both graphs show a positive and statistically

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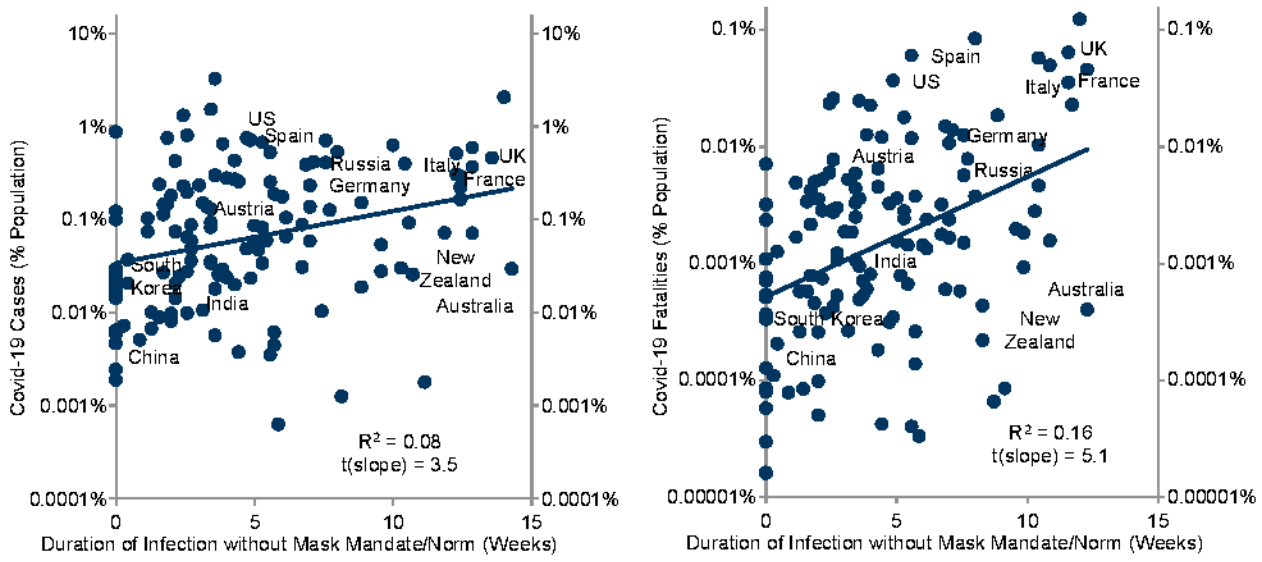
significant slope, indicating that countries which took longer to reach widespread mask usage (whether by policy or cultural norms) suffered more virus cases and fatalities. The better fit for fatalities than cases likely reflects the relatively better measurement of fatalities.

Exhibit 6: Countries Which Took Longer to Reach Widespread Mask Usage Experienced More COVID-19 Cases and Fatalities



Source: masks4all.co, Leffler et al. 2020, Goldman Sachs Global Investment Research

To formalize this finding, Exhibit 7 presents cross-sectional regression models of log cases and log fatalities for around 125 countries. In both regressions, we find statistically significant negative effects of masks on cumulative cases and fatalities after including controls such as the obesity rate, population density, age structure, and testing policy. Our numerical estimates are that cumulative cases grow 17.3% per week without a mask mandate but only 7.3% with a mask mandate, and that cumulative fatalities grow 29% per week without a mask mandate but only 16% with a mask mandate.

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Exhibit 7: Mask Policies and Norms Have Lowered COVID-19 Case Counts and Fatalities

	Country Cross-Section: Impact of Mask Wearing on COVID-19*			
	Log COVID-19 Cumulative Cases per Capita		Log COVID-19 Fatalities per Capita	
	Coefficient [t-stat]	$10^{coefficient}$	Coefficient [t-stat]	$10^{coefficient}$
Intercept	-4.896***	–	-6.953***	–
	[-18.07]		[-23.46]	
Weeks of Infection	0.069***	1.173	0.109***	1.285
	[3.22]		[4.27]	
Weeks of Infection with Mask Mandate/Norm**	-0.039***	0.915	-0.044***	0.904
	[-3.34]		[-3.09]	
Obesity Rate (%)	0.039***	1.093	0.031***	1.074
	[6.53]		[4.77]	
Population Density****	0.181***	1.519		
	[2.73]			
Testing Policy*****	0.570***	3.712		
	[4.49]			
% of Population Over 65			0.034***	1.081
			[3.74]	
Observations	121		131	
R-squared	0.49		0.49	

*Data as of 23 June.
**Calculated upto 28 days before June 23 for Fatalities and 14 days before June 23 for Cases.
***1000 people per square km of land area.
****Proportion of time testing available to anyone showing COVID-19 symptoms (based on Oxford COVID-19 Testing Policy Indicator) from 10 days before first fatality to 14 days before 23 June.

Source: World Bank, Blavatnik School of Government: Oxford, Leffler et al. 2020, Masks4all.co, Goldman Sachs Global Investment Research

Approach 3: Country Panel

Our third approach consists of a smaller country panel in which we relate the daily growth rate of infections and fatalities to lagged self-reported mask usage, plus a number of control variables. There are three main results, illustrated in Exhibit 8.

First, face masks have a large negative impact on infections and fatalities, controlling for population density and income inequality (columns 1 and 4). This negative and significant impact of face masks is robust to controlling for our Effective Lockdown Index (ELI), the share of the population that say they avoid crowded public places (columns 2 and 5), and country and time fixed effects (columns 3 and 6). Our estimates suggest that a 25pp increase in the self-reported mask usage, for instance as a result of a mask mandate, lowers the growth rate of cumulative cases by 1.9pp and the growth rate of cumulative fatalities by 0.8pp.[6]

Second, the share of respondents that avoid crowded public places also has a large and highly significant negative impact on infections and fatalities. This not only suggests a significant role for "super spreader" events, but also strengthens our main results because it implies that the face mask result is not just driven by the correlation between face masks and other risky activities.

Third, the virus impact of mask usage is large, not just in absolute terms but also relative to the effect of economically costly shutdowns (as measured by our ELI). In fact, the coefficients on the percentage of self-reported mask usage are slightly bigger than those on the ELI, which is interesting as both variables are on a 0-100 scale.

[6] Relative to the sample average growth rates of 3.8% and 2.8%, these estimates imply that a mask mandate raising mask usage by 25pp cuts the growth rates of infections and fatalities by nearly one half and one quarter respectively.

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Exhibit 8: Face Masks and Limiting Mass Gathering Lower COVID-19 Case and Fatality Growth

	International Panel: Impact of Mask Wearing on COVID-19 Spread					
	Daily Growth Rate of Confirmed Cases per Million*			Daily Growth Rate of Fatalities per Million*		
	(1)	(2)	(3)	(4)	(5)	(6)
Intercept	-12.37	4.29	8.05	-6.80	4.56	2.32
	[-3.83]***	[0.68]	[1.27]	[-3.77]***	[1.43]	[1.06]
% of Pop. Wearing Maks in Public, Lagged**	-0.11	-0.07	-0.08	-0.06	-0.03	-0.03
	[-5.2]***	[-3.21]***	[-3.63]***	[-5.05]***	[-2.00]**	[-2.19]**
GS Effective Lockdown Index, Lagged**		-0.05	-0.07		-0.04	-0.04
		[-1.59]	[-3.00]***		[-1.94]*	[-2.28]**
% of Pop.Avoiding Crowded Public Places, Lagged**		-0.23	-0.15		-0.15	-0.11
		[-3.11]***	[-2.39]**		[-4.79]***	[-2.30]**
Income Inequality	0.54	0.57	1.10	0.32	0.32	0.43
	[4.96]***	[5.76]***	[2.63]***	[5.98]***	[5.71]***	[2.59]***
Population Density	0.01	0.01	0.02	0.01	0.01	0.01
	[3.83]***	[3.05]***	[2.89]***	[3.03]***	[2.31]**	[3.74]***
Time FEs	No	No	Yes	No	No	Yes
Country FEs	No	No	Yes	No	No	Yes
Num. of Countries	22	18	18	22	18	18
Observations	2086	1743	1743	1711	1491	1491
R-squared	0.19	0.43	0.69	0.11	0.29	0.51

Note: T-statistics in brackets and robust standard errors clustered by country.

* Growth rates are natural log differences*100.

** Lagged 14 days for cases per million regressions; lagged 28 days for fatalities per million regressions.

Source: JHU CSSE, YoGov, Goldman Sachs Global Investment Research

The Impact of a Mandate on Infections

Before we translate our statistical results into a baseline estimate of the impact of face mask mandates on virus outcomes, we need to address two potential concerns about our analysis up front.

The first concern is that the correlation between face masks and virus outcomes might reflect the effect of other unobserved forms of cautious behavior that are correlated with mask mandates or usage, instead of a truly *causal* effect of masks. But there are some reasons to believe that this type of bias in not a big issue for our analysis. Not only do we obtain remarkably similar estimates across our three approaches, but we also control for a number of other observable forms of cautious behavior. Specifically, our cross-country results on masks include our Effective Lockdown Index among the explanatory variables, and they are largely unchanged when we include the share of respondents who say they stay home from work, don't touch objects, improve personal hygiene, avoid contact with tourists, avoid raw meat, and don't send their children to school.[7]

The second potential concern is that our main results are based on confirmed infections, which can be distorted by a lack of testing. However, it is important to note that this would, if anything, lead to an *understatement* of the effect assuming that increases in testing are positively correlated with increases in mask usage. Moreover, we control for

[7] The cross-country panel and cross-county panel results are also robust to controlling for the lagged levels of fatalities and infections per capita, which helps address the concern that the mask effects pick up the impact of other forms of unobserved cautious behavior in response to the size of the outbreak.

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testing regime indicators in our cross-sectional regression, and we obtain generally similar estimates for fatalities—which are better measured—across all three of our approaches.

So what is a reasonable baseline estimate of the impact of a US national mask mandate on the growth rate of confirmed infections? To generate such an estimate, we apply our country panel results separately to two groups of US states, namely ones with and without a state-level mask mandate in place.

States that currently don't have a state-level mandate account for 40% of US total confirmed cases, 45% of US GDP, half of the population, and two-thirds of new infections. This group has also experienced an average daily growth rate in confirmed infections of 2.9% in the past 7 days. Based on our analysis of state-level mandates, we estimate that a national mask mandate would raise mask usage by 25pp in these states. Our country panel shows that a 25pp increase in self-reported mask usage lowers the infection growth rate by 1.9pp (or just over 60%). The national mandate could therefore lower the daily growth rate in the group of states without a mandate from 2.9% to just over 1%.

States that currently do have a mandate have experienced a lower average daily growth rate in confirmed infections of 0.8% in the past 7 days. Combined with our assumption that a national mandate would lead to a smaller increase in mask usage of 5pp through extra awareness in this group of states, our country panel suggests a 0.4pp decline in the infection growth rate to 0.4-0.5%.

Combining the estimates for these two groups of states, we estimate that a national mandate could cut the national average growth rate of infections by nearly 1.0pp to 0.6-0.7%.

The Impact of a Mandate on GDP

If a face mask mandate meaningfully lowers coronavirus infections, it could be valuable not only from a public health perspective but also from an economic perspective because it could substitute for renewed lockdowns that would otherwise hit GDP.

How big is this potential effect? To generate an answer, we proceed in two steps. First, we use our cross-country panel analysis to ask how much our effective lockdown index (ELI) would need to increase in order to lower the daily case growth rate by 1.0pp, i.e. the estimated impact of a national face mask mandate. The answer is an increase in our ELI of 16pp.

Second, we ask how much a 16pp ELI increase would subtract from the level of GDP. As shown in Exhibit 9, the cross-country relationship implies that such an increase might reduce GDP by just under 5%.

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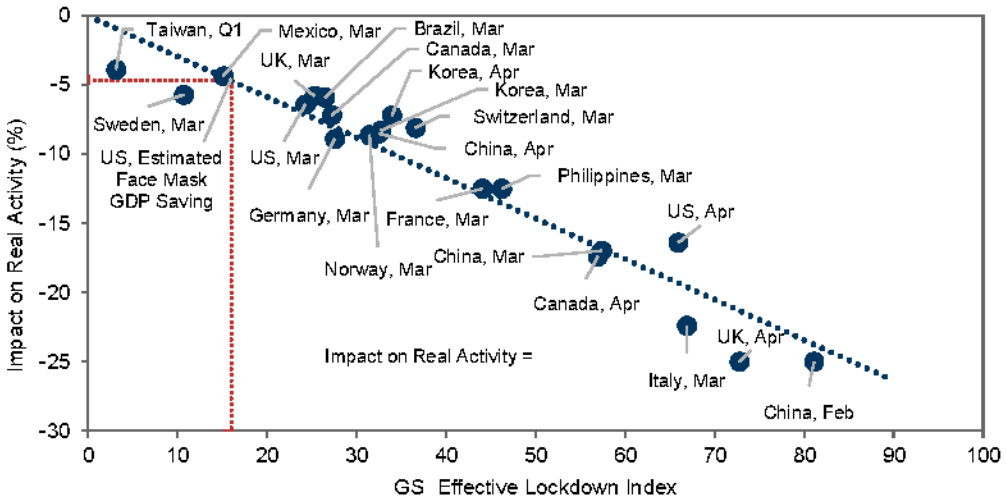
Exhibit 9: A Close Relationship Between the ELI and GDP



Note: Impact on real activity is estimated where data is not available.

References to China are to Mainland China

Source: Goldman Sachs Global Investment Research

Thus, the upshot of our analysis is that a national face mask mandate could potentially substitute for renewed lockdowns that would otherwise subtract nearly 5% from GDP. It is important to recognize that this estimate is quite uncertain because it is based on a number of statistical relationships that are all measured with error. Despite the numerical uncertainty, however, our analysis suggests that the economic benefit from a face mask mandate and increased face mask usage could be sizable.

So will the US adopt a national face mask mandate? This is uncertain, partly because masks have become such a politically and culturally charged issue. However, even in the absence of a national mandate, state and local authorities might well broaden mandates in ways that ultimately mimic the impact of a national mandate. Either way, our analysis suggests that the economy could benefit significantly from such moves, especially when compared with the alternative of a return to broader lockdowns.

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Disclosure Appendix

Reg AC

We, Jan Hatzius, Daan Struyven and Isabella Rosenberg, hereby certify that all of the views expressed in this report accurately reflect our personal views, which have not been influenced by considerations of the firm's business or client relationships.

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Face Masks, Public Policies and Slowing the Spread of COVID-19: Evidence from Canada
Alexander Karaivanov, Shih En Lu, Hitoshi Shigeoka, Cong Chen, and Stephanie Pamplona
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ABSTRACT

We estimate the impact of mask mandates and other non-pharmaceutical interventions (NPI) on COVID-19 case growth in Canada, including regulations on businesses and gatherings, school closures, travel and self-isolation, and long-term care homes. We partially account for behavioral responses using Google mobility data. Our identification approach exploits variation in the timing of indoor face mask mandates staggered over two months in the 34 public health regions in Ontario, Canada's most populous province. We find that, in the first few weeks after implementation, mask mandates are associated with a reduction of 25 percent in the weekly number of new COVID-19 cases. Additional analysis with province-level data provides corroborating evidence. Counterfactual policy simulations suggest that mandating indoor masks nationwide in early July could have reduced the weekly number of new cases in Canada by 25 to 40 percent in mid-August, which translates into 700 to 1,100 fewer cases per week.

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A Data Appendix is available at https://github.com/C19-SFU-Econ

1 Introduction

When government policies to stem the spread of COVID-19 were introduced in early 2020, the best available evidence supporting them was provided by studies of previous epidemics, epidemiological modeling, and case studies (OECD, 2020). Even when the efficacy of a given precaution in reducing COVID-19 transmission has been established, significant doubts regarding the usefulness of specific policy measures may persist due to uncertainty regarding adherence to the rules and other behavioral responses. For example, even though several observational studies, mostly in medical setting, have shown that face masks reduce the transmission of COVID-19 and similar respiratory illnesses (see Chu et al. (2020) for a comprehensive review), a face mask mandate may not be effective in practice if it fails to increase the prevalence of mask wearing (compliance), or if it leads to increased contacts due to a false sense of security. It is therefore important to directly evaluate and quantify the relationship between various policy measures and the rate of propagation of COVID-19.

The low cost and high feasibility of mask mandates relative to other containment measures for COVID-19 has generated keen interest worldwide for studying their effectiveness. This attention has been compounded by substantial variation, across jurisdictions and over time, in official advice regarding the use of masks. Figure B1 in the Appendix plots self-reported mask usage in select countries (Canada, United States, Germany and Australia) in the left panel, and across Canadian provinces in the right panel. The figure shows large differences in mask usage, both across countries and within Canada.[1]

We estimate and quantify the impact of mask mandates and other non-pharmaceutical interventions (NPI) on the growth of the number of COVID-19 cases in Canada. Canadian data has the important advantage of allowing two complementary approaches to address our objective. First, we estimate the effect of mask mandates by exploiting within-province geographic variation in the timing of indoor face mask mandates across 34 public health regions (PHUs) in Ontario, Canada's most populous province with a population of nearly 15 million or roughly 39% of Canada's population (Statistics Canada, 2020). The advantage of this approach is that it exploits variation over a relatively small geographic scale (PHU), holding all other province-level policies or events constant. In addition, the adoption of indoor face mask mandates in these 34 sub-regions was staggered over approximately two months, creating sufficient intertemporal policy variation across the PHUs.

[1] We show mask usage for the U.S. and Germany because related work by Chernozhukov et al. (2020) and Mitze et al. (2020) studies the effect of mask mandates in these countries respectively. We show Australia as an example of a country which did not mandate mask usage, except for Melbourne in late July. See Hatzius et al. (2020) for more cross-country comparisons of mask usage.

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Second, we evaluate the impact of NPIs in Canada as a whole, by exploiting variation in the timing of policies across the country's ten provinces. By studying inter-provincial variation, we are able to analyze the impact of not only mask mandates, but also other NPIs, for which there is little or no variation across Ontario's PHUs (regulations on businesses and gatherings, schooling, travel and long-term care). In addition, our province-level data include both the closing period (March-April) and the gradual re-opening period (May-August), providing variation from both the imposition and the relaxation of policies.

Our panel-data estimation strategy broadly follows the approach of Chernozhukov, Kasahara and Schrimpf (2020), hereafter CKS (2020), adapted to the Canadian context. We allow for behavioural responses (using Google Community Mobility Reports geo-location data as proxy for behaviour changes and trends), as well as lagged outcome responses to policy and behavioral changes. Our empirical approach also allows current epidemiological outcomes to depend on past outcomes, as an information variable affecting past policies or behaviour, or directly, as in the SIR model framework.

We find that, in the first few weeks after their introduction, mask mandates are associated with an average reduction of 25 to 31% in the weekly number of newly diagnosed COVID-19 cases in Ontario, holding all else equal. We find corroborating evidence in the province-level analysis, with a 36 to 46% reduction in weekly cases, depending on the empirical specification. Furthermore, using survey data, we show that mask mandates increase self-reported mask usage in Canada by 30 percentage points, suggesting that the policy has a significant impact on behaviour. Jointly, these results suggest that mandating indoor mask wear in public places is a powerful policy measure to slow the spread of COVID-19, with little associated economic disruption at least in the short run.[2]

Counterfactual policy simulations using our empirical estimates suggest that mandating indoor masks nationwide in early July could have reduced weekly new cases in Canada by 25 to 40% on average by mid-August relative to the actually observed numbers, which translates into 700 to 1,100 fewer cases per week.

We also find that the most stringent restrictions on businesses and gatherings observed in our data are associated with a decrease of 48 to 57% in weekly cases, relative to a lack of restrictions. The business/gathering estimates are, however, noisier than our estimates for mask mandates and do not retain statistical significance in all specifications; they appear driven by the smaller provinces and the re-opening period (May to August). School closures and travel restrictions are associated with a large decrease in weekly case growth in the

[2]Hatzius et al. (2020) estimate that a national mask mandate in the USA could replace alternative restrictions costing 5% of GDP.

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closing period. Our results on business/gathering regulations and school closure suggest that reduced restrictions and the associated increase in business or workplace activity and gatherings or school re-opening can offset, in whole or in part, the estimated effect of mask mandates on COVID-19 case growth, both in our sample and subsequently.

An additional contribution of this research project is to assemble, from original official sources only, and make publicly available a complete dataset of COVID-19 cases, deaths, tests and policy measures in all 10 Canadian provinces.[3] To this end, we constructed, based on official public health orders and announcements, time series for 17 policy indicators regarding face masks, regulations on businesses and gatherings, school closures, travel and self-isolation, and long-term care homes.

Our paper relates most closely to two recent empirical papers on the effects of mask mandates using observational data.[4] CKS (2020) and Mitze et al. (2020) study the effect of mask mandates in the United States and Germany, respectively. CKS (2020), whose estimation strategy we follow, exploit U.S. state-level variation in the timing of mask mandates for employees in public-facing businesses, and find that these mandates are associated with 9 to 10 percentage points reduction in the weekly growth rate of cases. This is substantially smaller that our estimates, possibly because the mask mandates that we study are much broader: they apply to all persons rather than just employees, and most apply to all indoor public spaces rather than just businesses. Mitze et al. (2020) use a synthetic control approach and compare the city of Jena and six regions in Germany that adopted a face mask policy in early to mid April 2020, before their respective state mandate. They find that mandatory masks reduce the daily growth rate of cases by about 40%.

Our paper has several advantages compared to the above two papers. First, we exploit both regional variation within the same province (like Mitze et al., 2020) and provincial variation in the whole country (like CKS, 2020), and find similar results, which strengthens the validity of our findings. Second, we show that self-reported mask usage has increased after introducing mask mandates. We view this "first-stage" result on mask usage as informative, as the effectiveness of any NPI or public policy critically depends on the compliance rate. Moreover, this result mitigates possible concerns that the estimated mask mandate effect on COVID-19 case growth may be caused by factors other than mask policy. Third, a key

[3]All data are available for download at https://github.com/C19-SFU-Econ. The COVID-19 cases, deaths and tests data that we collected and use in this paper incorporate all official ex-post revisions as of mid-August, unlike data from the Government of Canada COVID-19 website or other aggregator websites.

[4]Howard et al. (2020), a comprehensive review of the medical literature, stresses that "no randomized controlled trial (RCT) on the use of masks as source control for SARS-CoV-2 has been published." It is unlikely that an RCT on masks' effectiveness against COVID-19 will be feasible or ethical during the pandemic.

difference between our paper and CKS (2020) is that we evaluate the effect of *universal* (or *community*) mandatory indoor mask wearing for the public rather than the effect of mandatory mask wearing for *employees only*.[5] While other factors such as differences in mask wear compliance between Canada and the U.S. may contribute to the different estimated magnitude of the policy impact, our results suggest that more comprehensive mask policies can be more effective in reducing the case growth rate.

Other Related Literature

Abaluck et al. (2020) discuss the effectiveness of universal adoption of homemade cloth face masks and conclude that this policy could yield large benefits, in the $3,000–$6,000 per capita range, by slowing the spread of the virus. The analysis compares countries with pre-existing norms that sick people should wear masks (South Korea, Japan, Hong Kong and Taiwan) and countries without such norms.[6]

In the medical literature, Prather et al. (2020) argue that masks can play an important role in reducing the spread of COVID-19. Howard et al. (2020) survey the medical evidence on mask efficiency and recommend public use of masks in conjunction with existing hygiene, distancing, and contact tracing strategies. Greenhalgh et al. (2020) provide evidence on the use of masks during non-COVID epidemics (influenza and SARS) and conclude that even limited protection could prevent some transmission of COVID-19. Leung et al. (2020) study exhaled breath and coughs of children and adults with acute respiratory illness and conclude that the use of surgical face masks could prevent the transmission of the human coronavirus and influenza virus from symptomatic individuals. Meyerowitz et al. (2020) present a recent comprehensive review of the evidence on transmission of the virus and conclude that there is strong evidence from case and cluster reports indicating that respiratory transmission is dominant, with proximity and ventilation being key determinants of transmission risk, as opposed to direct contact or fomite transmission.

Our paper also complements recent work on COVID-19 policies in Canada. Mohammed et al. (2020) use public opinion survey data to study the effect of changes in mask-wear policy recommendations, from discouraged to mandatory, on the rates of mask adoption and public trust in government institutions. They show that Canadians exhibit high compliance with mask mandates and trust in public health officials remained consistent across time. Yuksel et al. (2020) use an outcome variable constructed from Apple mobility data along

[5]Lyu and Wehby (2020) provide suggestive evidence that community mask mandates are more effective than employees-only mandates.

[6]The authors report average daily case growth rate of 18% in countries with no pre-existing mask norms vs. 10% in countries with such norms. On a weekly basis, this translates to a reduction of 49 log points ($100(\log(1.18^7) - \log(1.1^7))$) in case growth, or 39% reduction in weekly cases.

with weather data and lagged COVID-19 cases or deaths as dependent variables to study compliance with social distancing measures.

2 Data

We use three main data sources, respectively for epidemiological variables, NPI and mask mandates, and behavioral responses. The time period is from the start of detected community transmission in Canada in March to mid-August, 2020.

We located and accessed the original official sources to collect a complete dataset of COVID-19 cases, deaths, tests and policy measures in all ten Canadian provinces.[7] In addition, our data include cases and policy measure indicators for each of the 34 public health units (PHUs) in Ontario. A detailed description is provided in the data source files shared at the project's Github webpage.

Implementation dates of NPIs and other public policies were collected from government websites, announcements, public health orders and staged re-opening plans collected from their official sources. In the national data, the raw policy measures data contain the dates or enactment and relaxation (if applicable) of 17 policy indicators including: mandatory mask wear; closure and re-opening of retail and non-essential businesses, restaurants, recreation facilities, and places of worship; school closures; limits on events and gatherings; international and domestic travel restrictions and self-isolation requirements; restrictions on visits and staff movement in long-term care homes. All policy indicator variables are defined in Table C1 in the Appendix.[8] Since many of these indicators are highly correlated with each other, we combine them into five policy aggregates in the empirical analysis (see Table A17 and Section 3.2). In the Ontario PHU data, the implementation dates of mask mandates and the relaxation dates of policies for businesses and gatherings vary across PHUs. Decisions about the former were made at the PHU level, while decisions about the latter were made by the province, which classified PHUs into three groups, with some exceptions.

Regarding behavioral responses, we use the Google COVID-19 Community Mobility Reports, which summarize daily cellphone geo-location data for each province as indices calculated relative to the median value for the same day of the week in the five-week baseline

[7] The provinces differ in the ease of accessibility of their official time series of COVID-19 cases, deaths and test numbers. In some cases, we located and used the hidden json sources feeding the public dashboard charts. In few instances in which data were not available, we used the numbers reported in the daily provincial government announcements. All COVID-19 outcome data sources are referenced and web-linked in Appendix Table C3.

[8] Additional survey data on mask usage is described and used in Section 4.4.

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period January 3 to February 6, 2020.[9] In Ontario, these location data are available for each of the 51 first-level administrative divisions (counties, regional municipalities, single-tier municipalities and districts).[10]

3 Empirical method

We follow the approach of CKS (2020), but modify and adapt it to the Canadian context. The empirical strategy uses the panel structure of the outcome, policy and behavioral proxy variables, and includes lags of outcomes as information, following the causal paths suggested by the epidemiological SIR model (Kermack and McKendrick, 1927). Specifically, we estimate the effect of policy interventions on COVID-19 outcomes while controlling for information and behaviour. In contrast to CKS (2020) and Hsiang et al. (2020), who study variation in NPIs across U.S. states or across countries, our identification strategy exploits policy variation at the sub-provincial level (Ontario's PHUs) in addition to cross-province variation, and our data captures both the closing down and gradual re-opening stages of the epidemic.

3.1 Estimation strategy

The main data used in our empirical analysis are summarized below; Section 3.2 describes the variables in detail. Everywhere i denotes province for national analysis, and health region (PHU) for Ontario analysis, and t denotes time measured in days.

1. Outcomes, Y_{it} – growth rate of weekly cases or deaths.

2. Information, I_{it} – lagged outcomes, i.e. past levels or growth rate of cases (or deaths). We also consider a specification that includes the past cases/deaths and case/death growth at the national level as additional information variables.

3. Behavioral responses, B_{it} – Google mobility data capturing changes in people's geolocation relative to a baseline period in January-February.

4. Policy/NPIs, P_{it} – for the national analysis, five policy aggregates by province and date; for the Ontario analysis, two policy variables (mask mandates and regulation on business and gathering) by PHU and date.

[9] The reports are available for download at https://www.google.com/covid19/mobility/.

[10] Each of these divisions is either entirely (in most cases) or predominantly located within a single PHU. In cases where a PHU corresponds to multiple divisions, 2016 Census population counts were used as weights to compute the PHU's mobility index.

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5. Controls, W_{it} – province or PHU fixed effects, growth rate of weekly new COVID-19 tests, and a time trend.

To assess and disentangle the impact of NPIs and behavioral responses on COVID-19 outcomes, we estimate the following equation:

$$Y_{it} = \alpha B_{it-l} + \pi P_{it-l} + \mu I_{it} + \delta_Y W_{it} + \varepsilon_{it}^Y \tag{1}$$

where l denotes a time lag measured in days. Equation (1) models the relationship between COVID-19 outcomes, Y_{it}, and lagged behaviour, B_{it-l}, lagged policy measures, P_{it-l} and information (past outcomes), $I_{it} = Y_{it-l}$. For case growth as the outcome, we use $l = 14$. For deaths growth as the outcome, we use $l = 28$.[11] The choice of these lags is discussed in Appendix D.

By including lagged outcomes, our approach allows for possible endogeneity of the policy interventions P_{it}, that is, the introduction or relaxation of NPIs based on information on the level or growth rate of cases or deaths. Also, past cases may be correlated with (lagged) government policies or behaviors that may not be fully captured by the policy and behaviour variables.

In Appendix Table A18, we also report estimates of the following equation:

$$B_{it} = \beta P_{it} + \gamma I_{it} + \delta_B W_{it} + \varepsilon_{it}^B \tag{2}$$

which models the relationship between policies P_{it}, information, I_{it} (weekly levels or growth of cases or deaths) and behaviour, B_{it}. It is assumed that behaviour reacts to the information without a significant lag. We find strong correlation between policy measures and the Google mobility behavioral proxy measure.

Equation (1) captures both the direct effect of policies on outcomes, with the appropriate lag, as well as the potential indirect effect on outcomes from changes in behaviour captured by the changes in geo-location proxy B_{it-l}. In Appendix Tables A19 and A20, we also report estimates of equation (1) without including the behavioral proxy, that is, capturing the total effect of policies on outcomes. Since our estimates of the coefficient α in equation (1) are not significantly different from zero, the results without controlling for the behavioral proxy are very similar to those from estimating equation (1).

[11] Our lag for deaths is one week longer than that used by CKS (2020). The difference is due to additional evidence from the medical literature and the construction of the weekly variables (see Appendix D).

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3.2 Variables and descriptive analysis

Outcomes. Our main outcome of interest is the growth rate of weekly new positive COVID-19 cases as defined below.[12] We use weekly outcome data to correct for the strong day-of-the-week effect present in COVID-19 outcome data.[13] Weekly case growth is a metric that can be helpful in assessing trends in the spread of COVID-19, and it is highlighted in the World Health Organization's weekly epidemiological updates (see, for example, World Health Organization (2020)).

Specifically, let C_{it} denote the cumulative case count up to day t and define ΔC_{it} as the weekly COVID-19 cases reported for the 7-day period ending at day t:

$$\Delta C_{it} \equiv C_{it} - C_{it-7}.$$

The weekly case (log) growth rate is then defined as:

$$Y_{it} = \Delta \log(\Delta C_{it}) = \log(\Delta C_{it}) - \log(\Delta C_{it-7}), \tag{3}$$

that is, the week-over-week growth in cases in region i ending on day t.[14] The weekly death growth rate is defined analogously, using cumulative deaths data.

Policy. In the Ontario analysis, we exploit regional variation in the timing of indoor mask mandates staggered over two months in the province's 34 regions ("public health units" or PHUs). Figure 1 displays the gradual introduction of mask mandates across the 34 PHUs in Ontario. The exact implementation dates of the mask mandates are reported in Table C2. Mandatory indoor masks were introduced first in the Wellington-Dufferin-Guelph PHU on June 12 and last in the Northwestern PHU on August 17.[15]

[12] We also report results using the growth rate of deaths as supplemental analysis in Section 4.5.

[13] Figures B9 and B10 in the Appendix respectively display the weekly and daily cases, deaths and tests in each Canadian province over time. There are markedly lower numbers reported on weekends or holidays.

[14] To deal with zero weekly values, which mostly occur in the smaller regions, as in CKS (2020), we replace log(0) with -1. We also check the robustness of our results by adding 1 to all ΔC_{it} observations before taking logs, by replacing log(0) with 0, and by using population weighted least squares; see Tables A5 and A8.

[15] There is no PHU-wide mask mandate in Lambton as of August 31, but its main city, Sarnia, enacted a mask mandate on July 31.

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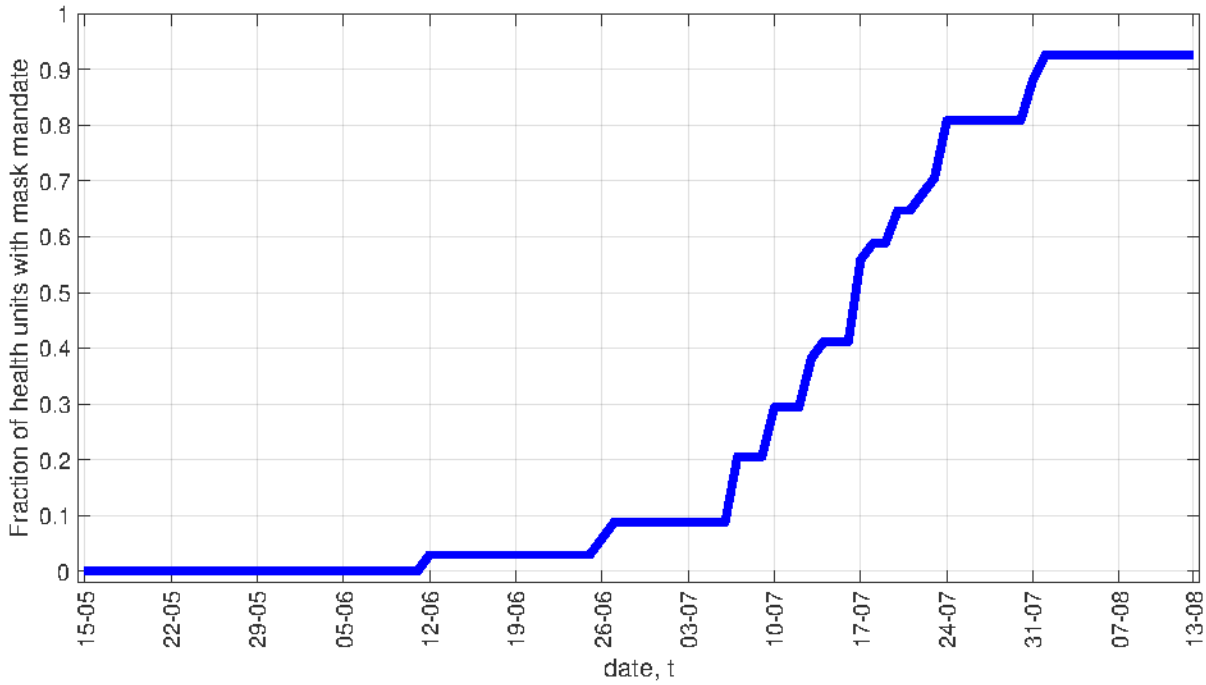
Figure 1: Ontario - mask mandates over time



Notes: There are a total of 34 public health units (PHU) in Ontario. See Table C2 for the exact date of mask mandate implementation in each PHU.

In the province-level analysis, we assign numerical values to each of the 17 policy indicators listed in Table C1 in Appendix C. The values are on the interval [0,1], with 0 meaning no or lowest level of restrictions and 1 meaning maximal restrictions. A policy value between 0 and 1 indicates partial restrictions, either in terms of intensity (see more detail and the definitions in Table C1) or by geographical coverage (in large provinces). The numerical values are assigned at the daily level for each region (PHU or province, respectively for the Ontario and national results), while maintaining comparability across regions.

Many NPIs were implemented at the same time, both relative to each other and/or across regions (especially during the March closing-down period), which causes many of the policy indicators to be highly correlated with each other (see Appendix Table A4). To avoid multi-collinearity issues, we group the 17 policy indicators into 5 policy aggregates via simple averaging: (i) *travel*, which includes international and domestic travel restrictions and self-isolation rules; (ii) *school*, which is an indicator of provincial school closure; (iii) *business/gathering*, which comprises regulations and restrictions on non-essential businesses and retail, personal businesses, restaurants, bars and nightclubs, places of worship, events,

gyms and recreation, and limits on gathering; (iv) *long-term care (LTC)*, which includes NPIs governing the operation of long-term care homes (visitor rules and whether staff are required to work on a single site) and (v) *mask* which takes value 1 if an indoor mask mandate has been introduced, 0 if not, or value between 0 and 1 if only part of a province has enacted such policy.[16]

The five policy aggregates are constructed at the daily level and capture both the closing-down period (an increase in the numerical value from 0 toward 1) and the re-opening period (decrease in the numerical value toward zero). In comparison, the policy indicators compiled by Raifman (2020) for the USA used in CKS (2020) are binary "on (1)"/"off (0)" variables.[17] For consistency with the weekly outcome and information variables and the empirical model timing, we construct the policy aggregates P_{it}^{j} used in the regressions (where j denotes policy type) by taking a weekly moving average of the raw policy data, from date $t-6$ to date t.

Figure 2 plots the values of the 5 policy aggregates over time for each of the 10 provinces. Travel restrictions, school closures (including Spring and Summer breaks) and business closures were implemented in a relatively short period in the middle of March. There is some variation in the travel policy aggregate since some Canadian provinces (the Atlantic provinces and Manitoba) implemented inter-provincial domestic travel or self-isolation restrictions in addition to the federal regulations regarding international travel. Restrictions on long-term care facilities were introduced more gradually. In the re-opening period (May-August), there is also more policy intensity variation across the provinces, especially in the business and gatherings category, as the different provinces implemented their own re-opening plans and strategies. Mask mandates were first introduced in Ontario starting from June in some smaller PHUs and early July in the most populous PHUs such as Toronto, Ottawa and Peel (see Appendix Table C2). In Quebec, indoor masks were mandated province-wide on July 18. Nova Scotia and Alberta's two main cities implemented mask mandates on July 31 and August 1, respectively.

[16] We do not use provincial declarations of emergency in our analysis as they are mostly legal tools enabling other restrictions rather than restrictions *per se*.

[17] The daily numerical values for each of the 17 basic policy indicators and the 5 policy aggregates for each province and date are available on the project's Github repository.

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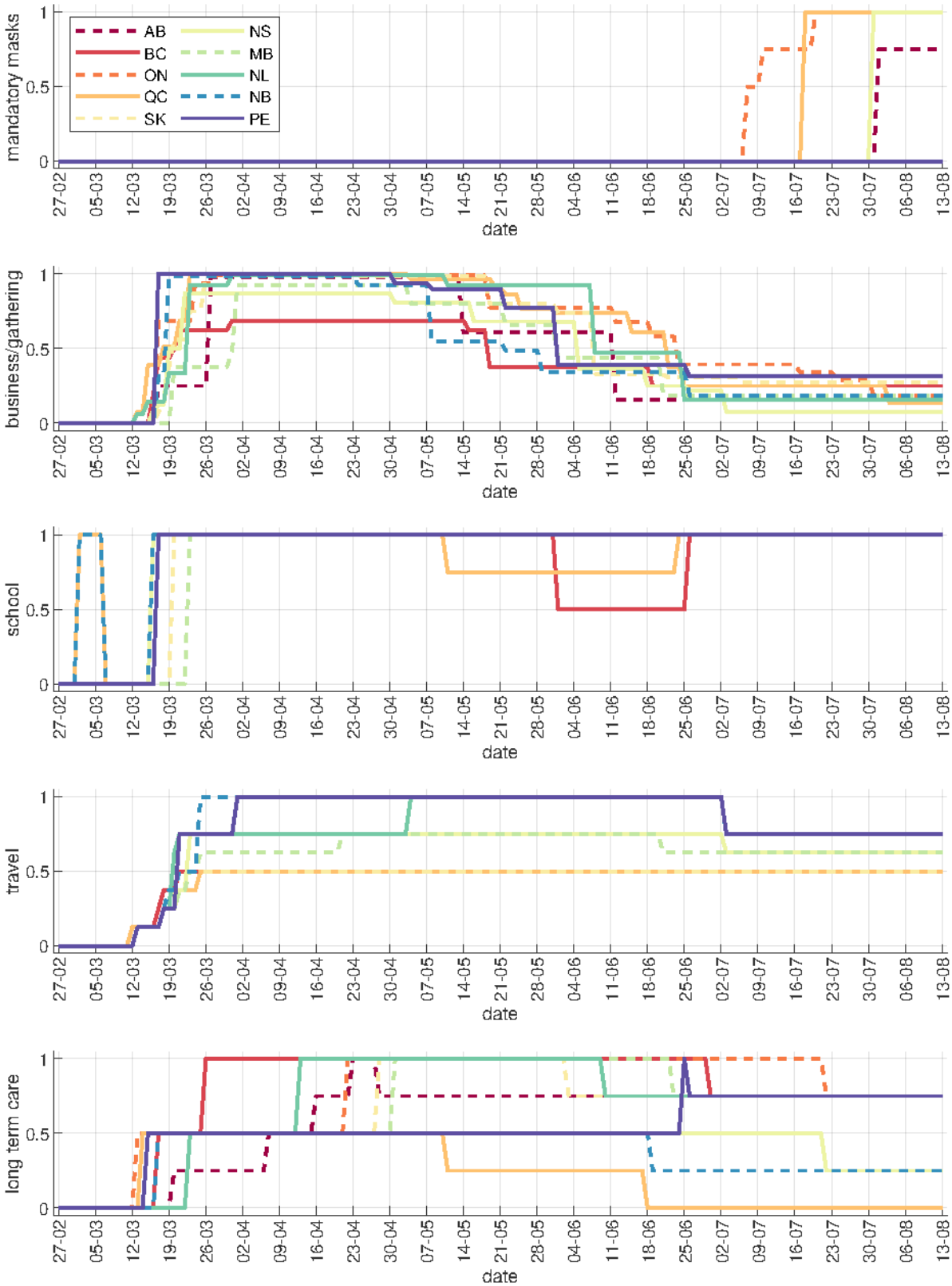
Figure 2: Policy aggregates - Canada



Notes: The figure plots the numerical values of the 5 policy aggregates (Mask, Business /gathering, School, Travel and Long-term care, LTC) over time, for each of the 10 provinces. The mask policy values for ON reflect the gradual adoption of mandates and the respective PHUs population sizes.

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There are two empirical challenges specific to our Canadian context and data. The first challenge is the presence of small provinces and sub-regions with very few COVID-19 cases or deaths. In Section 4.3, we perform a number of robustness checks using different ways of handling the observations with very few cases (in particular zero cases). The second data limitation is that there are only 10 provinces in Canada and 34 public health units in Ontario, unlike the 51 U.S. jurisdictions in CKS (2020). To account for the resulting small number of clusters in the estimation, we compute and report wild bootstrap standard errors and p-values, as proposed by Cameron et al. (2008).[18] On the flip side, our data has the advantage of a longer time horizon (March to August) and non-binary, more detailed policy variables compared to Raifman et al. (2020).

Behaviour proxy. We follow CKS (2020) and other authors in interpreting the location change indices from the Google Community Mobility reports as proxies for changes in people's behaviour during the pandemic, keeping in mind that location is only one aspect of behaviour relevant to COVID-19. The general pattern in the data (see Figure B3) shows sharply reduced frequency of recorded geo-locations in shops, workplaces and transit early in the pandemic (March), with a subsequent gradual increase back toward the baseline (except for transit), and a flattening out in July and August.

Several of the six location indicators (retail, grocery and pharmacy, workplaces, transit, parks and residential) are highly correlated with each other (see Tables A1 and A2) and/or contain many missing observations for the smaller provinces. To address these data limitations and the possible impact of collinearity on the estimation results, we use as proxy for behavioral changes the simple average of the following three mobility indicators: "retail", "grocery and pharmacy" and "workplaces". To be consistent with the weekly outcome variables and to mitigate day-of-week behavioural variation, we construct the Behaviour proxy B_{it} by taking a weekly moving average of the $\frac{1}{3}$ (retail + grocery and pharmacy + workplaces) data, from date $t-6$ to date t.[19,20] As a result, our empirical analysis uses weekly totals (for cases, tests and deaths) or weekly moving averages (for policies and the behaviour proxy) of all variables recorded on daily basis.[21]

[18] Alternative methods for computing the standard errors are explored in Section 4.3.

[19] We drop the "transit", "parks", and "residential" location indicators because, respectively, 10.6%, 13.7%, and 2.8% of the observations are missing in the provincial data, and 20.7%, 52.1%, and 11.1% are missing in the Ontario data. The "transit" and "residential" variables are also highly correlated with the three indicators we include in our aggregate behaviour proxy B_{it}. Furthermore, the "parks" indicator does not have clear implication for COVID-19 outcomes.

[20] In the Ontario analysis, 1.4% of the B_{it} values are imputed via linear interpolation.

[21] In estimation equation (1), we take moving average from date $t-14$ to date $t-20$ for policies and behaviour when the outcome is weekly case growth, and from date $t-28$ to date $t-34$ if the outcome is

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Tables A3 and A4 display the correlation between our behaviour proxy B_{it} and the five NPI policy aggregates P_{it}^{j}. Importantly, the behaviour proxy and mask mandate variables are not highly correlated, suggesting that the effect of mask mandates on COVID-19 outcomes should be independent of location behaviour changes.

Information. We use the weekly cases and case growth variables defined above, ΔC_{it} and Y_{it}, to construct the information variables I_{it} in equation (1). Specifically, we use as information the lagged value of the weekly case growth rate Y_{it-l} $(= \Delta \log(\Delta C_{it-l})$ and the log of past weekly cases, $\log(\Delta C_{it-l})$. We also use the lagged provincial (Ontario analysis) or national (Canada analysis) case growth rate and log of weekly cases as additional information variables in some specifications. A two-week information lag $l = 14$ is used in the baseline results. In the supplementary regressions using the death growth rate as the outcome, we use information on past deaths and a four-week lag (see Section 4.5).

Control variables. In all regressions, we control for region fixed effects (PHU or province) and the weekly COVID-19 tests growth rate $\Delta \log(\Delta T_{it})$, where T_{it} denotes cumulative tests in region i until date t and ΔT_{it} is defined analogously to ΔC_{it} above. We include a time trend: our baseline uses a cubic polynomial in days, but we also report results with no time trend and with week fixed effects. Robustness checks also include news or weather variables as controls (see Section 4.3).

Time period. We use the period May 15 to August 13 for the analysis with Ontario PHU level data and the period March 11 to August 13 for the national analysis with provincial data. The end date reflects data availability at the time of empirical analysis and writing. The start date for the Ontario sample (May 15) is approximately two weeks after the last restrictive measures were implemented and four weeks before the first mask mandate was introduced in Ontario. Robustness checks with different initial dates (May 1, June 1 and June 15) are reported in Section 4.3, with our results remaining stable. The initial date for the national sample (March 11) was chosen as the first date on which each province reported at least one COVID-19 test (so that cases could be potentially reported). Again, alternative initial dates are explored in Section 4.3.

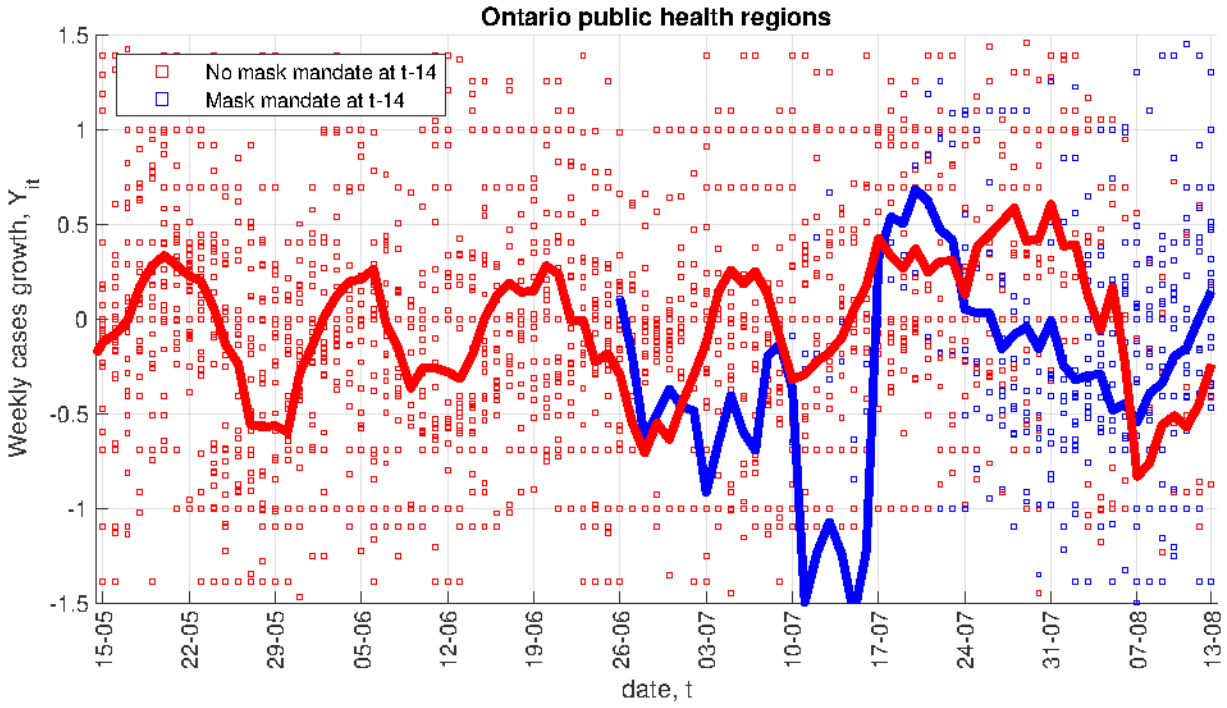
deaths growth. Alternative lags are explored in Section 4.3.

4 Results

4.1 Mask mandates in Ontario public health regions

We start with a simple graphical illustration of the effect of mask mandates on COVID-19 cases growth. Figure 3 displays the average log case growth, $Y_{it} = \Delta \log(\Delta C_{it})$ in Ontario PHUs with or without mask mandates. It shows that, on average, the PHUs with a mask mandate two weeks prior have lower case growth than the PHUs without a mask mandate two weeks prior.

Figure 3: Ontario - mask mandates and weekly case growth



Notes: The figure plots the average log weekly case growth $\Delta\log(\Delta C)$ in the PHUs with mask mandate (blue) vs. without (red) mask mandate 14 days prior.

Table 1 shows the estimates of equation (1), in which we control for other policies, behaviour and information, as explained in Section 3.1.[22] We report wild bootstrap p-values clustered at the PHU level to account for the small number of clusters.[23] The odd-numbered

[22]Mask mandates and regulations on business and gatherings vary at the PHU level. Long-term care policy changed only province-wide. The other policies (schooling and travel) do not vary during the sample period and hence are omitted from the regressions with Ontario PHU data.

[23]Table A6 in the Appendix reports alternative standard error specifications: regular clustering at the PHU level (Stata command "cluster"), wild bootstrap standard errors clustered at the PHU level, and wild

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columns in Table 1 use lagged cases and lagged cases growth at the PHU level as information; the even-numbered columns also include lagged cases and lagged case growth at the province level as additional information variables. In the tables, *Variable*_14 indicates a 14-day lag of *Variable*.

We present estimates of equation (1) from three specifications that handle possible time effects differently. Columns (1) and (2) in Table 1 are the most basic specifications, without including a time trend. The estimates in columns (1) and (2) suggest that, controlling for behavioural changes, mandatory indoor face masks reduce the growth rate of infections by 29–32 log points ($p < 0.05$), which is equivalent to a 25–28% reduction in weekly cases.[24]

In order to control for potential province-wide factors affecting the spread of COVID-19 such as income support policies or adaptation to the pandemic over time (so-called COVID fatigue), we also estimate (1) with a cubic time trend in days from the beginning of the sample, in columns (3) and (4) of Table 1, and with week fixed effects, in columns (5) and (6). Columns (3)-(6) show that our estimates of the mask mandate policy remain robust to the inclusion of a cubic time trend or week fixed effects. The results indicate that, depending on the specification, mask mandates are associated with a reduction of up to 38 log points in weekly case growth or, equivalently, a 31% reduction in weekly cases. The magnitude of the mask policy estimate is not very sensitive to whether lagged province-level data are included as additional information.

The results in Table 1 suggest that indoor mask mandates can be a powerful preventative measure in the COVID-19 context. Our estimates of the mask mandate impact across Ontario's PHUs are equivalent to a 25–31% reduction in weekly cases. This estimate is larger than the 9–10% reduction estimated by CKS (2020) for the U.S. One possible explanation is that Ontario's mask policy is more comprehensive: we evaluate the effect of *universal* indoor mask-wearing for the public rather than the effect of mask wearing for *employees only* in CKS (2020). Differences in the compliance rate may also contribute to this difference; we discuss this potential channel in Section 4.4.

The results in Table 1 also show a statistically significant negative association between information (log of past cases, log(ΔC)_14) and current weekly case growth ($p < 0.01$ in all specifications), indicating that a higher level of cases two weeks prior is correlated with lower current case growth. While B_{it} allows for behavioural responses to information, the negative estimate on log(ΔC)_14 in Table 1 suggests that our location-based proxy does not capture

bootstrap standard errors clustered by both PHU and date. Our results are robust to alternative ways of calculating standard errors.

[24] Using equation (3), a coefficient of x translates into a $1-\exp(x)$ reduction in weekly cases $\Delta C_{it}/\Delta C_{it-7}$.

Table 1: Main Results - Ontario public health regions

	Outcome: weekly case growth Y_{it}=$\Delta\log(\Delta C_{it})$					
	(1)	(2)	(3)	(4)	(5)	(6)
	no time trend		cubic time trend		week fixed effects	
Mask_14	-0.291 **	-0.323 **	-0.366 **	-0.376 ***	-0.319 **	-0.327 **
	[0.017]	[0.016]	[0.010]	[0.008]	[0.021]	[0.019]
Business/gathering_14	-0.625	-0.457	-0.137	0.279	-0.098	0.054
	[0.209]	[0.473]	[0.877]	[0.689]	[0.890]	[0.935]
Long-term care_14	0.643	0.544	0.747	-0.097	-1.044	-1.997
	[0.463]	[0.549]	[0.677]	[0.930]	[0.388]	[0.102]
Behaviour proxy_14	-0.020	-0.016	-0.018	-0.018	-0.016	-0.014
	[0.160]	[0.215]	[0.266]	[0.272]	[0.302]	[0.352]
$\Delta\log(\Delta C)$_14	0.030	0.029	0.024	0.028	0.013	0.012
	[0.614]	[0.649]	[0.692]	[0.665]	[0.817]	[0.834]
$\log(\Delta C)$_14	-0.214 ***	-0.214 ***	-0.203 ***	-0.209 ***	-0.199 ***	-0.201 ***
	[0.000]	[0.000]	[0.001]	[0.001]	[0.001]	[0.001]
$\Delta\log(\Delta PC)$_14		0.287		0.184		0.543 **
		[0.307]		[0.566]		[0.046]
$\log(\Delta PC)$_14		-0.028		0.528		0.112
		[0.907]		[0.124]		[0.744]
$\Delta\log(\Delta T)$	-0.313 *	-0.409 *	-0.260	-0.382	-0.230	-0.480
	[0.087]	[0.058]	[0.287]	[0.125]	[0.492]	[0.138]
R-squared	0.046	0.050	0.051	0.058	0.091	0.094
N	3,094	3,094	3,094	3,094	3,094	3,094
public health unit FE	X	X	X	X	X	X
cubic time trend (days)			X	X		
week fixed effects					X	X

Notes: The sample time period is May 15 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by public health unit (PHU) with 5000 repetitions are reported in the square brackets. Mask_14, Business/gathering_14, Behaviour_14, $\Delta\log(\Delta C)$_14, and $\log(\Delta C)$_14 are measured at the PHU level, while Long-term care_14, $\Delta\log(\Delta PC)$_14, $\log(\Delta PC)$_14, and $\Delta\log(\Delta T)$ are measured at the province level. PC denotes provincial total cases. ***, ** and * denote 10%, 5% and 1% significance level respectively. Missing values (1.3% of all observations) for Behaviour proxy_14 are imputed via linear interpolation.

important aspects of behaviour, such as frequent hand-washing or physical distancing. In fact, our coefficient estimate on the behavioral proxy B_{it} is very close to zero (both in Table

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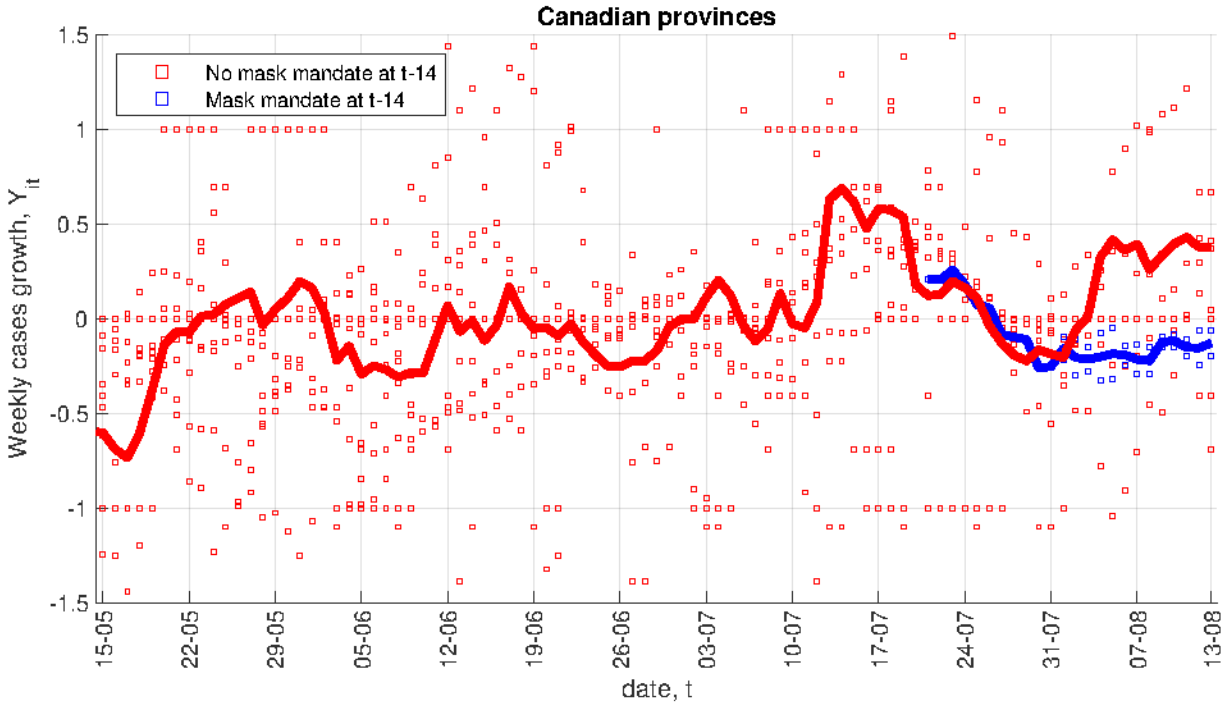
1 and in Section 4.2's province-level results), unlike in CKS (2020).[25] In Appendix Table A18, we find strong contemporaneous correlations between the policy measures, log cases, and the Google mobility behavioral proxy from estimating equation (2). This suggests that the information (lagged cases) and the lagged policy variables included in equation (1) may absorb lagged behavioral responses proxied by B_{it-l} or other latent behavioral changes not captured by B_{it-l}.

4.2 Province-level results

We next evaluate the impact of NPIs on COVID-19 cases growth in Canada as a whole by exploiting variation in the timing of policies across the 10 provinces. Here, we examine NPIs for which there is no variation across Ontario's PHUs (i.e., schooling, travel, and LTC) in addition to mask mandates. Also, provincial data contain variation in the timing of policy changes in both the closing and re-opening phases, allowing us to study both the imposition and relaxation of restrictions.

Figure 4: Canada - mask mandates and weekly case growth



Notes: The figure plots the average weekly case growth $\Delta \log(\Delta C)$ in the provinces with mask mandate (blue) vs. without mask mandate (red) 14 days prior.

[25] We also tried including each location change measure separately and the results are similar (not shown).

As in the Ontario analysis, we begin with a graphical illustration of mask mandates and COVID-19 case growth across Canadian provinces, in the period March 11 to August 13, 2020. Figure 4 plots the average log weekly case growth in the provinces with vs. without mask mandates. While mask mandates are implemented relatively late in our sample period, average case growth in the provinces with a mask mandate (Ontario and Quebec) diverged from the average case growth in the provinces without a mandate begin roughly four weeks after the mandates are imposed.[26]

Table 2 displays the estimates of equation (1) for weekly case growth, along with wild bootstrap p-values, clustered at the province level (see Table A9 for other methods of computing the standard errors). The odd-numbered columns use lagged cases and lagged case growth at the provincial level as information while the even-numbered columns include in addition lagged cases and case growth at the national level as additional information variables.

As in the Ontario analysis, we present in Table 2 estimates from three specifications: no time trend (columns (1)-(2)), including cubic time trend in days (columns (3)-(4)) and including week fixed effects (columns (5)-(6)). The most robust result is the estimated effect of mask mandates: they are associated with a large reduction in weekly case growth of 45 to 62 log points, which is equivalent to a 36 to 46% reduction in weekly cases across the different specifications. The estimates are statistically significantly different from zero in all cases, with a p-value of less than 0.001 in columns (1)-(4). It is reassuring that these results regarding mask mandates are consistent with the Ontario analysis in the previous section.

Table 2 further shows that restrictions on businesses and gatherings are associated with a reduction in the weekly case growth of 65 to 85 log points or, vice versa, that relaxing business/gathering restrictions is associated with higher case growth. The estimate is equivalent to a 48 to 57% decrease in weekly cases in our sample period. The business/gathering estimates are, however, more noisy than our estimates for mask mandates and do not retain statistical significance in the specifications with week fixed effects ($p = 0.15$ and 0.14). Tables A8 and A15 further suggest that the results on business and gathering NPIs are driven by the smaller provinces and the re-opening period (May to August). Still, these results suggest that lowered restrictions and the associated increase in business/workplace activity or gatherings can be an important offsetting factor for the estimated effect of mask mandates on COVID-19 case growth, both in our sample and in the future.

We also find that school closures (the School_14 variable in Table 2) can be negatively

[26]Figure 4 assumes a July 7 mask mandate implementation date for Ontario (when its most populous PHU, Toronto, adopted a mask mandate, along with Ottawa), and July 18 for Quebec (province-wide mandate).

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Table 2: Main Results – Canada

	Outcome: weekly case growth Y_{it}=$\Delta\log(\Delta C_{it})$					
	(1)	(2)	(3)	(4)	(5)	(6)
	no time trend		cubic time trend		week fixed effects	
Mask_14	-0.446 ***	-0.484 ***	-0.618 ***	-0.613 ***	-0.581 **	-0.567 **
	[0.000]	[0.000]	[0.000]	[0.000]	[0.030]	[0.026]
Business/gathering_14	-0.654 **	-0.827 **	-0.835 **	-0.846 **	-0.648	-0.694
	[0.018]	[0.019]	[0.031]	[0.033]	[0.146]	[0.137]
School_14	-0.336	-0.480	-0.425 **	-0.433 **	-0.261	-0.347
	[0.352]	[0.196]	[0.015]	[0.019]	[0.235]	[0.130]
Travel_14	-0.585	-0.772	-0.375	-0.412	-0.396	-0.553
	[0.146]	[0.118]	[0.613]	[0.636]	[0.695]	[0.559]
Long-term care_14	-0.052	-0.119	0.023	0.032	0.063	0.056
	[0.824]	[0.715]	[0.958]	[0.920]	[0.889]	[0.898]
Behaviour proxy_14	-0.009	-0.008	-0.001	0.000	-0.003	0.001
	[0.257]	[0.350]	[0.880]	[0.972]	[0.858]	[0.935]
$\Delta\log(\Delta C)$_14	-0.061	-0.062	-0.078 *	-0.072	-0.055	-0.054
	[0.177]	[0.262]	[0.090]	[0.198]	[0.449]	[0.459]
$\log(\Delta C)$_14	-0.223 ***	-0.244 ***	-0.227 **	-0.227 *	-0.224	-0.232
	[0.000]	[0.003]	[0.019]	[0.090]	[0.102]	[0.113]
$\Delta\log(\Delta NC)$_14		0.015		-0.107		-0.050
		[0.895]		[0.631]		[0.807]
$\log(\Delta NC)$_14		0.141		0.055		0.302 **
		[0.326]		[0.825]		[0.048]
$\Delta\log(\Delta T)$	0.112	0.166 *	0.172 **	0.169 *	0.158	0.166 *
	[0.170]	[0.074]	[0.043]	[0.056]	[0.110]	[0.073]
R-squared	0.406	0.410	0.414	0.414	0.430	0.433
N	1,560	1,560	1,560	1,560	1,560	1,560
province fixed effects	X	X	X	X	X	X
cubic time trend (days)			X	X		
week fixed effects					X	X

Notes: The time period is March 11 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. ***, ** and * denote 10%, 5% and 1% significance level respectively. NC denotes national total cases.

associated with case growth. However, the estimates are statistically significant from zero only in the specifications with cubic time trend (columns (3) and (4)). As seen in Figure

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2, provincial school closures occurred in a very short time interval during March, so we may lack statistical power to separately identify its effect from other NPIs (especially the travel-related). Hence, we interpret this result with caution.

As in Table 1, the level of past cases, $\log(\Delta C)$, is negatively and statistically significantly associated with current weekly case growth in columns (1)-(4).

Since the specification with cubic time trend in Tables 1 and 2 allows for possible non-monotonic aggregate time trends in case growth in a parsimonious way, we choose it as our baseline specification with which to perform robustness checks in the next section. Robustness checks with the other specifications are available upon request.

4.3 Robustness

Policy collinearity

A possible concern about our data for the national analysis is that some NPIs (e.g. international travel restrictions or closing of schools) were implemented within a very short time interval.[27] Thus, we may lack enough regional variation to distinguish and identify the separate effect of each policy.[28] Collinearity could also affect the standard errors and the signs of the estimated coefficients.

To check robustness with respect to potential collinearity in the NPI policies, Tables A7 and A10 report estimates from our baseline specification, omitting one policy at a time, for Ontario and Canada respectively. First, it is reassuring that the mask mandate estimates are hardly affected by omitting any of the other policies. This is expected since mask mandates were imposed during a period where other NPIs changed little (see Figure 2). Similarly, the effects of business/gathering regulations and school closures in Table A10 are not sensitive to omitting other policies one at a time, which suggests that there is sufficient statistical power and variation to identify them in the national analysis.

Treatment of zero weekly cases

Another concern for our empirical strategy is that the usual formula for our dependent variable, $\Delta \log(\Delta C_{it})$, cannot be applied when the weekly case total ΔC_{it} is zero. We follow CKS (2020) and replace ln(0) with -1 in our baseline specifications in Tables 1 and 2. We now check the robustness of our estimates to alternative treatments of zero weekly cases.

For easier comparison, the first two columns in Table A5 repeat columns (3) and (4)

[27] For example, Table A4 shows a correlation of 0.61 between the Travel and School policy aggregates.

[28] Aggregating the 17 basic policy indicators into five groups mitigates this issue. Here, we test whether any remaining collinearity poses a problem.

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from Table 1 for Ontario.[29] Our main results on mask mandates across Ontario PHUs are robust to replacing log(0) with 0 and to adding 1 to all ΔC_{it} observations before taking logs, as shown in columns (3)-(6) of Table A5. Another way to mitigate the issue of PHUs with very few cases is to estimate a weighted least squares regression where PHUs are weighted by population. Columns (7) and (8) in Table A5 show that the resulting mask estimate has a slightly smaller magnitude and, due to the reduced effective sample size, weaker statistical significance.

Similarly, Table A8 shows that our province-level estimates, in particular for mask mandates, are also robust to the same manipulations as above.[30] In columns (9) and (10) of Table A8, we restrict the sample to only the largest 4 provinces (British Columbia, Ontario, Quebec and Alberta), which have only 0.3% (2 out of 624) zero observation cases. Again, the estimated mask effects are little changed.

Alternative dates

Figure B4 shows that our estimates and confidence intervals for the effect of mask mandates in the Ontario baseline regressions do not vary much by the initial date of the sample. Similarly, Figure B5 shows that, in the national analysis, our results about mask mandates and business/gathering restrictions are also robust to alternative sample start dates.

Alternative lags

We explore alternative time lags, either shorter or longer in duration, centered around the baseline value of 14 days. Figure B6 (with Ontario data) and Figure B7 (with province-level data) plot the estimates and confidence intervals from the baseline regressions and show that our mask effect estimates remain fairly consistent for different lags.

Omitted variables

Our behaviour proxy variable (Google geo-location trends) likely misses some aspects of behaviour relevant for COVID-19 transmission. One factor that may meaningfully impact behaviour is weather. For example, good weather could entice more people to spend time outside, lowering the chance of viral transmission. Columns (3) and (4) in Table A11 report national estimates with lagged weather variables (daily maximum and minimum temperatures and precipitation for the largest city in each province[31]) as additional regressors. Our NPI estimates, in particular mask mandates, are little changed from the baseline results in columns (1) and (2).

[29] 535 out of 3,094 observations (17%) had to be replaced.

[30] 230 out of 1,560 observations (15%) had to be replaced.

[31] Vancouver, BC; Calgary, AB; Saskatoon, SK; Winnipeg, MB; Toronto, ON; Montreal, QC; Moncton, NB; Halifax, NS; Charlottetown, PE; and St. John's, NL.

Another possible concern is that our information variables, lagged cases and lagged case growth, may not fully capture the information based on which people react or adjust their behaviour, possibly affecting the observed weekly case growth. Columns (5) and (6) in Table A11 add a national-level "news" variable to the baseline specification. The news variable is defined as the number of daily search results from a news aggregator website (*Proquest Canadian Newsstream*) for the terms "coronavirus" or "COVID-19" (see Appendix C for more details). In column (6), the lagged news variable approaches the 10% significance level ($p = 0.103$). Our estimates on masks and business/gathering remain very close to those in the baseline.

4.4 Self-reported mask usage

The effectiveness of any NPI or public policy crucially depends on whether it affects behaviour. In this section, we use self-reported data on mask usage to examine whether mask mandates indeed increase mask use in Canada ("first-stage" analysis).

We use data from the YouGov COVID-19 Public Monitor, which includes multiple waves of public opinion surveys fielded regularly since early April in many countries.[32] Here, we focus on inter-provincial comparison within Canada. Our variable of interest is based on responses to the question "Thinking about the last 7 days, how often have you worn a face mask outside your home (e.g. when on public transport, going to a supermarket, going to a main road)?" The answer choices are "Always", "Frequently", "Sometimes", "Rarely", and "Not at all". We create a binary variable taking value 1 if the response is "Always" and 0 otherwise, as well as another variable taking value of 1 if the respondent answered either "Always" or "Frequently" and 0 otherwise.

We begin with a simple illustration of self-reported mask usage in Canada from April to August 2020. Figure B2 plots the average self-reported mask usage (the response "Always") in the provinces with and without mask mandates.[33] The figure clearly shows that self-reported mask usage is higher, by up to 50 percentage points, in the provinces with a mask mandate than in the provinces without mask mandates. Since Figure B2 does not account for compositional changes in the data, we formally estimate equation (2), using self-reported mask usage as the behavioral outcome.[34]

[32]The YouGov data can be accessed at: https://yougov.co.uk/covid-19.

[33]As on Figure 4, we use July 7 as the mask mandate implementation date in Ontario.

[34]Since mask usage is reported only for specific dates within each survey wave, we use our mask policy variable daily values for these same dates instead of the weekly moving average.

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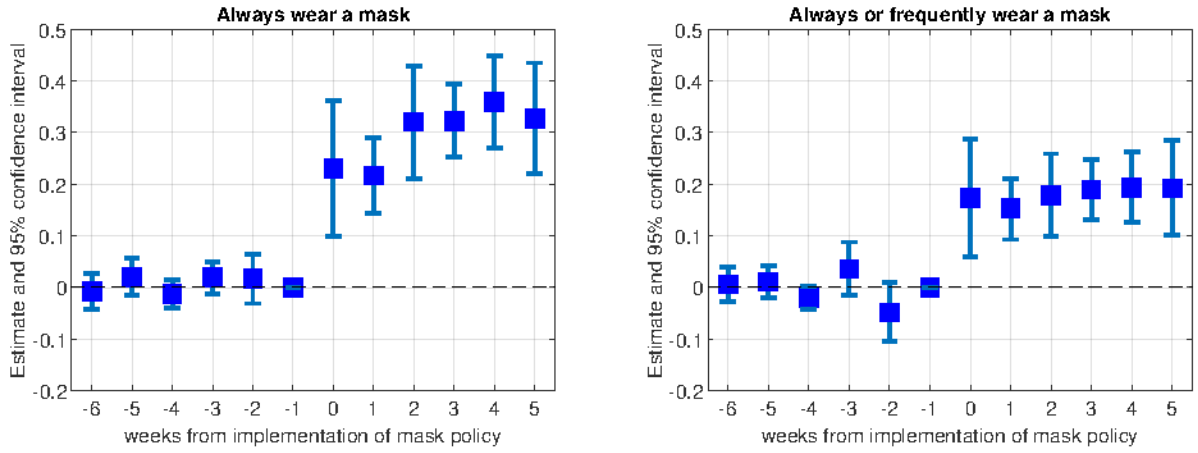
Figure 5: Event Study of Self-reported Mask Usage – Canada



Notes: The data source is YouGov. The outcome is a binary variable taking value 1 if the respondent respectively answered "Always" (in the left panel) or "Always" or "Frequently" (in the right panel) to "Thinking about the last 7 days, how often have you worn a face mask outside your home?" The figure plots the estimates from a version of equation (2) where the mask policy variable is replaced by the interaction of the variables corresponding to being in the treatment group (imposed mask mandate) and a series of dummies for each week, ranging from 6 weeks before the mask mandate to 6 weeks after ($T = -6$ to $+5$, where $T = 0$ is the mandate implementation date). The reference point is 1 week before the implementation ($T = -1$). Wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are used to construct the confidence intervals. Sample weights are used.

Figure 5 shows a graphical event study analysis on mask mandates and changes in mask usage. The event study approach is appropriate for the mask usage outcome variable, since the policy impact is expected to be immediate, unlike the other outcomes we study, for which any impact is expected to occur with a lag and we use weekly totals or moving averages. We replace the mask policy variable in equation (2) by the interaction of variables corresponding to being in the treatment group (i.e. under a mask mandate), and a series of dummies for each week, ranging from 6 weeks before the mask mandate to 5 weeks after the mask mandate ($T = -6$ to $+5$, where $T = 0$ is the implementation date of the mask mandate). The reference point is one week before the implementation of the mask mandate ($T = -1$), and we use the same y-axis scale on both panels.

The left and right panels of Figure 5 present the results from the event study analysis for the "Always" and "Always" or "Frequently" mask usage answers, respectively. We make several observations. First, neither panel shows a pre-trend – the estimates are close to zero before the mask mandates. This addresses the potential concern that provinces that implemented mask mandates may have had a different trend in mask usage than provinces that did not. Second, the effect of mask mandates on mask usage is immediate: an increase

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of roughly 20 percentage points as soon as the mask policy is implemented at ($T = 0$). Third, the effect appears persistent rather than transitory, since mask usage after $T = 0$ does not revert to its level before $T = 0$.

Table 3: Self-reported mask usage – Canada

	Outcome: "Always wear mask"					
	(1)	(2)	(3)	(4)	(5)	(6)
	no time trend		cubic time trend		week fixed effects	
Mask	0.404 ***	0.396 ***	0.304 ***	0.315 ***	0.310 ***	0.310 ***
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
$\Delta\log(\Delta C)$	-0.017	-0.006	-0.008	-0.006	-0.004	-0.008
	[0.663]	[0.611]	[0.524]	[0.595]	[0.656]	[0.464]
$\log(\Delta C)$	-0.025	0.015 **	0.004	0.006	0.006	0.007
	[0.127]	[0.025]	[0.662]	[0.544]	[0.504]	[0.502]
$\Delta\log(\Delta NC)$		-0.106 *		-0.023		0.191
		[0.054]		[0.324]		[0.108]
$\log(\Delta NC)$		-0.089 ***		-0.028		-0.068
		[0.000]		[0.669]		[0.582]
R-squared	0.157	0.169	0.172	0.172	0.173	0.174
N	8,859	8,859	8,859	8,859	8,859	8,859
individual characteristics	X	X	X	X	X	X
province fixed effects	X	X	X	X	X	X
cubic time trend (days)			X	X		
week fixed effects					X	X
† average mask usage rate without mask mandate = 0.298						

Notes: The time period is April 2 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. NC denotes national total cases. The data source is YouGov. The outcome is a dummy which takes value 1 if the respondent answered "Always" to the survey question "Thinking about the last 7 days, how often have you worn a face mask outside your home?" Sample weights are used. Individual characteristics include a gender dummy, age dummy (in years), dummies for each household size, dummies for each number of children, and dummies for each employment status. ***, ** and * denote 10%, 5% and 1% significance level respectively.

Table 3 displays the estimates on self-reported mask usage (answer "Always") in equation (2) along with wild bootstrap p-values clustered at the province level. The odd-numbered columns use lagged cases and lagged case growth at the provincial level as information while the even-numbered columns include in addition lagged cases and case growth at the national level as additional information variables. As in Table 1 and Table 2, we present estimates

without time trend, including cubic time trend (in days), and including week fixed effects. Our preferred specification with cubic time trend, column (4) of Table 3, shows that mask mandates are associated with 31.5 percentage point increase in self-reported mask usage ($p < 0.001$), from a base of self-reported mask usage without mask mandate of 29.8%.[35,36]

These "first-stage" results show that mask mandates exhibit significant compliance in Canada and establish a basis for the significant impact of mask mandates on the spread of COVID-19 that we find. That said, given that mask mandates do not change everyone's behaviour, our estimates in Tables 1 and 2 represent intent-to-treat effects. The full effect of the entire population shifting from not wearing to wearing masks is likely significantly larger.[37]

There is a heated debate on whether community use of masks may create a false sense of security that reduces adherence to other preventive measures. We also investigate this question using YouGov survey data. As Tables A13 and A14 indicate, we find no evidence that mask mandates in Canada have had an offsetting effect on other preventive measures such as hand washing, using sanitizer, avoiding gatherings, and avoiding touching objects in public during the period we study. On the contrary, mask mandates may slightly increase social distancing in one out of the eight precaution categories (avoiding crowded areas) ($p < 0.10$).[38]

4.5 Counterfactuals

We evaluate several counterfactuals corresponding to replacing the actual mask policy in a province or Canada-wide with a counterfactual policy, including absence of mask mandate.

Letting t_0 be the implementation date of a counterfactual policy, we set the counterfactual weekly case count, ΔC_{it}^c, equal to ΔC_{it} for all $t < t_0$. For each date $t \geq t_0$, using the definition of Y_{it} from (3), we then compute the counterfactual weekly cases, ΔC_{it}^c and the counterfactual

[35]Similarly, in Table A12, column (4) shows that "Always" or "Frequent" mask usage increases by 21.5 percentage points. The finding that the increase in mask usage among the "Always" respondents is larger than among the "Always" or "Frequent" respondents is consistent with some people switching from wearing masks "frequently" to "always."

[36]Hatzius et al. (2020) document that state mask mandates in the US increased mask usage roughly by 25 percentage points in 30 days. The compliance with mask mandates may differ across countries or regions based on social norms, peer effects, political reasons or the consequences of noncompliance (e.g., fines).

[37]If we take the increase of about 30 percentage points in reported mask usage induced by mask mandates at face value, the full effect of mask wearing (treatment-on-the-treated effect) would be roughly triple our estimates. It could be larger still if there is desirability bias in answering the mask usage survey question, so that the actual increase in mask use may be smaller than our estimate.

[38]Consistent with this result, Seres et al. (2020) find that wearing masks increased physical distancing based on a randomized field experiment in stores in Germany.

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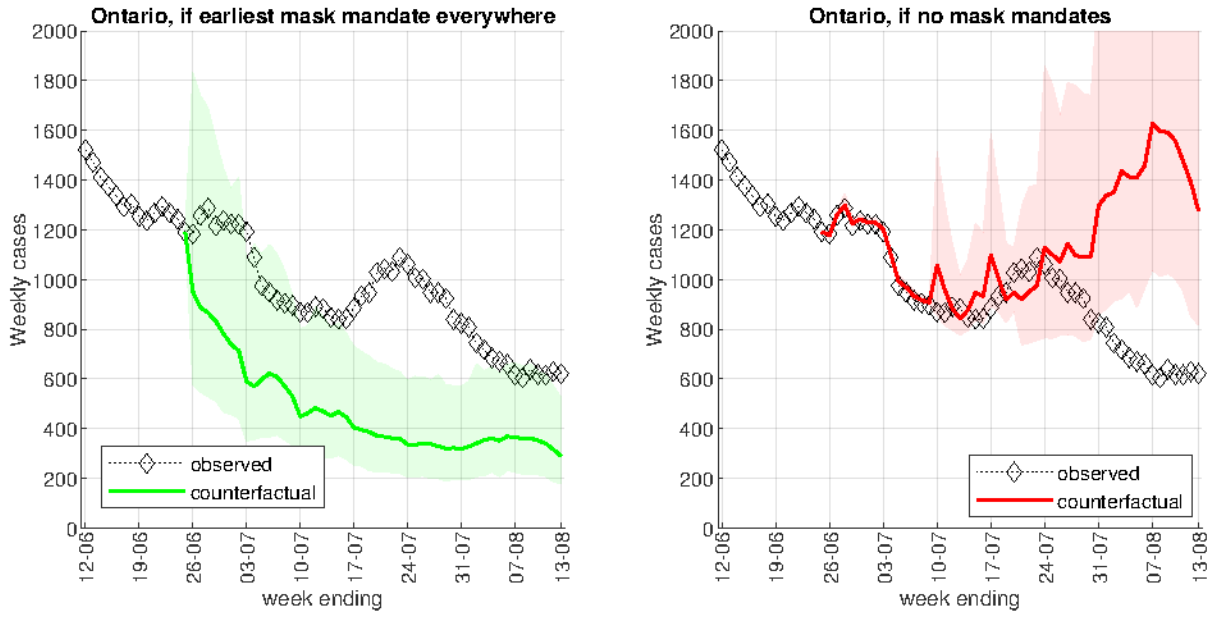
case growth rate, Y_{it}^c, as follows:

$$\Delta C_{it}^c = \exp(Y_{it}^c)\left(\Delta C_{it-7}^c\right) \text{ and}$$

$$Y_{it}^c = \hat{Y}_{it} + \beta_{Mask\_14}\left(\text{Mask}^c\_14 - \text{Mask}\_14\right) + \beta_{log\_dC\_14}\left(\ln(\Delta C_{it-14}^c) - \ln(\Delta C_{it-14})\right),$$

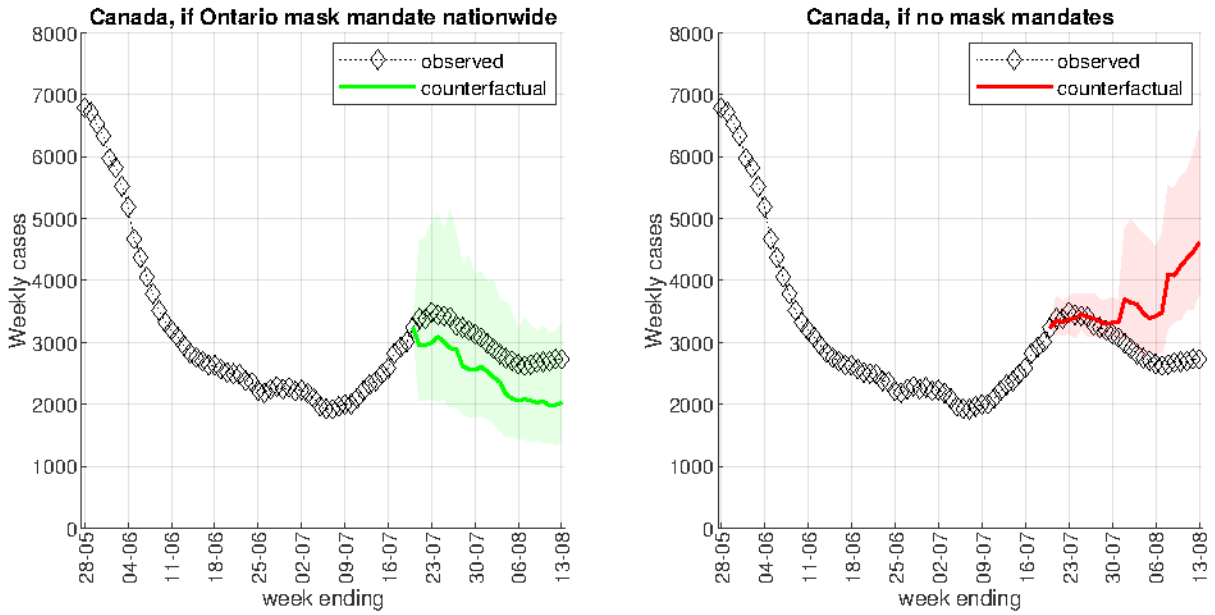
where $\hat{Y}_{it}$ is the regression-fitted value of weekly case growth; β_{Mask_14} is the coefficient estimate on the mask mandate variable Mask_14 in baseline specification (4) in Table 1 or 2, depending on the counterfactual; Mask^c_14 is the counterfactual mask policy (e.g. different implementation date, wider geographic coverage or absence of mask mandate); and $\beta_{log\Delta C\_14}$ is the coefficient estimate (-0.227 or -0.209) on lagged cases log(ΔC)_14 in Table 1 or 2, column 4. The coefficient $\beta_{log\Delta C\_14}$ adjusts the counterfactual case growth rate for the negative statistically significant association between the weekly case total two weeks prior and time-t case growth. This effect may be due to people being more careful when they perceive the risk of infection to be higher or less careful vice versa.

Figure 6: Counterfactuals - Ontario public health regions



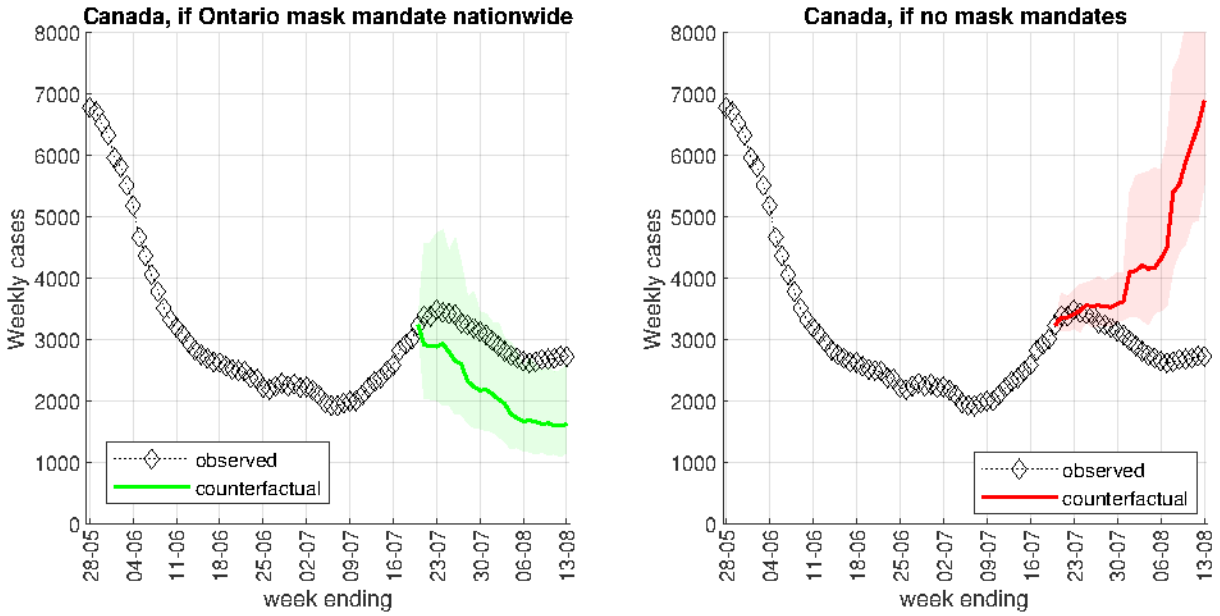
Notes: The left panel assumes that mask mandates were adopted in all PHUs on June 12 (date of the first mask mandate in ON). The right panel assumes that mask mandates were not adopted in any PHU. We use the mask estimate (-0.376) from column (4) of Table 1.

Figure 7: Counterfactuals – Canada (Table 1 mask estimate)



Notes: The left panel assumes that mask mandates were adopted in all provinces on July 7 (the adoption date in Toronto and Ottawa). The right panel assumes that mask mandates were not adopted in any province. We use the mask estimate (-0.376) from column (4) of Table 1.

Figure 8: Counterfactuals – Canada (Table 2 mask estimate)



Notes: The left panel assumes that mask mandates were adopted in all provinces on July 7 (the adoption date in Toronto and Ottawa). The right panel assumes that mask mandates were not adopted in any province. We use the mask estimate (-0.613) from column (4) of Table 2.

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Figures 6, 7 and 8 show results from two counterfactual policy evaluations. The first exercise, depicted in the left-hand side panel of the figures, assumes that masks are adopted everywhere at the earliest date observed in the data. Specifically, Figure 6 considers the counterfactual of all Ontario PHUs adopting mask mandates on June 12, while Figures 7 and 8 assume that all provinces adopt a mask mandate on July 7.[39]

Using our mask policy estimate from Table 1, Figure 6 shows that an earlier face mask mandate across Ontario PHUs could have lead to an average reduction of about 300 cases per week as of August 13, holding all else equal. For Canada as a whole, a nation-wide adoption of mask mandates in early July is predicted to reduce total cases per week in the country by 700 to 1,100 cases on average as of August 13, depending on whether we use the more conservative mask estimate (-0.376) from column (4) of Table 1 (see Figure 7) or the larger estimate (-0.613) from column (4) of Table 2 (see Figure 8). In all cases, the indirect feedback effect via $\beta_{log\Delta C\_14}$ (lagged cases as information) starts moderating the decrease in cases two weeks after the start of the counterfactual mask policy.

In the right-hand side panel of Figures 6, 7 and 8, we perform the opposite exercise, namely assuming instead that mask mandates were *not* adopted in any Ontario PHU or any Canadian province. Our estimates imply that the counterfactual absence of mask mandates would have led to a large increase in new cases, both in Ontario and Canada-wide, especially when using the larger mask coefficient estimate from Table 2 (see Figure 8).

Finally, in Figure B11 in the Appendix, we also evaluate the counterfactual in which British Columbia and Alberta, the third and fourth largest Canadian provinces by population, adopt province-wide mask mandates on July 15. The results, using the Mask_14 estimate from Table 2, suggest a reduction of about 300 cases per week in each province by mid-August.

The counterfactual simulations assume that all other variables, behaviour and policies (except the mask policy and $t-14$ cases) remain fixed, as observed in the data. This is a strong assumption, but it may be plausible over the relatively short time period that we analyze. Moreover, the counterfactuals assume that regions without a mask mandate would react in the same way, on average, as the regions that imposed a mandate. Therefore, these results should be interpreted with caution and only offer a rough illustration and projection of the estimated effect of mask mandates on COVID-19 cases.

[39] June 12 is the date of the earliest mask mandate in Ontario. For the national analysis, July 7, the effective date for Toronto and Ottawa, is considered Ontario's first significant date of mask mandate enactment: PHUs with earlier mandates account for less than 10% of Ontario's population.

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4.6 Additional analysis

Closing and re-opening sub-periods

We investigate whether policy impact varied in different phases of the pandemic by splitting the full sample period into two sub-periods: "closing" (March 11 to May 14) and "re-opening" (May 15 to August 13). The dividing date of May 15 (referring to the NPIs in place around May 1) was chosen because very few policies were relaxed before May 1, and very few non-mask policies were tightened after May 1 in our sample period (see Figure 2).

In Table A15, we report estimates and wild bootstrap standard errors using our baseline specification with cubic time trend, separately for the closing and re-opening periods. We find that the imposition of school closures and travel restrictions early in the closing period is associated with a very large subsequent reduction in weekly case growth, as can be also seen on Figure B8 – the average observed log growth rate of cases $\Delta \log(\Delta \text{C})$ falls from 2.4 (ten-fold growth in weekly cases) to -0.4 (33% decrease in weekly cases) between March 15 and April 5. Long-term care restrictions are also associated with reduced case growth two weeks later during the March to May closing period. We interpret these results with caution, however, since many of these policy measures and restrictions were enacted in a brief time interval during March and there is not much inter-provincial variation (see Figure 2). No mask mandates were present in the closing period.

In the re-opening period, our results in Table A15 are in line with our full-sample results for mask mandates and business/gathering regulations (Table 2), with slightly larger coefficient estimates and less statistically significant p-values, possibly due to the smaller sample. Travel and school closures are not statistically significant in the re-opening period. This is unsurprising: relaxation of travel policies was minor and endogenous (only re-open to safe areas within Canada), and the schools that re-opened (in parts of Quebec and, on a part-time basis, in British Columbia) did so on voluntary attendance basis, yielding smaller class sizes.

Deaths

We also examine the weekly death growth as an outcome. We only have access to disaggregated deaths data at the province level (not at PHU levels in Ontario). We thus estimate regression equation (1) using $Y_{it} = \Delta \log(\Delta D_{it})$ for each province i as the dependent variable. In addition, we use a 28-day lag for the policy, behaviour proxy, and information variables to reflect the fact that deaths occur on average about two weeks after case detection; see Appendix D for details and references.[40]

[40] In Table 4, *Variable*_28 denotes the *Variable* lagged by 28 days.

Table 4 reports the estimates from the same specifications as those for case growth in Table 2. In all specifications, mask mandates are associated with a large reduction in the observed weekly deaths growth rate four weeks later (more than 90 log points, or equivalently more than 60% reduction in weekly deaths). These results are larger than our case growth results, but consistent with them given the substantial uncertainty. See also Figure B12, which plots the average weekly death growth in the provinces without a mask mandate four weeks prior vs. that for Ontario, the only province with mask mandate four weeks prior in our sample period.

The robustness checks in Table A16, however, show that, unlike for case growth, the mask mandate estimates in Table 4 are not robust to weighing by population or to restricting the sample to the largest 4 provinces. This suggests that the estimated effect is largely driven by observations from the small provinces, which have a disproportionately larger number of zero or small weekly death totals.[41] Furthermore, given the 28-day lag, there are only 9 days with observations (from Ontario only) for which the mask mandate variable takes value of 1. Due to these serious data limitations, the relation between mask mandates and COVID-19 deaths in Table 4 is suggestive at best, and we urge caution in interpreting or extrapolating from these results.

That said, our main findings about the growth in cases may have implications about future growth in deaths, particularly if the affected demographics become less skewed toward the young in later periods.

[41] 205 out of the 1,470 observations (14%) had log(0) replaced by -1.

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Table 4: Canada – deaths growth rate and policies

	Outcome: weekly deaths growth, $\Delta\log(\Delta D)$					
	(1)	(2)	(3)	(4)	(5)	(6)
	no time trend		cubic time trend		week fixed effects	
Mask_28	-1.391 ***	-1.453 ***	-0.922 **	-0.983 **	-0.904 **	-0.915 **
	[0.000]	[0.000]	[0.022]	[0.032]	[0.036]	[0.045]
Business/gathering_28	0.241	0.271	-0.134	-0.224	-0.279	-0.268
	[0.529]	[0.521]	[0.762]	[0.748]	[0.712]	[0.732]
School_28	0.002	0.018	0.441	0.440	0.624	0.630
	[0.974]	[0.924]	[0.317]	[0.341]	[0.114]	[0.113]
Travel_28	-0.176	-0.287	-0.005	-0.027	-0.191	-0.161
	[0.553]	[0.432]	[0.972]	[0.935]	[0.638]	[0.718]
Long-term care_28	-0.091	-0.140	-0.035	-0.036	-0.024	-0.017
	[0.592]	[0.600]	[0.900]	[0.900]	[0.936]	[0.948]
Behaviour proxy_28	0.003	0.000	0.002	0.003	0.005	0.005
	[0.718]	[1.000]	[0.815]	[0.737]	[0.675]	[0.695]
$\Delta\log(\Delta D)$_28	0.151	0.175	0.141	0.152	0.154	0.153
	[0.194]	[0.245]	[0.361]	[0.345]	[0.266]	[0.266]
$\log(\Delta D)$_28	-0.238 ***	-0.248 ***	-0.216 ***	-0.220 ***	-0.229 ***	-0.227 ***
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
$\Delta\log(\Delta ND)$_28		-0.110		-0.121		-0.019
		[0.471]		[0.476]		[0.806]
$\log(\Delta ND)$_28		-0.015		0.018		-0.053
		[0.743]		[0.858]		[0.557]
$\Delta\log(\Delta T)$	0.081	0.018	-0.038	-0.051	-0.037	-0.037
	[0.409]	[0.922]	[0.758]	[0.735]	[0.752]	[0.748]
R-squared	0.233	0.239	0.251	0.254	0.286	0.286
N	1,470	1,470	1,470	1,470	1,470	1,470
province fixed effects	X	X	X	X	X	X
cubic trend in days			X	X		
week fixed effects					X	X

Notes: The time period is March 11 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. ***, ** and * denote 10%, 5% and 1% significance level respectively. ND denotes national total deaths.

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5 Conclusion

The wearing of face masks by the general public has been a very contentious policy issue during the COVID-19 pandemic, with health authorities in many countries and the World Health Organization giving inconsistent or contradictory recommendations over time. "Conspiracy theories" and misinformation surrounding mask wear abound in social media, fuelled by some individuals' perception that mask mandates constitute significant restrictions on individual freedoms. Given the absence of large-scale randomized controlled trials or other direct evidence on mask effectiveness in preventing the spread of COVID-19, quantitative observational studies like ours are essential for informing both public policy and the public opinion.

We estimate the impact of mask mandates and other public policy measures on the spread of COVID-19 in Canada. We use both within-province and cross-province variation in the timing of mask mandates and find a robust and significantly negative association between mask mandates and subsequent COVID-19 case growth – 25 to 46% average reduction in weekly cases in the first several weeks after adoption, depending on the data sample and empirical specification used. These results are supported by our analysis of survey data on compliance with the mask mandates, which show that the mandates increase the proportion of reporting as always wearing a mask in public by around 30 percentage points. However, our sample period does not allow us to determine whether their effect lasts beyond the first few weeks after implementation. We conclude that mask mandates can be a powerful policy tool for at least temporarily reducing the spread of COVID-19.

Mask mandates were introduced in Canada during a period where other policy measures were relaxed, as part of the economy's re-opening. Specifically, we find that relaxed restrictions on businesses or gatherings are positively associated with subsequent COVID-19 case growth – a factor that could offset and obscure the health benefits of mask mandates. Past case totals were also found to matter for subsequent COVID-19 outcomes, suggesting that riskier behaviour based on favourable lagged information may limit how low mask mandates and other restrictions – short of a lockdown – can push the number of new cases.

We have deliberately abstained from studying the direct economic impacts of COVID-19, focusing instead on the unique features of the Canadian data for identifying the effect of NPIs, in particular mask mandates, on COVID-19 case growth. Future research combining epidemiological finding with the economic benefits and costs of various public policies or restrictions would enrich the ongoing policy debate and provide further guidance.

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Appendix A. Additional tables

Table A1: Ontario – Correlations between the Google mobility indicators

category	retail	grocery	workplaces	transit	residential	parks	N
retail	1						3,008
grocery	0.82	1					3,064
workplaces	0.39	0.26	1				3,082
transit	0.57	0.47	0.65	1			2,453
residential	-0.54	-0.38	-0.92	-0.69	1		2,751
parks	0.50	0.31	0.40	0.40	-0.47	1	1,483

Notes: The time period is May 1 to July 30 (two weeks before the May 15 - August 13 sample period). Daily PHU-level data.

Table A2: Canada – Correlations between the Google mobility indicators

category	retail	grocery	workplaces	transit	residential	parks	N
retail	1						1,560
grocery	0.84	1					1,560
workplaces	0.69	0.53	1				1,560
transit	0.82	0.60	0.86	1			1,394
residential	-0.80	-0.58	-0.91	-0.85	1		1,516
parks	0.53	0.43	0.19	0.25	-0.46	1	1,347

Notes: The time period is February 26 to July 30 (two weeks before the March 11 - August 13 sample period). Daily province-level data.

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Table A3: Ontario – Correlations between policies and location behaviour

	Behaviour proxy	Mask	Business/gathering	LTC
Behaviour proxy	1			
Mask	0.17	1		
Business/gathering	-0.55	-0.63	1	
Long-term care (LTC)	-0.27	-0.75	0.66	1

Notes: The time period is May 15 to August 13 ($N = 3,094$). Each variable is a 7-day moving average. All variables are at the PHU level, except LTC which is measured at the province level.

Table A4: Canada – Correlations between policies and location behaviour

	Behaviour proxy	Mask	Business/gathering	School	Travel	LTC
Behaviour proxy	1					
Mask	0.09	1				
Business/gathering	-0.86	-0.23	1			
School	-0.37	0.08	0.37	1		
Travel	-0.14	-0.09	0.30	0.61	1	
Long-term care (LTC)	-0.14	-0.11	0.24	0.44	0.22	1

Notes: The time period is March 11 to August 13 ($N = 1,560$). Province-level, 7-day moving averages.

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Table A5: Ontario – Robustness (treatment of zero weekly cases)

	Outcome: weekly case growth, $\Delta\log(\Delta C)$							
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Baseline		Alternative 1		Alternative 2		Alternative 3	
p-values in [ ] brackets	replace log(0) by -1		replace log(0) by 0		add 1 before taking log		weighted by population	
Mask_14	-0.366 **	-0.376 ***	-0.310 **	-0.315 ***	-0.272 **	-0.280 **	-0.249 *	-0.259 *
	[0.010]	[0.008]	[0.010]	[0.008]	[0.017]	[0.013]	[0.096]	[0.082]
Business/	-0.137	0.279	0.021	0.290	-0.006	0.270	0.350	0.529 *
gathering_14	[0.877]	[0.689]	[0.945]	[0.613]	[1.000]	[0.616]	[0.226]	[0.092]
Long-term care_14	0.747	-0.097	-0.003	-0.568	0.196	-0.327	-1.652	-1.927 *
	[0.677]	[0.930]	[0.973]	[0.667]	[0.908]	[0.782]	[0.137]	[0.070]
Behaviors_14	-0.018	-0.018	-0.016	-0.016	-0.013	-0.014	-0.008	-0.009
	[0.266]	[0.272]	[0.188]	[0.194]	[0.278]	[0.270]	[0.416]	[0.418]
$\Delta\log(\Delta C)$_14	0.024	0.028	0.043	0.045	0.028	0.030	0.038	0.038
	[0.692]	[0.665]	[0.330]	[0.322]	[0.520]	[0.494]	[0.578]	[0.562]
$\log(\Delta C)$_14	-0.203 ***	-0.209 ***	-0.184 ***	-0.188 ***	-0.164 ***	-0.169 ***	-0.223 ***	-0.231 ***
	[0.001]	[0.001]	[0.001]	[0.000]	[0.001]	[0.001]	[0.000]	[0.000]
$\Delta\log(\Delta PC)$_14		0.184		0.132		0.094		0.066
		[0.566]		[0.647]		[0.722]		[0.696]
$\log(\Delta PC)$_14		0.528		0.302		0.437		0.300
		[0.124]		[0.302]		[0.101]		[0.257]
$\Delta\log(\Delta T)$	-0.260	-0.382	-0.189	-0.266	-0.129	-0.215	-0.012	-0.063
	[0.287]	[0.125]	[0.361]	[0.203]	[0.486]	[0.242]	[0.942]	[0.677]
R-squared	0.051	0.058	0.059	0.062	0.057	0.063	0.066	0.069
N	3,094	3,094	3,094	3,094	3,094	3,094	3,094	3,094
PHU fixed effects	X	X	X	X	X	X	X	X
cubic time trend	X	X	X	X	X	X	X	X
population weighted	No	No	No	No	No	No	Yes	Yes

Notes: The time period is May 15 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by public health unit (PHU) with 5000 repetitions are reported in the square brackets. Columns (1) and (2) repeat columns (3) and (4) from Table 1 where we replace log(0) with -1. Columns (3) and (4) replace log(0) with 0, and columns (5) and (6) add 1 to all ΔC_{it} observations. Columns (7) and (8) report estimates from a weighted least squares regression with weights equal to the PHU population sizes. ***, ** and * denote 10%, 5% and 1% significance level respectively.

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Table A6: Ontario – Robustness (standard errors)

Outcome: weekly case growth $\Delta\log(\Delta C)$				
	(1)		(2)	
Mask_14	-0.366		-0.376	
	(0.014)	**	(0.012)	**
	[0.010]	**	[0.008]	***
	{0.022}	**	{0.016}	**
Business/gathering_14	-0.137		0.279	
	(0.849)		(0.688)	
	[0.877]		[0.689]	
	{0.887}		{0.703}	
Long-term care_14	0.747		-0.097	
	(0.657)		(0.951)	
	[0.677]		[0.930]	
	{0.702}		{0.935}	
Behaviour proxy_14	-0.018		-0.018	
	(0.183)		(0.197)	
	[0.266]		[0.272]	
	{0.281}		{0.272}	
R-squared	0.054		0.060	
N	3,094		3,094	
$\Delta\log(\Delta C)$_14	X		X	
$\log(\Delta C)$_14	X		X	
$\Delta\log(\Delta PC)$_14			X	
$\log(\Delta PC)$_14			X	
$\Delta\log(\Delta T)$	X		X	
PHU fixed effects	X		X	
cubic time trend	X		X	

Notes: The time period is May 15 - August 13. P-values from standard clustering by PHU (Stata command cluster) in the ( ) parentheses, wild bootstrap with one-way clustering by PHU and 5000 repetitions in the [ ] square brackets, and wild bootstrap with two-way clustering by PHU and day with 5000 repetitions in the { } curly braces. PC denotes provincial cases.

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Table A7: Ontario – Robustness (policy collinearity)

	Outcome: weekly case growth $\Delta\log(\Delta C)$							
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Baseline		Drop Mask_14		Drop Business/gathering_14		Drop LTC_14	
Mask_14	-0.366 **	-0.376 **			-0.362 **	-0.382 ***	-0.363 **	-0.376 ***
	[0.010]	[0.008]			[0.012]	[0.009]	[0.010]	[0.008]
Business/gathering_14	-0.137	0.279	-0.041	0.398			-0.047	0.260
	[0.877]	[0.689]	[0.976]	[0.565]			[0.947]	[0.682]
Long-term care (LTC)_14	0.747	-0.097	0.650	-0.271	0.653	0.229		
	[0.677]	[0.930]	[0.728]	[0.836]	[0.682]	[0.890]		
Behaviour proxy_14	-0.018	-0.018	-0.014	-0.014	-0.017	-0.019	-0.018	-0.018
	[0.266]	[0.272]	[0.323]	[0.336]	[0.199]	[0.174]	[0.268]	[0.268]
$\Delta\log(\Delta C)$_14	0.024	0.028	0.035	0.039	0.025	0.027	0.027	0.027
	[0.692]	[0.665]	[0.541]	[0.512]	[0.696]	[0.676]	[0.678]	[0.669]
$\log(\Delta C)$_14	-0.203 ***	-0.209 ***	-0.215 ***	-0.221 ***	-0.202 ***	-0.210 ***	-0.206 ***	-0.209 ***
	[0.001]	[0.001]	[0.001]	[0.001]	[0.001]	[0.001]	[0.000]	[0.001]
$\Delta\log(\Delta PC)$_14		0.184		0.217		0.122		0.174
		[0.566]		[0.485]		[0.722]		[0.611]
$\log(\Delta PC)$_14		0.528		0.486		0.544		0.532
		[0.124]		[0.158]		[0.115]		[0.132]
$\Delta\log(\Delta T)$	-0.260	-0.382	-0.243	-0.367	-0.263	-0.364	-0.239	-0.382
	[0.287]	[0.125]	[0.322]	[0.136]	[0.291]	[0.162]	[0.287]	[0.125]
R-squared	0.051	0.058	0.049	0.054	0.054	0.060	0.053	0.060
N	3,094	3,094	3,094	3,094	3,094	3,094	3,094	3,094
public health unit FE	X	X	X	X	X	X	X	X
cubic time trend	X	X	X	X	X	X	X	X

Notes: The time period is May 15 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by public health unit (PHU) with 5000 repetitions are reported in the square brackets. Columns (1) and (2) repeat columns (3) and (4) from Table 1. We drop each policy at at time in columns (3)-(8). ***, ** and * denote 10%, 5% and 1% significance level respectively.

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Table A8: Canada - Robustness (treatment of zero weekly cases)

	Outcome: Weekly case growth, $\Delta\log(\Delta C)$									
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	Baseline		Alternative 1		Alternative 2		Alternative 3		Alternative 4	
	Replace log(0) by -1		Replace log(0) by 0		Add 1 before taking log		Weighted by population		4 largest provinces	
Mask_14	-0.618 ***	-0.613 ***	-0.599 ***	-0.591 ***	-0.594 ***	-0.587 ***	-0.618 ***	-0.613 ***	-0.593 ***	-0.588 ***
	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]	[0.000]
Business /	-0.835 **	-0.846 **	-0.794 *	-0.812 *	-0.698 **	-0.711 *	-0.224	-0.216	0.049	0.160
gathering_14	[0.031]	[0.033]	[0.076]	[0.070]	[0.046]	[0.055]	[0.513]	[0.615]	[0.754]	[0.509]
School_14	-0.425 **	-0.433 **	-0.393 **	-0.410 **	-0.366 **	-0.381 **	-0.148	-0.211 **	-0.029	-0.060
	[0.015]	[0.019]	[0.023]	[0.020]	[0.050]	[0.042]	[0.278]	[0.010]	[0.599]	[0.478]
Travel_14	-0.375	-0.412	-0.499	-0.565	-0.283	-0.338	-1.513 *	-1.811 *	-2.368	-4.980 ***
	[0.613]	[0.636]	[0.446]	[0.437]	[0.646]	[0.630]	[0.077]	[0.071]	[0.358]	[0.000]
LTC_14	0.023	0.032	0.093	0.108	0.051	0.063	0.097	0.119	-0.054	-0.076
	[0.958]	[0.920]	[0.772]	[0.746]	[0.866]	[0.831]	[0.360]	[0.274]	[0.626]	[0.132]
Behaviour_14	-0.001	0.000	-0.002	0.000	0.001	0.002	-0.015 *	-0.013	-0.025 ***	-0.030 ***
	[0.880]	[0.972]	[0.864]	[0.946]	[0.910]	[0.692]	[0.054]	[0.100]	[0.000]	[0.000]
$\Delta\log(\Delta C)$_14	-0.078 *	-0.072	-0.034	-0.025	-0.042	-0.035	0.002	0.005	0.036	0.023
	[0.090]	[0.198]	[0.456]	[0.599]	[0.221]	[0.359]	[1.000]	[0.942]	[0.611]	[0.746]
$\log(\Delta C)$_14	-0.227 **	-0.227 *	-0.236 ***	-0.236 ***	-0.209 ***	-0.210 **	-0.265 ***	-0.276 ***	-0.281	-0.290 ***
	[0.019]	[0.090]	[0.000]	[0.000]	[0.000]	[0.012]	[0.000]	[0.000]	[0.109]	[0.000]
$\Delta\log(\Delta NC)$_14		-0.107		-0.180		-0.144		-0.174 ***		-0.297 ***
		[0.631]		[0.335]		[0.384]		[0.000]		[0.000]
$\log(\Delta NC)$_14		0.055		0.100		0.085		0.255		0.615 ***
		[0.825]		[0.738]		[0.731]		[0.295]		[0.000]
$\Delta\log(\Delta T)$	0.172 **	0.169 *	0.098 *	0.093	0.113 *	0.109	0.079	0.074	0.072	0.071
	[0.043]	[0.056]	[0.094]	[0.130]	[0.075]	[0.109]	[0.776]	[0.781]	[0.754]	[0.639]
R-squared	0.414	0.414	0.483	0.484	0.471	0.471	0.651	0.653	0.804	0.813
N	1,560	1,560	1,560	1,560	1,560	1,560	1,560	1,560	624	624
Province FE	X	X	X	X	X	X	X	X	X	X
Cubic trend	X	X	X	X	X	X	X	X	X	X
Weighted	No	No	No	No	No	No	Yes	Yes	No	No

Notes: The time period is March 11 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions in the square brackets. Columns (1) and (2) repeat columns (3) and (4) from Table 2 where we replace log(0) with -1. Columns (3) and (4) replace log(0) with 0, and columns (5) and (6) add 1 to all ΔC_{it} observations. Columns (7) and (8) report results from a weighted least squares regression with the province populations as weights. Finally, columns (9) and (10) restrict the sample to only the largest 4 provinces (BC, ON, QC, and AB) which have only 0.3% zero observation cases. ***, ** and * denote 10%, 5% and 1% significance level respectively.

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Table A9: Canada – Robustness (standard errors)

Outcome: weekly case growth $\Delta\log(\Delta C)$				
	(1)		(2)	
Mask_14	-0.618		-0.613	
	(0.014)	**	(0.014)	**
	[0.000]	***	[0.000]	***
	{0.000}	***	{0.000}	***
Business/gathering_14	-0.835		-0.846	
	(0.027)	**	(0.023)	**
	[0.031]	**	[0.033]	**
	{0.035}	**	{0.039}	**
School_14	-0.425		-0.433	
	(0.042)	**	(0.025)	**
	[0.015]	**	[0.019]	**
	{0.015}	**	{0.014}	**
Travel_14	-0.375		-0.412	
	(0.526)		(0.534)	
	[0.613]		[0.636]	
	{0.612}		{0.637}	
Long-term care_14	0.023		0.032	
	(0.948)		(0.926)	
	[0.958]		[0.920]	
	{0.958}		{0.920}	
Behaviour proxy_14	-0.001		0.000	
	(0.857)		(0.962)	
	[0.880]		[0.972]	
	{0.878}		{0.972}	
R-squared	0.406		0.410	
N	1,560		1,560	
$\Delta\log(\Delta C)$_14	X		X	
$\log(\Delta C)$_14	X		X	
$\Delta\log(\Delta NC)$_14			X	
$\log(\Delta NC)$_14			X	
$\Delta\log(\Delta T)$	X		X	
province fixed effects	X		X	
cubic time trend	X		X	

Notes: The time period is March 11 - August 13. P-values from standard clustering by province in the ( ) parentheses, wild bootstrap with one-way clustering by province and 5000 repetitions in the [ ] square brackets, and wild bootstrap with two-way clustering by province and day with 5000 repetitions in the { } curly braces.

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Table A10: Canada - Robustness (policy collinearity)

	Outcome: weekly case growth, $\Delta\log(\Delta C)$									
	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
	drop Mask_14		drop Business /gathering_14		drop School_14		drop Travel_14		drop LTC_14	
Mask_14			-0.621 ***	-0.614 ***	-0.588 ***	-0.592 ***	-0.635 ***	-0.636 ***	-0.618 ***	-0.614 ***
			[0.000]	[0.000]	[0.006]	[0.004]	[0.000]	[0.004]	[0.000]	[0.000]
Business/	-0.837 **	-0.847 **			-0.827 **	-0.847 **	-0.895 **	-0.909 **	-0.829 **	-0.837 **
gathering_14	[0.033]	[0.040]			[0.031]	[0.034]	[0.012]	[0.013]	[0.035]	[0.030]
School_14	-0.389 **	-0.406 **	-0.413 **	-0.434 **			-0.494 ***	-0.476 **	-0.419 **	-0.424 **
	[0.040]	[0.041]	[0.019]	[0.042]			[0.008]	[0.018]	[0.013]	[0.036]
Travel_14	-0.421	-0.472	-0.571	-0.623	-0.525	-0.502			-0.383	-0.422
	[0.548]	[0.566]	[0.378]	[0.411]	[0.445]	[0.556]			[0.544]	[0.562]
LTC_14	0.024	0.033	-0.075	-0.069	-0.041	-0.028	0.061	0.068		
	[0.961]	[0.908]	[0.842]	[0.848]	[0.918]	[0.926]	[0.850]	[0.821]		
Behaviour_14	-0.001	0.000	0.007	0.008	0.003	0.003	0.001	0.001	-0.002	0.000
	[0.883]	[0.982]	[0.527]	[0.338]	[0.767]	[0.704]	[0.826]	[0.814]	[0.856]	[0.930]
$\Delta\log(\Delta C)$_14	-0.074	-0.069	-0.059	-0.055	-0.084 *	-0.077	-0.089 **	-0.083 *	-0.078 *	-0.072
	[0.110]	[0.217]	[0.180]	[0.302]	[0.069]	[0.184]	[0.043]	[0.095]	[0.078]	[0.172]
$\log(\Delta C)$_14	-0.227 **	-0.228 *	-0.230 ***	-0.232 *	-0.227 **	-0.223	-0.214 ***	-0.211 **	-0.228 ***	-0.228 **
	[0.019]	[0.090]	[0.007]	[0.068]	[0.036]	[0.107]	[0.002]	[0.040]	[0.000]	[0.034]
$\Delta\log(\Delta NC)$_14		-0.122		-0.092		-0.071		-0.063		-0.106
		[0.572]		[0.659]		[0.755]		[0.820]		[0.642]
$\log(\Delta NC)$_14		0.080		0.083		-0.036		-0.022		0.054
		[0.743]		[0.742]		[0.893]		[0.932]		[0.823]
$\Delta\log(\Delta T)$	0.170 *	0.167 *	0.153 *	0.151	0.174 **	0.169 *	0.180 *	0.176 *	0.173 **	0.170 **
	[0.055]	[0.072]	[0.080]	[0.102]	[0.048]	[0.060]	[0.060]	[0.070]	[0.024]	[0.037]
R-squared	0.410	0.411	0.408	0.408	0.412	0.412	0.413	0.413	0.414	0.414
N	1,560	1,560	1,560	1,560	1,560	1,560	1,560	1,560	1,560	1,560
Province FE	X	X	X	X	X	X	X	X	X	X
Cubic in days	X	X	X	X	X	X	X	X	X	X

Notes: The time period is March 11 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. We drop each policy one at a time in columns (3)-(12). ***, ** and * denote 10%, 5% and 1% significance level respectively.

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Table A11: Canada – Robustness (news and weather)

	Outcome: weekly case growth $\Delta\log(\Delta C)$					
	(1)	(2)	(3)	(4)	(5)	(6)
	baseline		add weather		add news	
Mask_14	-0.618 ***	-0.613 ***	-0.676 **	-0.666 **	-0.629 ***	-0.616 ***
	[0.000]	[0.000]	[0.020]	[0.026]	[0.000]	[0.002]
Business/	-0.835 **	-0.846 **	-0.903 *	-0.912 *	-0.884 **	-0.892 **
gathering_14	[0.031]	[0.033]	[0.078]	[0.070]	[0.018]	[0.024]
School_14	-0.425 **	-0.433 **	-0.497 *	-0.528 *	-0.297	-0.292
	[0.015]	[0.019]	[0.068]	[0.085]	[0.205]	[0.111]
Travel_14	-0.375	-0.412	-0.242	-0.318	-0.302	-0.415
	[0.613]	[0.636]	[0.777]	[0.727]	[0.687]	[0.627]
Long-term care_14	0.023	0.032	0.052	0.063	0.043	0.056
	[0.958]	[0.920]	[0.908]	[0.884]	[0.900]	[0.881]
Behaviour proxy_14	-0.001	0.000	-0.002	-0.001	-0.001	0.002
	[0.880]	[0.972]	[0.868]	[0.962]	[0.918]	[0.814]
$\Delta\log(\Delta C)$_14	-0.078 *	-0.072	-0.083 *	-0.078	-0.071	-0.072
	[0.090]	[0.198]	[0.068]	[0.170]	[0.118]	[0.202]
$\log(\Delta C)$_14	-0.227 **	-0.227 *	-0.221 *	-0.224	-0.216 *	-0.221
	[0.019]	[0.090]	[0.054]	[0.120]	[0.090]	[0.110]
$\Delta\log(\Delta NC)$_14		-0.107		-0.136		-0.066
		[0.631]		[0.470]		[0.774]
$\log(\Delta NC)$_14		0.055		0.130		0.338
		[0.825]		[0.612]		[0.332]
$\Delta\log(\Delta T)$	0.172 **	0.169 *	0.189 **	0.187 *	0.161 *	0.158 *
	[0.043]	[0.056]	[0.033]	[0.052]	[0.064]	[0.078]
Rain_14			0.053	0.054		
			[0.189]	[0.177]		
Max temp_14			0.037	0.039		
			[0.434]	[0.389]		
Min temp_14			-0.031	-0.034		
			[0.562]	[0.519]		
News_14					-0.003	-0.007
					[0.278]	[0.103]
R-squared	0.414	0.414	0.419	0.419	0.415	0.416
N	1,560	1,560	1,560	1,560	1,560	1,560
Province FE	X	X	X	X	X	X
Cubic in days	X	X	X	X	X	X
Weather			X	X		
News					X	X

Notes: The time period is March 11 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. Columns (1) and (2) repeat columns (3) and (4) from Table 2. Columns (3) and (4) report estimates with lagged weather variables as additional controls. Columns (5) and (6) add a "news" variable to the baseline specification (see Appendix C for more details). ***, ** and * denote 10%, 5% and 1% significance level respectively.

Table A12: Self-reported Mask Usage ("Always" or "Frequently") – Canada

	Outcome: Wear mask "Always" or "Frequently"					
	(1)	(2)	(3)	(4)	(5)	(6)
	no time trend		cubic time trend		week fixed effects	
Mask	0.371 ***	0.354 ***	0.217 ***	0.215 ***	0.212 ***	0.211 ***
	[0.000]	[0.000]	[0.002]	[0.006]	[0.000]	[0.000]
$\Delta\log(\Delta C)$	-0.029	-0.015	-0.017 **	-0.015 *	-0.016 **	-0.019 **
	[0.503]	[0.164]	[0.032]	[0.086]	[0.047]	[0.021]
$\log(\Delta C)$	-0.037 *	0.028 ***	0.015 ***	0.015 **	0.016 ***	0.016 **
	[0.079]	[0.004]	[0.000]	[0.031]	[0.002]	[0.012]
$\Delta\log(\Delta NC)$		-0.158 **		-0.044		0.185
		[0.036]		[0.236]		[0.132]
$\log(\Delta NC)$		-0.148 ***		0.025		-0.024
		[0.000]		[0.582]		[0.907]
R-squared	0.132	0.162	0.173	0.173	0.174	0.175
N	8,859	8,859	8,859	8,859	8,859	8,859
mean wo mask mandates	0.464	0.464	0.464	0.464	0.464	0.464
individual characteristics	X	X	X	X	X	X
province fixed effects	X	X	X	X	X	X
cubic time trend (days)			X	X		
week fixed effects					X	X

Notes: The time period is April 2 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. NC denotes national total cases. The data source is YouGov. The outcome is a dummy which takes one for the respondent who answers "Always" or "Frequently" to the survey question "Thinking about the last 7 days, how often have you worn a face mask outside your home?" Sample weights are used. Individual characteristics include a gender dummy, dummies for each age (in years), dummies for each household size, dummies for each number of children, and dummies for each employment status. ***, ** and * denote 10%, 5% and 1% significance level respectively.

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Table A13: Self-reported precautions – Canada

	Outcome: "Always" response							
	(1) wash hands	(2) use sanitizer	(3) avoid going out in general	(4) avoid small gatherings	(5) avoid medium gatherings	(6) avoid large gatherings	(7) avoid crowded areas	(8) avoid touching objects
Mask	-0.013	-0.013	0.014	0.047	0.015	0.058	0.083 *	0.030
	[0.560]	[0.864]	[0.452]	[0.122]	[0.766]	[0.386]	[0.069]	[0.417]
$\Delta\log(\Delta C)$	0.006	0.006	0.003	0.002	0.011	0.007	0.021 **	-0.003
	[0.348]	[0.512]	[0.607]	[0.914]	[0.385]	[0.562]	[0.016]	[0.748]
$\log(\Delta C)$	-0.011 *	-0.005	0.013 **	0.019 *	0.011	0.011	0.011	0.011
	[0.071]	[0.523]	[0.021]	[0.056]	[0.556]	[0.348]	[0.388]	[0.162]
$\Delta\log(\Delta NC)$	-0.031	-0.025	-0.028	0.069 ***	-0.012	0.008	-0.030	-0.038
	[0.333]	[0.518]	[0.420]	[0.000]	[0.740]	[0.726]	[0.296]	[0.264]
$\log(\Delta NC)$	0.063 ***	0.066	-0.014	-0.012	0.043	0.004	0.051	0.033
	[0.002]	[0.256]	[0.725]	[0.806]	[0.461]	[0.937]	[0.424]	[0.525]
R-squared	0.045	0.049	0.048	0.133	0.146	0.126	0.081	0.042
N	8,859	8,859	8,859	8,859	8,859	8,859	8,859	8,859
individual characteristics	X	X	X	X	X	X	X	X
province FE	X	X	X	X	X	X	X	X
cubic trend (in days)	X	X	X	X	X	X	X	X
average w/o mask mandate	0.719	0.477	0.274	0.470	0.601	0.770	0.654	0.491
survey item # (i12_)	health_2	health_3	health_6	health_12	health_13	health_14	health_15	health_20

Notes: The time period is April 2 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. NC denotes national total cases. The data source is YouGov. The outcome is a dummy which takes value 1 if the respondent answered "Always" to each survey question listed in Table C4. Sample weights are used. Individual characteristics include a gender dummy, age dummy (in years), dummies for each household size, dummies for each number of children, and dummies for each employment status. ***, ** and * denote 10%, 5% and 1% significance level respectively.

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Table A14: Self-reported precautions – Canada (continued)

	Outcome: "Always" or "Frequently" response							
	(1) wash hands	(2) use sanitizer	(3) avoid going out in general	(4) avoid small gatherings	(5) avoid medium gatherings	(6) avoid large gatherings	(7) avoid crowded areas	(8) avoid touching objects
Mask	-0.005	0.003	0.035	0.046	0.009	0.050	0.074 ***	0.016
	[0.858]	[0.899]	[0.272]	[0.192]	[0.869]	[0.140]	[0.009]	[0.717]
$\Delta\log(\Delta C)$	-0.001	0.002	-0.006	-0.010	-0.004	-0.005	0.006	-0.005
	[0.716]	[0.775]	[0.568]	[0.167]	[0.688]	[0.614]	[0.291]	[0.666]
$\log(\Delta C)$	0.000	-0.004	0.018 ***	0.017 ***	0.012	0.005	0.009	-0.001
	[0.938]	[0.596]	[0.000]	[0.000]	[0.168]	[0.536]	[0.288]	[0.760]
$\Delta\log(\Delta NC)$	-0.004	-0.004	-0.094	-0.089	-0.075 *	0.038	0.001	-0.047
	[0.912]	[0.933]	[0.265]	[0.102]	[0.072]	[0.382]	[0.963]	[0.052]
$\log(\Delta NC)$	0.011	0.074	0.029	0.073	0.100 *	0.002	-0.001	0.056
	[0.578]	[0.177]	[0.533]	[0.285]	[0.085]	[0.972]	[0.998]	[0.092]
R-squared	0.076	0.050	0.074	0.109	0.101	0.089	0.079	0.046
N	8,859	8,859	8,859	8,859	8,859	8,859	8,859	8,859
individual characteristics	X	X	X	X	X	X	X	X
province FE	X	X	X	X	X	X	X	X
cubic trend (in days)	X	X	X	X	X	X	X	X
average wo mask mandate	0.929	0.755	0.629	0.696	0.777	0.869	0.859	0.796
survey item # (i12_)	health_2	health_3	health_6	health_12	health_13	health_14	health_15	health_20

Notes: The time period is April 2 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. NC denotes national total cases. The data source is YouGov. The outcome is a dummy which takes value 1 if the respondent answered "Always" or "Frequently" to each survey question in Table C4. Sample weights are used. Individual characteristics include a gender dummy, age dummy (in years), dummies for each household size, dummies for each number of children, and dummies for each employment status. ***, ** and * denote 10%, 5% and 1% significance level respectively.

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Table A15: Canada – Closing vs. Re-opening Sub-periods

	Outcome: weekly case growth $\Delta\log(\Delta C)$			
	Closing: March 11 - May 14		Re-opening: May 15 - August 13	
	(1)	(2)	(3)	(4)
Mask_14	n.a.	n.a.	-0.788 *	-0.797 *
	n.a.	n.a.	[0.070]	[0.056]
Business/gathering_14	-0.045	-0.095	-1.115 **	-1.148 *
	[0.914]	[0.874]	[0.038]	[0.056]
School_14	-0.998 ***	-1.041 ***	0.005	-0.016
	[0.000]	[0.000]	[1.000]	[0.939]
Travel_14	-2.433 ***	-2.623 ***	0.910	0.929
	[0.000]	[0.000]	[0.351]	[0.376]
Long-term care_14	-0.803 ***	-0.906 **	-0.260	-0.264
	[0.006]	[0.010]	[0.578]	[0.563]
Behaviour proxy_14	-0.036 *	-0.034	-0.012	-0.013
	[0.087]	[0.139]	[0.841]	[0.834]
$\Delta\log(\Delta C)$_14	0.075	0.076	-0.156	-0.157
	[0.184]	[0.250]	[0.105]	[0.136]
$\log(\Delta C)$_14	-0.399 ***	-0.413 ***	-0.221	-0.221
	[0.000]	[0.000]	[0.148]	[0.161]
$\Delta\log(\Delta NC)$_14		-0.120		-0.346
		[0.535]		[0.709]
$\log(\Delta NC)$_14		0.285		0.494
		[0.312]		[0.657]
$\Delta\log(\Delta T)$	0.110	0.099	0.233	0.261
	[0.256]	[0.299]	[0.479]	[0.423]
R-squared	0.689	0.689	0.169	0.170
N	650	650	910	910
province fixed effects	X	X	X	X
cubic time trend (days)	X	X	X	X

Notes: P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. ***, ** and * denote 10%, 5% and 1% significance level respectively. NC denotes national total cases. No mask mandates are present in the closing period.

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Table A16: Canada – Deaths growth (treatment of zero weekly deaths)

	Outcome: weekly deaths growth $\Delta\log(\Delta D)$					
	(1)	(2)	(3)	(4)	(5)	(6)
	baseline		4 largest provinces		population weighted	
Mask_28	-0.922 **	-0.983 **	0.139	0.009	-0.260	-0.480
	[0.022]	[0.032]	[0.762]	[0.762]	[0.592]	[0.488]
Business/gathering_28	-0.134	-0.224	-2.067 ***	-2.277 ***	-1.300	-1.442
	[0.762]	[0.748]	[0.000]	[0.000]	[0.102]	[0.106]
School_28	0.441	0.440	0.599	0.601	0.355	0.371
	[0.317]	[0.341]	[0.381]	[0.255]	[0.500]	[0.557]
Travel_28	-0.005	-0.027	1.645	2.101	0.906	0.741
	[0.972]	[0.935]	[0.259]	[0.244]	[0.216]	[0.405]
Long-term care_28	-0.035	-0.036	-0.024	-0.088	-0.053	-0.056
	[0.900]	[0.900]	[0.878]	[0.762]	[0.896]	[0.808]
Behaviour proxy_28	0.002	0.003	-0.012	-0.001	-0.009	-0.001
	[0.815]	[0.737]	[0.244]	[0.861]	[0.500]	[0.958]
$\Delta\log(\Delta D)$_28	0.141	0.152	-0.037 ***	0.006	0.010	0.065
	[0.361]	[0.345]	[0.000]	[0.599]	[0.818]	[0.344]
$\log(\Delta D)$_28	-0.216 ***	-0.220 ***	-0.139	-0.164	-0.164 *	-0.181
	[0.000]	[0.000]	[0.381]	[0.253]	[0.056]	[0.100]
$\Delta\log(\Delta ND)$_28		-0.121		-0.197		-0.262 *
		[0.476]		[0.244]		[0.065]
$\log(\Delta ND)$_28		0.018		0.203		0.147
		[0.858]		[0.125]		[0.448]
$\Delta\log(\Delta T)$	-0.038	-0.051	0.194 ***	0.125	0.176	0.130
	[0.758]	[0.735]	[0.000]	[0.255]	[0.050]	[0.124]
R-squared	0.251	0.254	0.474	0.480	0.496	0.507
N	1,470	1,470	588	588	1,470	1,470
Province FE	X	X	X	X	X	X
cubic time trend (days)	X	X	X	X	X	X
population weighted	No	No	Yes	Yes	No	No

Notes: The time period is March 11 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. Columns (1) and (2) repeat columns (3) and (4) from Table 4. Columns (3) and (4) report results from a weighted least squares regression with the province populations used as weights. Columns (5) and (6) restrict the sample to only the largest 4 provinces (BC, ON, QC, and AB) with only 5% (29 out of 588) observations with zero weekly deaths. ***, ** and * denote 10%, 5% and 1% significance level respectively. ND denotes national total deaths.

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Table A17: Canada - Correlations between the policy indicators

Policy	indicator	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15	P16	P17
Mask	P1. mandatory indoor masks	1																
	P2. non-essential business/retail	-0.11	1															
	P3. personal services	-0.18	0.67	1														
	P4. restaurants	-0.14	0.64	0.83	1													
Business/	P5. bars/nightclubs	-0.14	0.55	0.75	0.84	1												
gathering	P6. religious worship	-0.05	0.66	0.76	0.80	0.77	1											
	P7. events gathering	-0.07	0.65	0.81	0.84	0.76	0.79	1										
	P8. recreation/parks/gyms	-0.17	0.74	0.78	0.78	0.73	0.75	0.81	1									
	P9. gathering maximum index	-0.02	0.56	0.70	0.72	0.71	0.79	0.76	0.64	1								
School	P10. no school	0.05	0.18	0.27	0.26	0.41	0.27	0.42	0.20	0.51	1							
	P11. travel ban international	0.04	0.16	0.27	0.26	0.43	0.34	0.41	0.16	0.57	0.77	1						
Travel	P12. travel ban domestic	-0.09	0.09	0.07	-0.02	0.14	0.04	-0.01	0.06	0.15	0.15	0.14	1					
	P13. self-isolation international	0.04	0.16	0.27	0.23	0.38	0.30	0.40	0.13	0.53	0.72	0.86	0.15	1				
	P14. self-isolation domestic	-0.14	0.12	0.20	0.07	0.19	0.21	0.06	0.07	0.26	0.24	0.23	0.63	0.23	1			
LTC	P15. LTC visits	-0.16	0.40	0.56	0.58	0.59	0.54	0.57	0.48	0.54	0.35	0.35	0.13	0.32	0.33	1		
	P16. LTC single site	0.05	-0.23	-0.17	-0.08	-0.13	-0.20	-0.05	-0.20	-0.03	0.18	0.25	-0.15	0.26	-0.23	-0.06	1	
	P17. provincial emergency	-0.07	0.21	0.33	0.39	0.56	0.44	0.42	0.30	0.51	0.55	0.63	0.16	0.57	0.26	0.40	0.01	1

Notes: The time period is Feb 26 to July 30 (two weeks before the March 11 - August 13 sample period). Daily province-level data.

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Table A18: Canada – Location behaviour and policies

	Outcome: location behaviour							
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Retail		Grocery		Workplaces		Behaviour proxy, B_{it}	
Mask	-4.204	-4.175	-0.670	-0.810	-0.385	-0.403	-1.753	-1.796
	[0.440]	[0.429]	[0.814]	[0.770]	[0.806]	[0.795]	[0.563]	[0.514]
Business/gathering	-18.959 *	-14.359 *	-12.243 **	-8.640	-12.110 *	-7.636	-14.437 **	-10.212
	[0.055]	[0.092]	[0.044]	[0.153]	[0.084]	[0.195]	[0.049]	[0.150]
School	-16.524 **	-8.927	-7.111 **	-1.894	-24.795 ***	-17.613 **	-16.143 ***	-9.478
	[0.020]	[0.297]	[0.013]	[0.663]	[0.004]	[0.028]	[0.003]	[0.114]
Travel	-15.648	-10.505	-18.913 ***	-13.735 **	-7.354	-2.029	-13.971 *	-8.756
	[0.162]	[0.340]	[0.000]	[0.019]	[0.174]	[0.607]	[0.058]	[0.223]
Long-term care	0.131	-0.717	-0.237	-1.088	-1.987	-2.864 *	-0.698	-1.556
	[0.980]	[0.914]	[0.960]	[0.768]	[0.480]	[0.079]	[0.873]	[0.610]
$\Delta\log(\Delta C)$	1.614 **	1.235 *	1.905 ***	1.397 ***	1.134 *	0.707	1.551 ***	1.113 **
	[0.023]	[0.051]	[0.000]	[0.004]	[0.075]	[0.132]	[0.004]	[0.034]
$\log(\Delta C)$	-2.545 ***	-2.062 ***	-1.935 ***	-1.537 ***	-1.387 **	-0.912 *	-1.956 ***	-1.504 ***
	[0.005]	[0.000]	[0.007]	[0.006]	[0.013]	[0.075]	[0.007]	[0.000]
$\Delta\log(\Delta NC)$		5.462 **		8.543 ***		6.511 ***		6.839 ***
		[0.034]		[0.000]		[0.000]		[0.000]
$\log(\Delta NC)$		-9.372 ***		-7.206 **		-9.076 ***		-8.551 ***
		[0.004]		[0.018]		[0.000]		[0.000]
R-squared	0.935	0.942	0.866	0.880	0.910	0.925	0.927	0.938
N	1,560	1,560	1,560	1,560	1,560	1,560	1,560	1,560
province fixed effects	X	X	X	X	X	X	X	X
cubic time trend (days)	X	X	X	X	X	X	X	X

Notes: The time period is March 11 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. The behaviour proxy B_{it} in columns (7) and (8) is the unweighted average of the "retail", "grocery" and "workplaces" Google mobility indices. ***, ** and * denote 10%, 5% and 1% significance level respectively. NC denotes national total cases.

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Table A19: Ontario – Policies and information only

	Outcome: weekly case growth $\Delta\log(\Delta C)$					
	(1)	(2)	(3)	(4)	(5)	(6)
	no time trend		cubic time trend		week fixed effects	
Mask_14	-0.228 *	-0.286 **	-0.333 **	-0.341 **	-0.286 **	-0.298 **
	[0.050]	[0.036]	[0.025]	[0.025]	[0.036]	[0.028]
Business/gathering_14	0.041	0.132	0.039	0.512	0.128	0.256
	[0.816]	[0.710]	[0.937]	[0.437]	[0.824]	[0.670]
Long-term care_14	0.467	0.366	0.799	-0.240	-1.022	-2.033 *
	[0.570]	[0.670]	[0.653]	[0.856]	[0.393]	[0.099]
$\Delta\log(\Delta C)$_14	0.028	0.026	0.027	0.030	0.014	0.014
	[0.645]	[0.682]	[0.676]	[0.652]	[0.804]	[0.825]
$\log(\Delta C)$_14	-0.198 ***	-0.202 ***	-0.200 ***	-0.207 ***	-0.195 ***	-0.198 ***
	[0.002]	[0.001]	[0.001]	[0.000]	[0.001]	[0.001]
$\Delta\log(\Delta PC)$_14		0.391		0.260		0.572 **
		[0.170]		[0.401]		[0.038]
$\log(\Delta PC)$_14		-0.045		0.462		0.128
		[0.841]		[0.168]		[0.712]
$\Delta\log(\Delta T)$	-0.363 **	-0.481 **	-0.209	-0.343	-0.194	-0.464
	[0.050]	[0.028]	[0.381]	[0.169]	[0.564]	[0.144]
R-squared	0.046	0.050	0.051	0.058	0.091	0.094
N	3,094	3,094	3,094	3,094	3,094	3,094
public health unit FE	X	X	X	X	X	X
cubic time trend (days)			X	X		
week fixed effects					X	X

Notes: The time period is May 15 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by public health unit (PHU) with 5000 repetitions are reported in the square brackets. ***, ** and * denote 10%, 5% and 1% significance level respectively.

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Table A20: Canada – Policy and Information only

	Outcome: weekly case growth, $\Delta\log(\Delta C)$					
	(1)	(2)	(3)	(4)	(5)	(6)
	no time trend		cubic time trend		week fixed effects	
Mask_14	-0.413 ***	-0.416 ***	-0.629 ***	-0.618 ***	-0.567 ***	-0.561 ***
	[0.000]	[0.000]	[0.000]	[0.002]	[0.000]	[0.004]
Business	-0.288	-0.425	-0.665	-0.716 **	-0.500	-0.579
/gathering_14	[0.112]	[0.165]	[0.103]	[0.032]	[0.138]	[0.112]
School_14	-0.244	-0.381	-0.431	-0.443 *	-0.250	-0.353
	[0.461]	[0.334]	[0.144]	[0.066]	[0.258]	[0.137]
Travel_14	-0.509	-0.794	-0.293	-0.368	-0.430	-0.592
	[0.270]	[0.106]	[0.579]	[0.580]	[0.612]	[0.481]
Long-term care_14	-0.100	-0.193	0.027	0.037	0.081	0.064
	[0.67]	[0.494]	[0.917]	[0.904]	[0.805]	[0.849]
$\Delta\log(\Delta C)$_14	-0.024	-0.010	-0.040	-0.026	-0.017	-0.015
	[0.56]	[0.824]	[0.385]	[0.555]	[0.772]	[0.797]
$\log(\Delta C)$_14	-0.182 ***	-0.208 ***	-0.197 ***	-0.200 **	-0.201 *	-0.214 *
	[0.000]	[0.000]	[0.000]	[0.01]	[0.064]	[0.067]
$\Delta\log(\Delta NC)$_14		-0.073		-0.221		-0.106
		[0.636]		[0.291]		[0.581]
$\log(\Delta NC)$_14		0.121		0.012		0.281 *
		[0.359]		[0.938]		[0.090]
$\Delta\log(\Delta T)$	0.139	0.187 *	0.185 *	0.176 *	0.155	0.162 *
	[0.107]	[0.052]	[0.069]	[0.080]	[0.131]	[0.100]
R-squared	0.382	0.386	0.391	0.393	0.414	0.416
N	1,560	1,560	1,560	1,560	1,560	1,560
province fixed effects	X	X	X	X	X	X
cubic time trend (days)			X	X		
week fixed effects					X	X

Notes: The time period is March 11 to August 13, 2020. P-values from wild bootstrap (cgmwildboot) standard errors clustered by province with 5000 repetitions are reported in the square brackets. ***, ** and * denote 10%, 5% and 1% significance level respectively.

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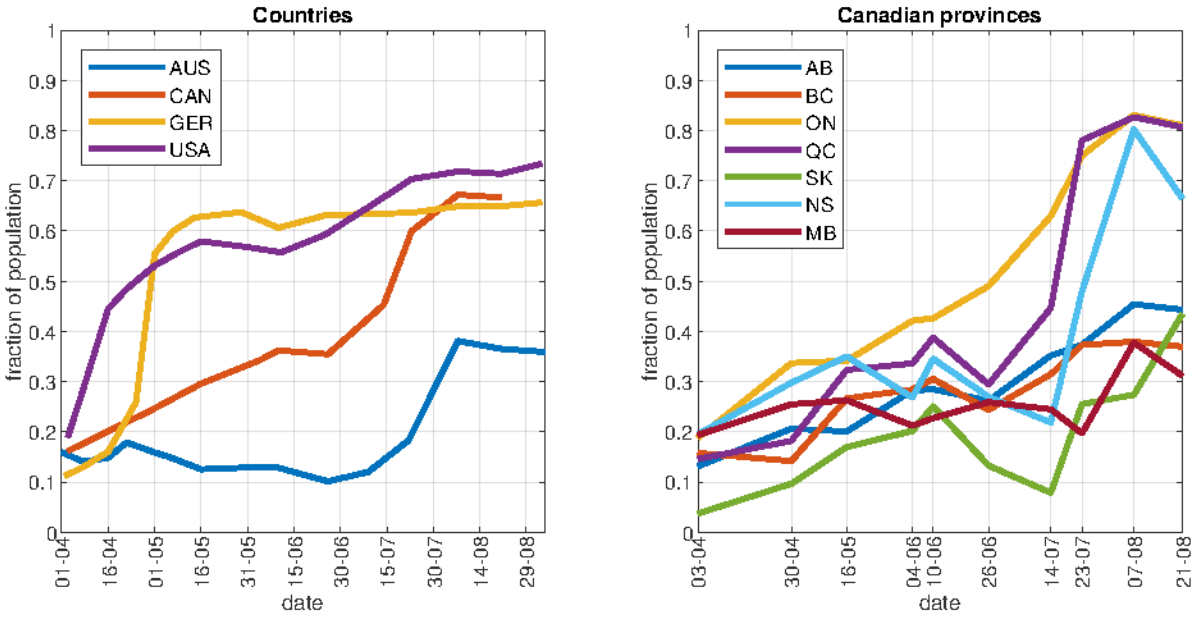
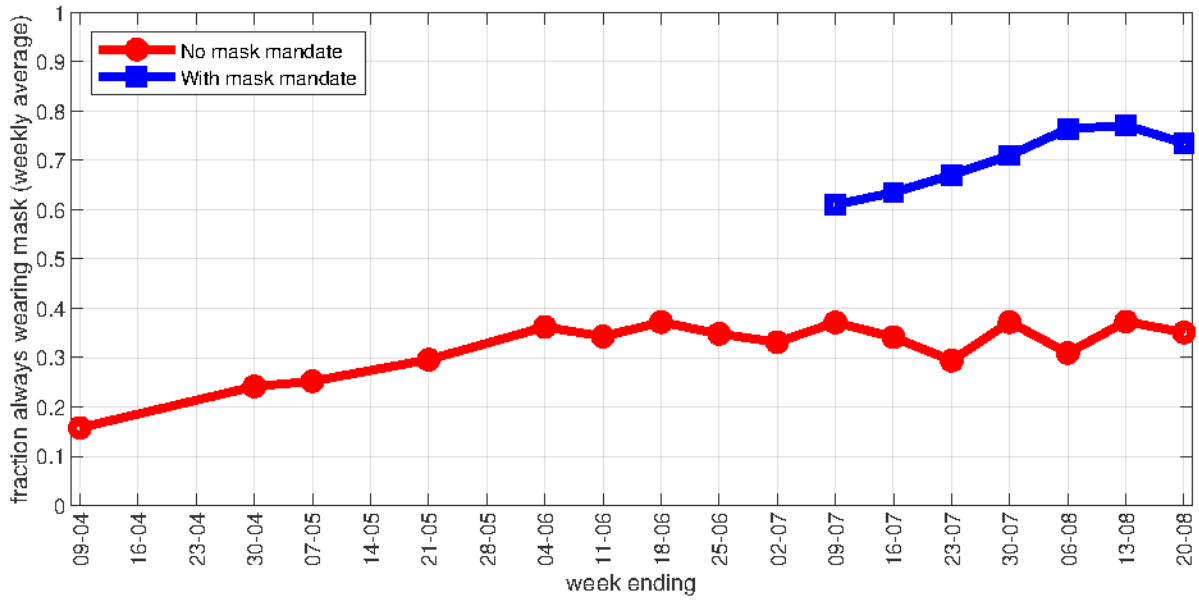
Appendix B. Additional Figures

Figure B1: Self-reported mask usage in selected countries and Canadian provinces



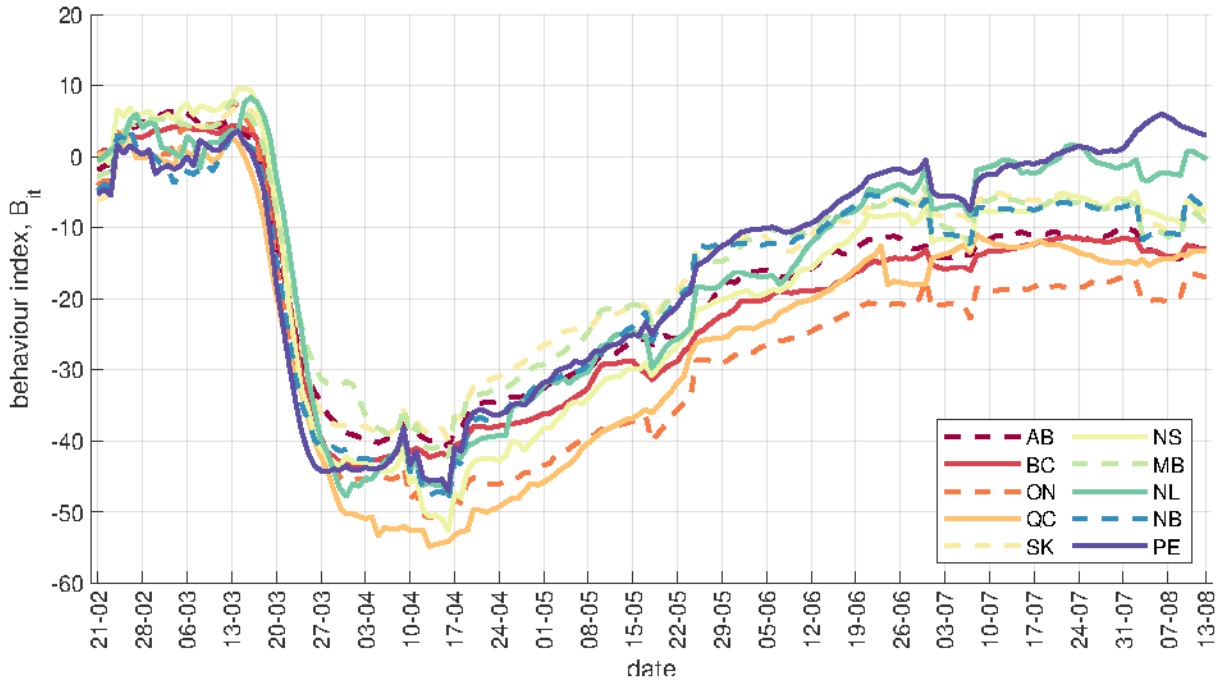
Notes: The data source is YouGov. The outcome equals 1 if the respondent answered "Always" to the question "Worn a face mask outside your home" and 0 otherwise. The sample weights are used to construct the country and provincial averages.

Figure B2: Canada - mask mandates and self-reported mask usage



Notes: The data source is YouGov. The figure plots the average self-reported mask usage by week (the fraction of respondents who answered "Always" to the survey question "Worn a face mask outside your home") in the provinces with vs. without mask mandates. Sample weights used to compute the averages.

Figure B3: Canada - Behaviour proxy, B_{it}



Notes: The Behaviour proxy B_{it} is the average of the "retail", "grocery and pharmacy", and "workplaces" Google mobility indicators. Province-level 7-day moving averages are plotted.

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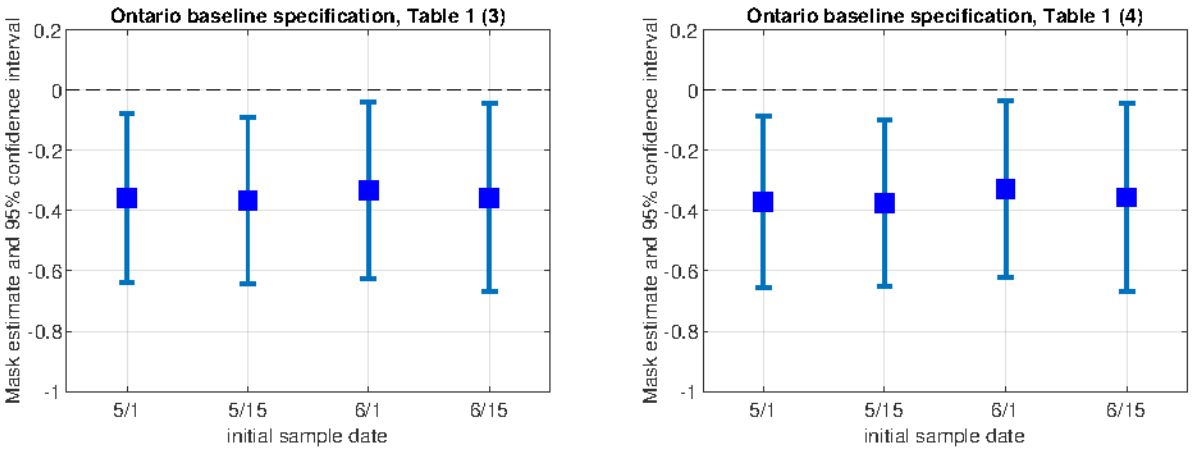
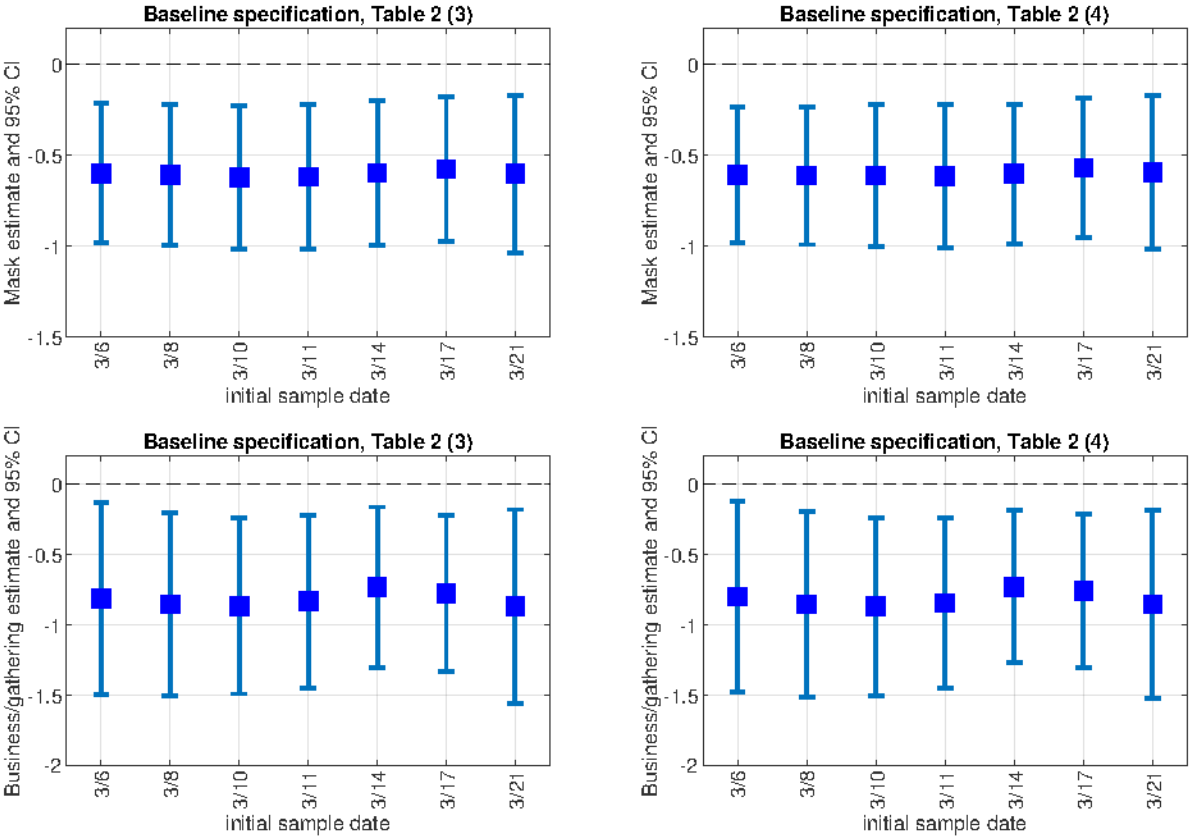
Figure B4: Ontario - different initial dates



Notes: We plot the coefficient estimates on mask policy, with 95% confidence intervals, from equation (1), for different initial dates of the sample. The initial sample date in the baseline specifications reported in Table 1 is May 15. The left panel corresponds to baseline column (3) in Table 1, the right column corresponds to column (4) in Table 1.

Figure B5: Canada - different initial dates



Notes: We plot the coefficient estimates on mask policy, with 95% confidence intervals, in the upper panel and the estimates on business/gathering policy in the lower panel, from equation (1) for different initial dates of the sample. The initial date in our baseline specification (Table 2) is March 11. The left panels correspond to column (3) in Table 2; the right panels correspond to column (4) in Table 2.

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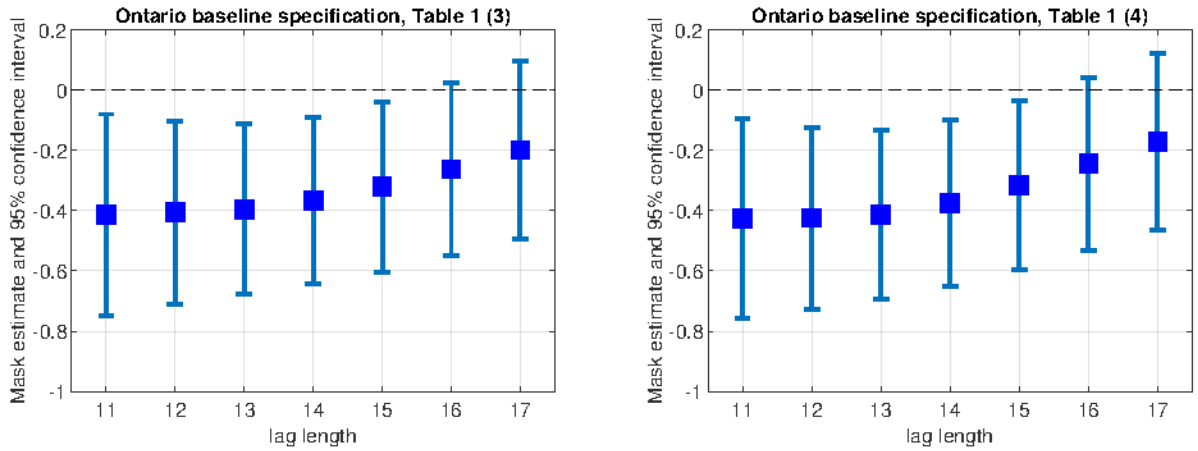
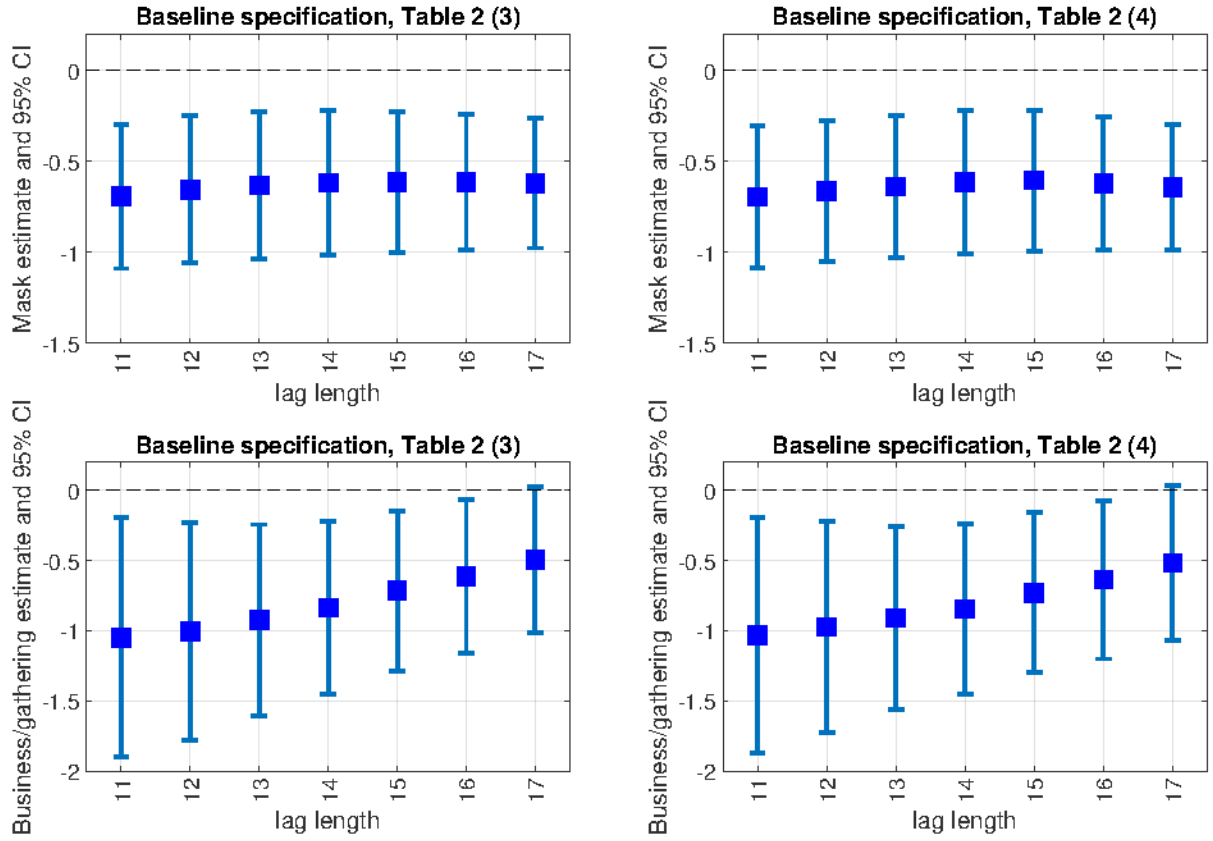
Figure B6: Ontario - different lags



Notes: We plot the coefficient estimates on mask policy, with 95% confidence intervals, in equation (1) for different lag values. The lag used in the baseline specifications in Table 1 is 14 days. The left panel corresponds to column (3) in Table 1, the right column corresponds to column (4) in Table 1.

Figure B7: Canada - different lags



Notes: We plot the estimates on mask policy in the upper panel and the business/gathering policy in the lower panel, in equation (1) for different lag values. The lag in our baseline specification (Table 2) is 14 days. The left panels correspond to column (3) in Table 2; the right panels correspond to column (4) in Table 2.

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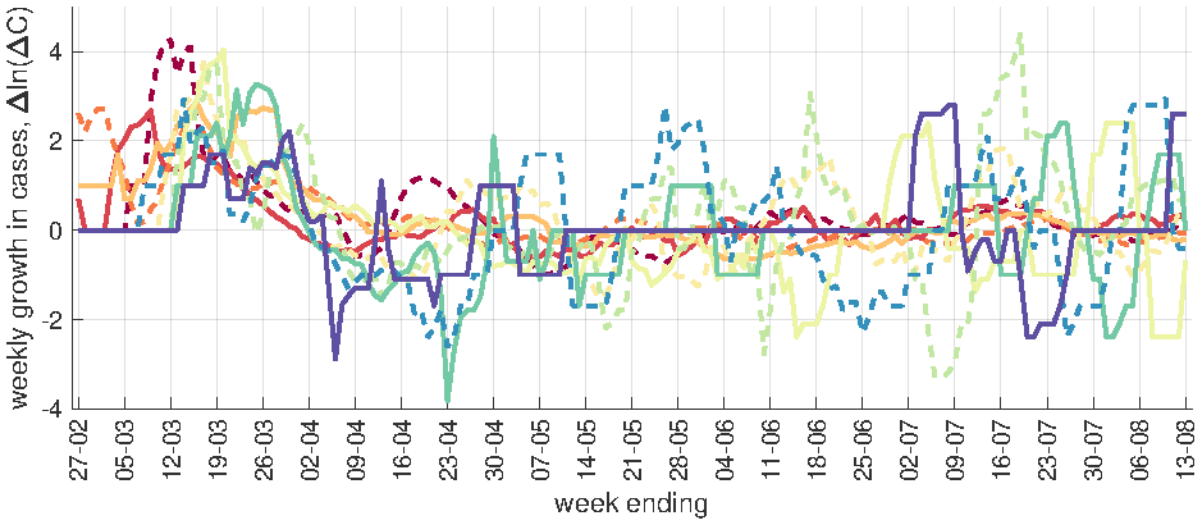
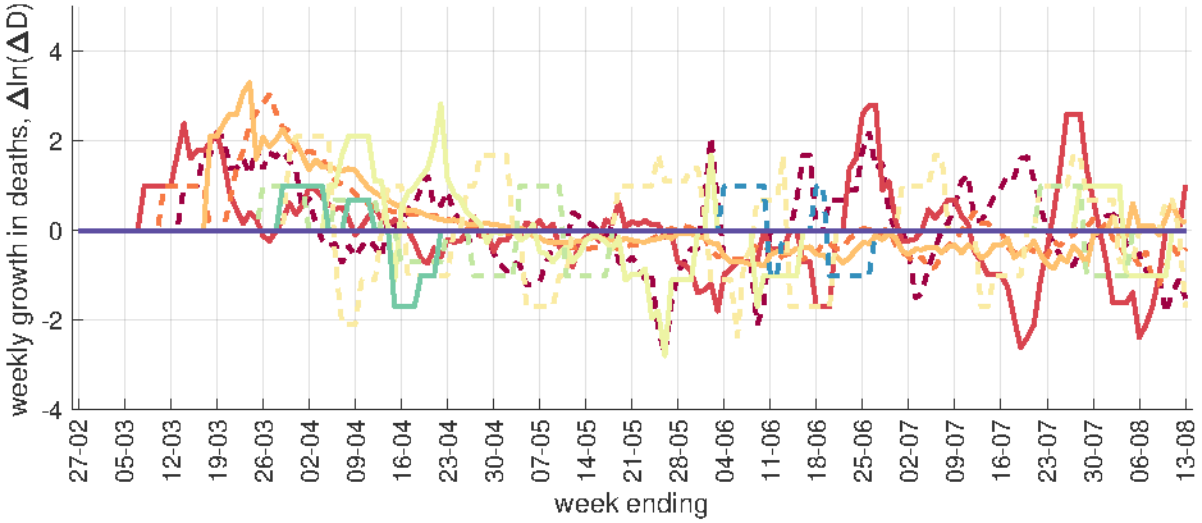
Figure B8: Canada – Weekly cases, deaths and tests (growth rate)





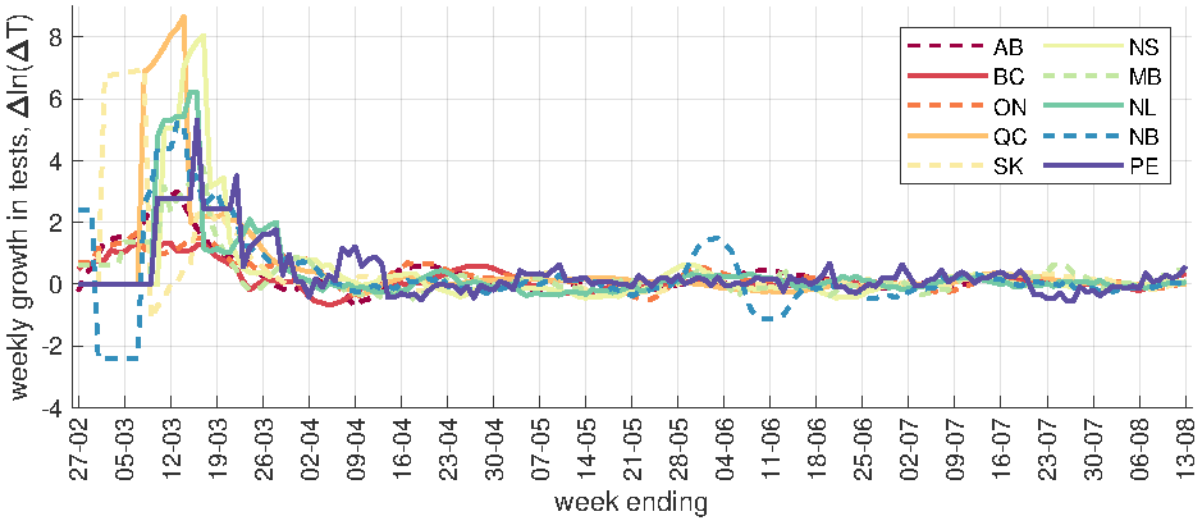


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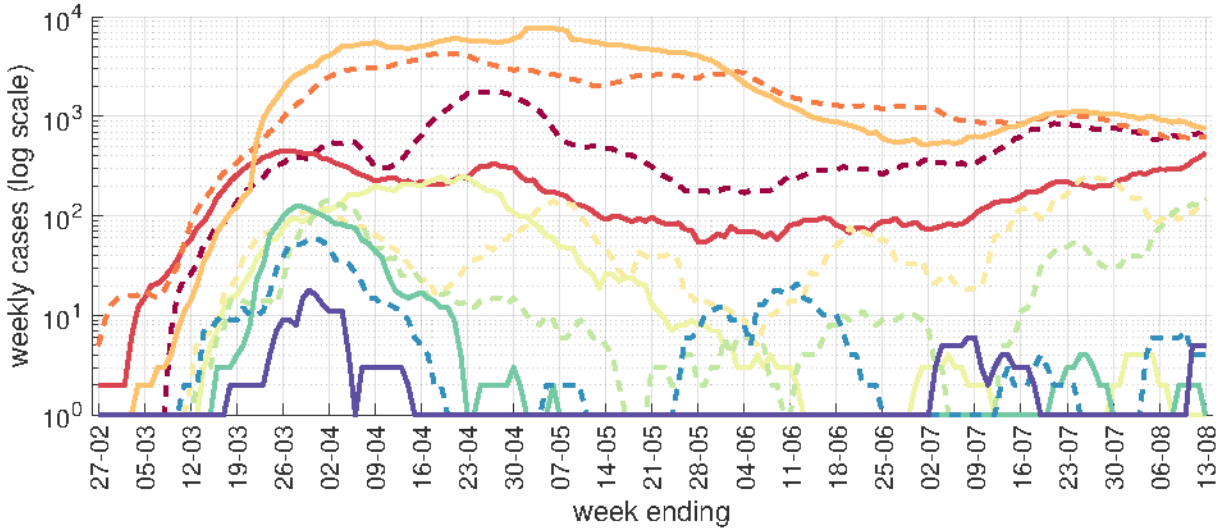
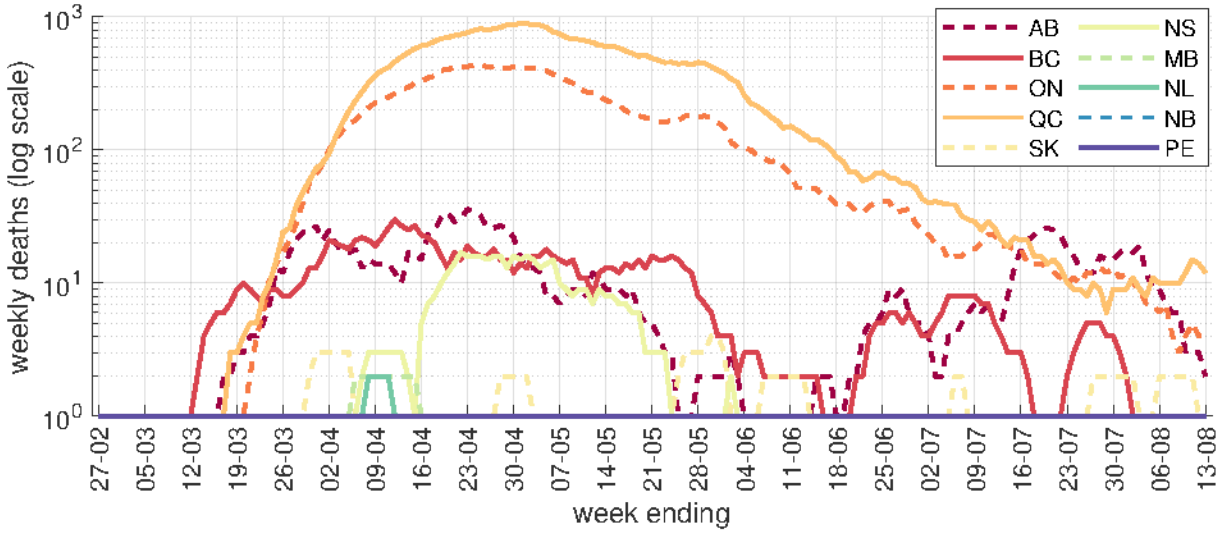
Figure B9: Canada – Weekly cases, deaths and tests (level)





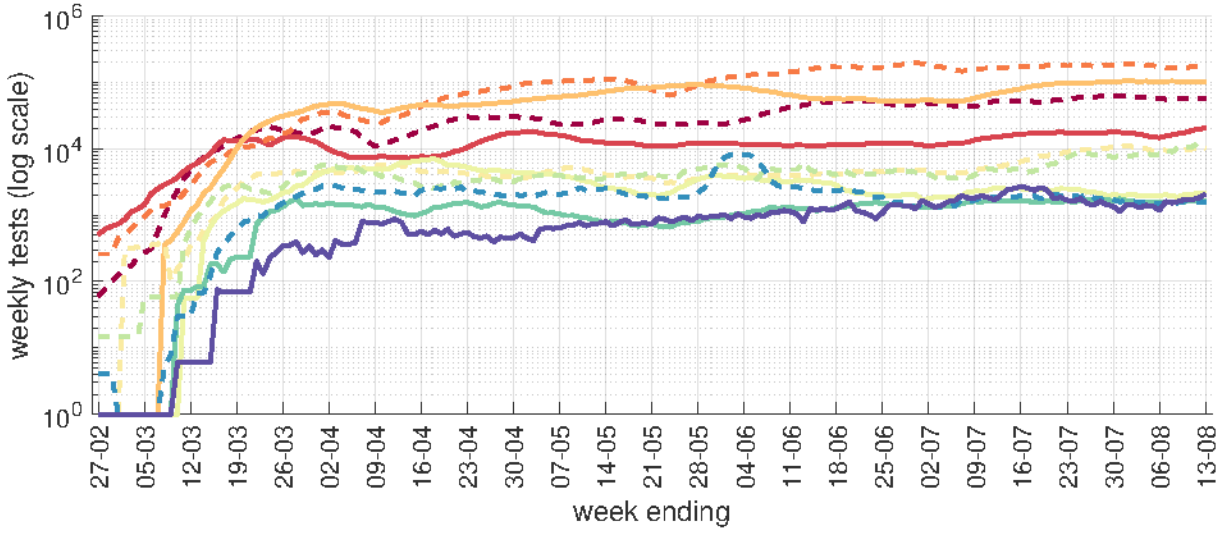


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Figure B10: Canada – Daily cases, deaths and tests

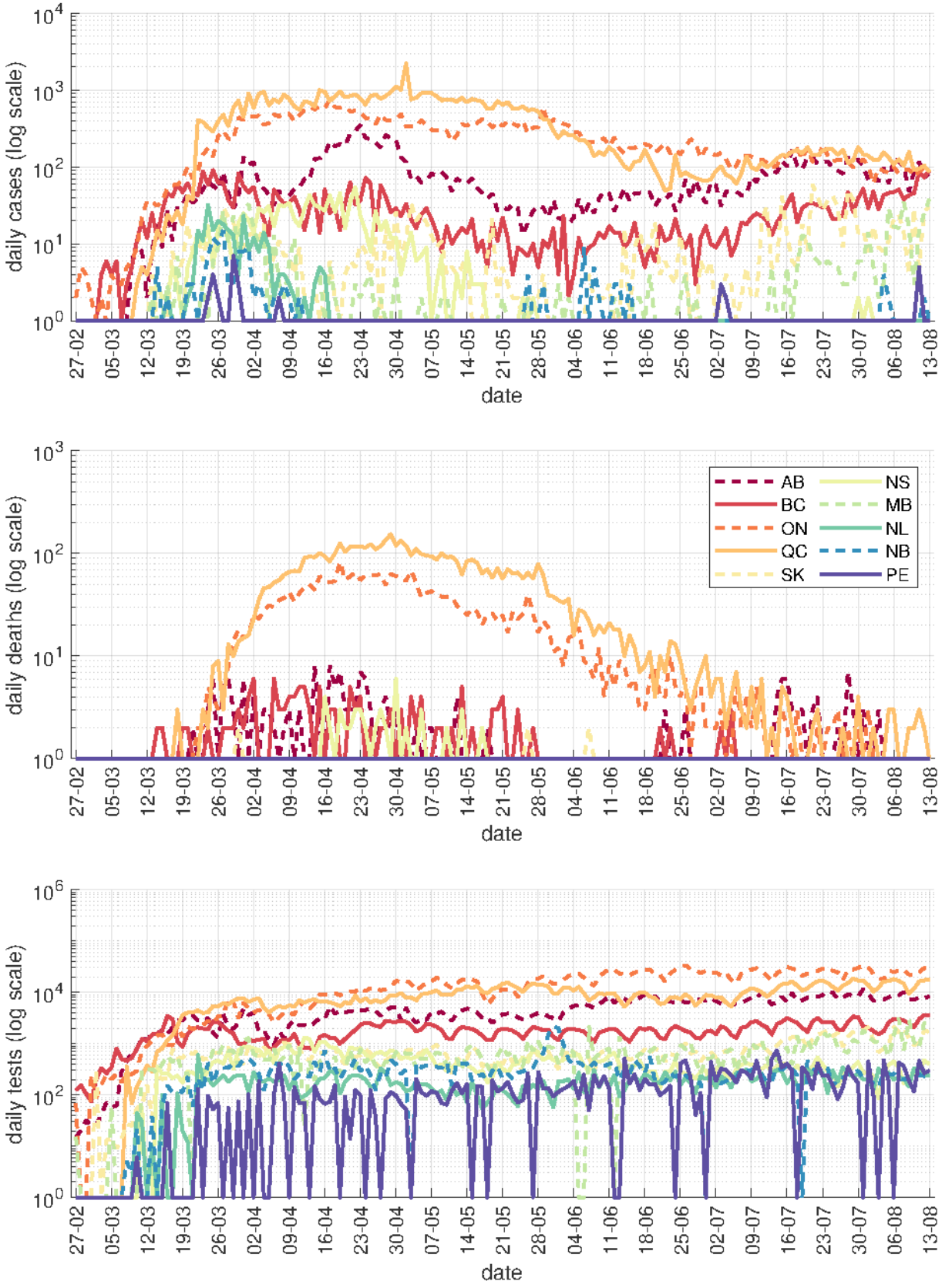

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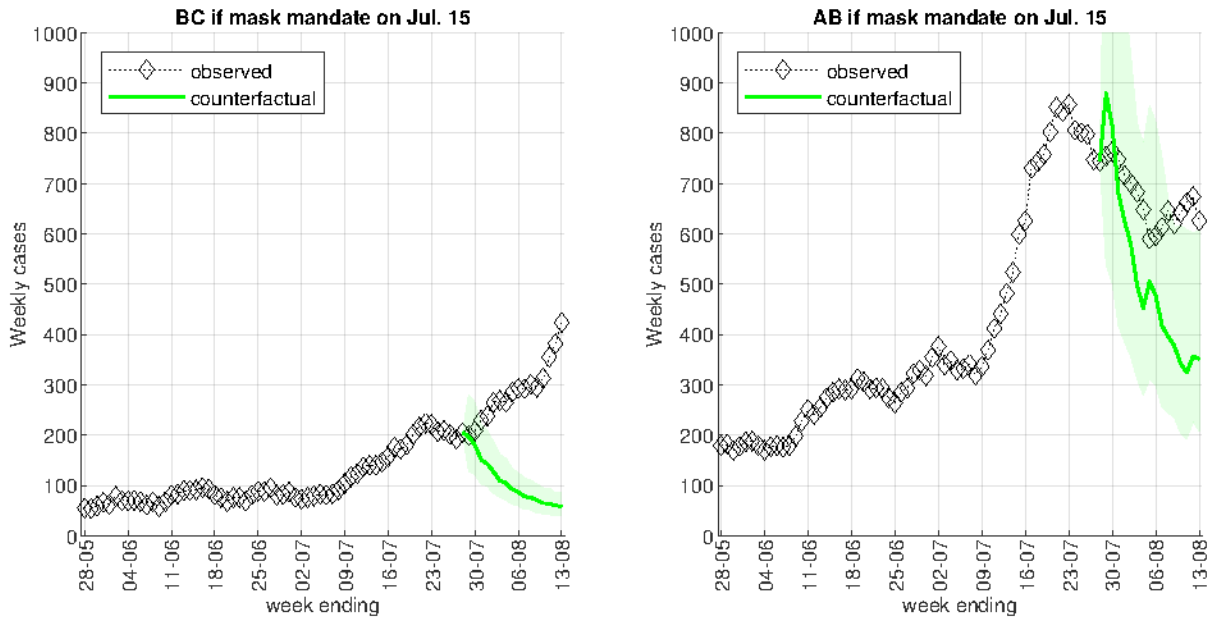
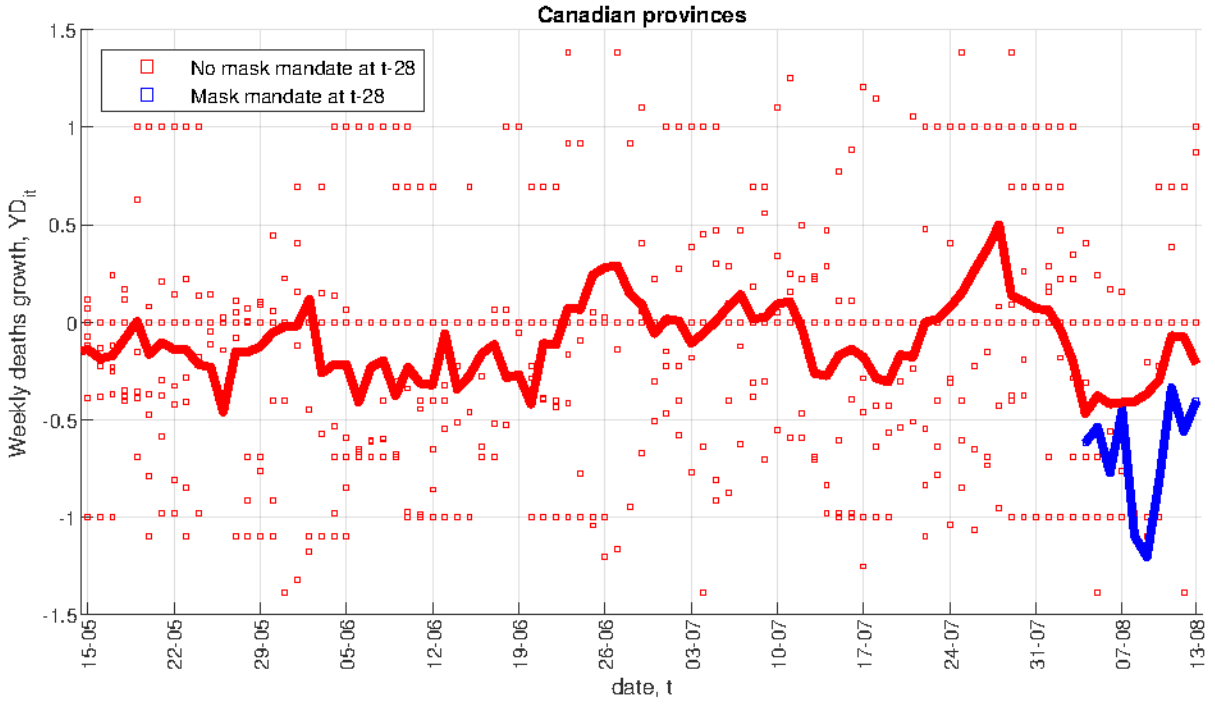
Figure B11: Counterfactuals – Mask mandates in Alberta and British Columbia



Notes: The figure assumes mask adoption on July 15 for two provinces that have not yet adopted mask mandates, specifically British Columbia (BC, left panel) and Alberta (AB, right panel). The counterfactual uses the mask mandate estimate -0.613 from Table 2, column (4).

Figure B12: Canada - mask mandates and weekly deaths growth



Notes: Average log weekly death growth in provinces with vs. without mask mandates 28 days prior.

Appendix C. Definitions and data sources

Table C1: Policy indicators and aggregates

Non-Essential Travel	
restrictions - international	1: travelers that are neither citizens nor residents 0.5: same as 1, but US citizens allowed
restrictions - inter-provincial	1: residents of all other provinces 0.5: residents of some other provinces
self-isolation - international	1: required (by provincial or federal government) 0.5: recommended (by provincial or federal government)
self-isolation - inter-provincial	1: required of residents of all other provinces 0.5: required of residents of some other provinces, or recommended
Primary and Secondary Schools	
schools closed	1: no classes (includes Spring and Summer breaks) 0.5: part-time classes; 0: classes in session
Business and Gathering Regulations	
non-essential and retail business personal services business restaurants bars and nightclubs places of worship events and gatherings recreation, gyms and parks	0: no or lowest restrictions; 1: strictest restrictions; values between 0 and 1: partial restrictions
indoor gatherings maximum	1: no gathering allowed; $x \in [0.5, 1]$: limit of $100(1-x)$ $x \in [0, 0.5]$: limit of $25/x$
Long-Term Care (LTC) Regulations	
visiting restrictions	1: no visits (with limited exceptions such as end of life) 0.5: number of visitors restricted
single-site work requirement[1]	1: requirement in effect 0.5: requirement with explicit later implementation deadline
Mandatory Masks	
indoor public places[2]	1: mask mandate in effect; 0: no mandate
provincial declaration of emergency	1: in effect; 0: not in effect

Notes: 1. We do not consider recommendations or requirements limited to outbreak facilities. 2. We do not consider limited mask mandates such as applying only to transit or personal service establishments.

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Table C2: Ontario public health regions and date of mask mandate

1	Algoma Public Health Unit	July 17, 2020
2	Brant County Health Unit	July 20, 2020
3	Chatham-Kent Health Unit	August 14, 2020
4	Durham Region Health Department	July 10, 2020
5	Eastern Ontario Health Unit	July 07, 2020
6	Grey Bruce Health Unit	July 17, 2020
7	Haldimand-Norfolk Health Unit	August 01, 2020
8	Haliburton, Kawartha, Pine Ridge District Health Unit	July 13, 2020
9	Halton Region Health Department	July 22, 2020
10	Hamilton Public Health Services	July 20, 2020
11	Hastings and Prince Edward Counties Health Unit	July 10, 2020
12	Huron Perth District Health Unit	July 17, 2020
13	Kingston, Frontenac and Lennox & Addington Public Health	June 27, 2020
14	Lambton Public Health	July 31, 2020*
15	Leeds, Grenville and Lanark District Health Unit	July 07, 2020
16	Middlesex-London Health Unit	July 18, 2020
17	Niagara Region Public Health Department	July 31, 2020
18	North Bay Parry Sound District Health Unit	July 24, 2020
19	Northwestern Health Unit	August 17, 2020
20	Ottawa Public Health	July 07, 2020
21	Peel Public Health	July 10, 2020
22	Peterborough Public Health	August 01, 2020
23	Porcupine Health Unit	July 23, 2020
24	Region of Waterloo, Public Health	July 13, 2020
25	Renfrew County and District Health Unit	July 14, 2020
26	Simcoe Muskoka District Health Unit	July 13, 2020
27	Southwestern Public Health	July 31, 2020
28	Sudbury & District Health Unit	July 17, 2020
29	Thunder Bay District Health Unit	July 24, 2020
30	Timiskaming Health Unit	July 24, 2020
31	Toronto Public Health	July 07, 2020
32	Wellington-Dufferin-Guelph Public Health	June 12, 2020
33	Windsor-Essex County Health Unit	June 26, 2020
34	York Region Public Health Services	July 17, 2020

*Lambton Public Health did not enact a mask mandate as of the end of August 2020. However, the City of Sarnia, which has 58 % of Lambton's population according to the 2016 Census, enacted a mask mandate on July 31, 2020. The mask variable for Lambton is coded as 0.5 from July 31, 2020 onward.

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Table C3: Canada COVID-19 official data sources

Province	Cases	Deaths	Tests
Alberta (AB)	link	link	link
British Columbia (BC)	link	link	link
Ontario (ON)	link	link	link
Quebec (QC)	link	link	link
Saskatchewan (SK)	link[1]	link	link
Nova Scotia (NS)	link	link	link
Manitoba (MB)	link	link	link[2]
Newfoundland and Labrador (NL)	link[1]	link	link
New Brunswick (NB)	link	link	link
Prince Edward Island (PE)	link	link	link

Notes: 1. Saskatchewan and Newfoundland and Labrador do not revise their posted data series. We made data adjustments based on subsequent revisions announced in government bulletins; 2. The Manitoba tests numbers were manually collected from the COVID-19 provincial government bulletins.

Weather – we downloaded historical weather data for the largest city in each province from the Weather Canada website. The data provide daily information on 11 variables: maximum temperature (C), minimum temperature (C), mean temperature (C), heating degree-days, cooling degree-days, total rain (mm), total snow (cm), total precipitation (mm), snow on the ground (cm), direction of maximum wind gust (tens of degrees), and speed of maximum wind gust (km/h). We only use the temperature and precipitation data in Table A11 as possible factors determining outside vs. inside activity.

News – we collected data from *Proquest Canadian Newsstream*, a subscription service to all major and small-market daily or weekly Canadian news sources. We recorded the number of search results for each day from Feb 1, 2020 to Aug 20, 2020 by searching the database for the keywords "Coronavirus" or "COVID-19". We only counted the results with source listed as "newspaper" since other sources, such as blogs or podcasts, tend to duplicate the same original content.

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Table C4: YouGov Survey Questions

Survey item	Question
i12_health_2	Washed hands with soap and water
i12_health_3	Used hand sanitiser
i12_health_6	Avoided going out in general
i12_health_12	Avoided small social gatherings (not more than 2 people)
i12_health_13	Avoided medium-sized social gatherings (between 3 and 10 people)
i12_health_14	Avoided large-sized social gatherings (more than 10 people)
i12_health_15	Avoided crowded areas
i12_health_20	Avoided touching objects in public (e.g. elevator buttons or doors)

Notes: the data source is YouGov. Possible responses to each survey item are "Always", "Frequently", "Sometimes", "Rarely", and "Not at all". For Table A13, we create a binary variable taking value 1 if the response is "Always" and 0 otherwise. For Table A14, we create a binary variable taking value of 1 if the respondent answered either "Always" or "Frequently" and 0 otherwise.

All data used in the paper are available at https://github.com/C19-SFU-Econ/data.

Appendix D. Lags Determination

As discussed in Section 3.1, we assume a lag of 14 days between a change in policy or behaviour and its hypothesized effect on weekly case growth, and a lag of 28 days between such a change and its effect on weekly death growth.

First, we consider the lag between infection and a case being reported. As most identified cases of COVID-19 in Canada are symptomatic, we focus on symptomatic individuals. For most provinces cases are listed according to the date of report to public health. In provinces where the dates instead refer to the public announcement, we shifted them back by one day, as announcements typically contain the cases reported to public health on the previous day. The relevant lag therefore has two components:

1. Incubation period: Most studies suggest an average incubation period of 5-6 days (e.g. 5.2 days in Li et al. (2020), 5.5 days in Lauer et al. (2020), 5.6 days in Linton et al. (2020), 6.4 days in Backer et al. (2020)).

2. Time between symptoms onset and reporting of the case to public health: the Ontario data contain an estimate of the symptom onset date ("episode date") for each case. For our sample period the average difference between the date of report and the episode date is 4.8 days (median: 4 days) including only values from 1 to 14 days, and 6.3

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days (median: 5 days) including only values from 2 to 28 days. We assume that the lags in Ontario and in other provinces are similar, and use a value of 5-6 days between symptom onset and report to public health authorities.

Adding these together implies that the typical lag between infection and a positive case being reported to public health is around 11 days.

Second, we consider the effect of weekly averaging on the appropriate lag for our analysis. Suppose a policy or behavioural change starts on date t, impacting the daily growth in infections between dates $t-1$ and t and in each subsequent day. Then, assuming a lag of 11 days between infection and case reporting, case counts C are affected from date $t+11$ onward. Our outcome variable $\Delta \log(\Delta \mathrm{C})$ thus would react to the original policy or behavioral change on date $t+11$. The change is complete on $t+23$, when the week from $t+17$ to $t+23$ is compared to the week from $t+10$ to $t+16$. The midpoint of the change is $t+17$.

Choosing a lag of l days implies that the policy/behaviour variable phases in from $t+l$ to $t+l+6$. To match the midpoint of this phase-in to the midpoint of the change in the outcome variable, we set $l=14$. The chosen lag matches the lag used by other authors who study COVID-19 policy interventions, e.g., CKS (2020). We explore sensitivity to alternative lags in Section 4.3.

With respect to deaths, our data are, in most cases, backdated (revised by the authorities ex-post) to the actual date of death. The medical literature suggests that the mean time from symptom onset to death is around 19 days (20 days in Wu et al. (2020), 17.8 days in Verity et al. (2020), 20.2 days when accounting for right truncation in Linton et al. (2020), 16.1 days in Sanche et al. (2020), etc.), that is, two weeks longer than our estimate of the time from symptom onset to reporting of a positive test result. We correspondingly set the lag used in our analysis of the death growth rate (Section 4.5) to 28 days.

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By Wei Lyu and George L. Wehby

Community Use Of Face Masks And COVID-19: Evidence From A Natural Experiment Of State Mandates In The US

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ABSTRACT **State policies mandating public or community use of face masks or covers in mitigating the spread of coronavirus disease 2019 (COVID-19) are hotly contested. This study provides evidence from a natural experiment on the effects of state government mandates for face mask use in public issued by fifteen states plus Washington, D.C., between April 8 and May 15, 2020. The research design is an event study examining changes in the daily county-level COVID-19 growth rates between March 31 and May 22, 2020. Mandating face mask use in public is associated with a decline in the daily COVID-19 growth rate by 0.9, 1.1, 1.4, 1.7, and 2.0 percentage points in 1–5, 6–10, 11–15, 16–20, and 21 or more days after state face mask orders were signed, respectively. Estimates suggest that as a result of the implementation of these mandates, more than 200,000 COVID-19 cases were averted by May 22, 2020. The findings suggest that requiring face mask use in public could help in mitigating the spread of COVID-19.**

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One of the most contentious issues being debated worldwide in the response to the coronavirus disease 2019 (COVID-19) pandemic is the value of wearing masks or face coverings in public settings.[1] A key factor fueling the debate is the limited direct evidence thus far on how much widespread community use would affect COVID-19 spread. However, there is now substantial evidence of asymptomatic transmission of COVID-19.[2,3] For example, a recent study of antibodies in a sample of customers in grocery stores in New York State reported an infection rate of 14.0 percent by March 29 (projected to represent more than 2.1 million cases), which substantially exceeds the number of confirmed COVID-19 cases.[4] Moreover, all public health authorities call on symptomatic people to wear masks to reduce transmission risk. Even organizations that at the time of our study had not yet recommended widespread community use of face masks for COVID-19 mitigation (that is, everyone without symptoms should use a face mask outside of their home), such as the World Health Organization, strongly recommend that symptomatic individuals wear them.[5] Because mask wearing by infected people can reduce transmission risk, and because of the high proportion of asymptomatic infected individuals and transmissions, there appears to be a strong case for the effectiveness of widespread use of face masks in reducing the spread of COVID-19. However, there is no direct evidence thus far on the magnitude of such effects, especially at a population level.

Researchers have been reviewing evidence from previous randomized controlled trials for other respiratory illnesses, examining mask use and types among people at higher risk of contracting infections (such as health care workers or people in infected households). Systematic reviews and meta-analyses of such studies have provided suggestive, although generally weak, evidence.[6] The estimates from the meta-analyses

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based on randomized controlled trials suggest declines in transmission risk for influenza or influenza-like illnesses to mask wearers, although estimates are mostly statistically insignificant possibly because of small sample sizes or design limitations, especially those related to assessing compliance.[7–9] There is also a relationship between increased adherence to mask use, specifically, and effectiveness of reducing transmission to mask wearers: In one randomized study of influenza transmission in infected households in Australia, transmission risk for mask wearers was lower with greater adherence.[10] Further, the evidence is mixed from randomized studies on types of masks and risk for influenza-like illness transmission to mask wearers; for example, a recent systematic review and meta-analysis comparing N-95 respirators versus surgical masks found a statistically insignificant decline in influenza risk with N-95 respirators.[11]

Positions on widespread face mask use have differed worldwide but are changing over time. In the US, public health authorities did not recommend widespread face mask use in public at the start of the pandemic. The initially limited evidence on asymptomatic transmission and concern about mask shortages for the health care workforce and people caring for patients contributed to that initial decision. On April 3, 2020, the Centers for Disease Control and Prevention (CDC) issued new guidance advising everyone to wear cloth face covers in public areas where close contact with others is unavoidable, citing new evidence on virus transmission from asymptomatic or presymptomatic people.[12] Guidelines differ between countries, and some, including Germany, France, Italy, Spain, China, and South Korea, have mandated the use of face masks in public.[13–16]

This study adds complementary evidence to the literature on the impacts of widespread community use of face masks on COVID-19 spread from a natural experiment based on whether or not US states had mandated the use of face masks in public for COVID-19 mitigation as of May 2020. Fifteen states plus Washington, D.C., issued mandates for face mask use in public between April 8 and May 15.

We identified the effects of state mandates for the use of face masks in public on the daily COVID-19 growth rate, using an event study that examined the effects over different periods. We considered the impact of mandates for mask use targeted only to employees in some work settings, as opposed to communitywide mandates. This evidence is critical, as states and countries worldwide begin to shift to "reopening" their economies and as foot traffic increases. Mandating the public use of masks has become a socially and politically contentious issue, with multiple protests and even acts of violence directed against masked employees and those asking customers to wear face masks.[17] Face cover recommendations and mandates are part of the current set of measures, following earlier social distancing measures such as school and nonessential business closures, bans on large gatherings, and shelter-in-place orders being considered by states and local governments, especially as regions of the country reopen. For example, during Virginia's phase one reopening, begun May 22, 2020, everyone in the state was required to wear a face mask in public where people congregate.[18] Even though more states have issued such orders since the study was completed, it is critical to provide direct evidence on this question not only for public health authorities and governments but also for educating the public.

Study Data And Methods

DATA We collected information on statewide face cover mandate orders from public data sets on such policies and from searching and reviewing all state orders issued between April 1 and May 21, 2020. Our study focused on state executive orders or directives signed by governors that mandate use. Recommendations or guidelines from state departments of public health were not included, as these largely follow the CDC guidelines and might not necessarily add further information or impact. See online appendix A for a more detailed description of the data sources and measuring of the mandates.[19]

States differ in whether or not they require their citizens to wear face masks (covers) to limit COVID-19 spread. Between April 8 and May 15, governors of fifteen states and the mayor of Washington, D.C., signed orders mandating all individuals who can medically tolerate the wearing of a face mask do so in public settings (for example, public transportation, grocery stores, pharmacies, or other retail stores) where maintaining six feet of "social distance" might not always be practicable. These sixteen jurisdictions also have specific mandates requiring employees in certain professions to wear masks at all times while working.

In addition to these sixteen jurisdictions, twenty additional states have employee-only mandates (but no community mandate) requiring that some employees (for example, close-contact service providers such as in barber shops and nail salons) wear a face mask at all times while providing services. The face mask defined in these orders primarily refers to cloth face coverings or nonmedical masks. The state orders

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strongly discourage the use of any medical or surgical masks and N-95 respirators, which should be reserved for health care workers and first responders. The orders also clearly specify that the face masks are not a replacement for any other social distancing protocols. More information on dates and links to these state orders are in appendix exhibit A1 and appendices D and E.[19] Fifteen states had not yet issued community or employee mandates when we performed the study.

The main model used publicly available daily county-level data of confirmed COVID-19 cases from March 25 through May 21.[20] The data covered all states plus Washington, D.C., and the analytical sample included 2,930 unique counties plus New York City (five boroughs combined). See appendix A for a more detailed description of COVID-19 data.[19]

STATISTICAL ANALYSIS We employed an event study, which is generally similar to a difference-in-differences design, to examine whether statewide mandates to wear face masks in public affect the spread of COVID-19 based on the state variations noted earlier. This design allowed us to estimate the effects in the context of a natural experiment, comparing the pre-post mandate changes in COVID-19 spread in the states with mandates versus changes in COVID-19 spread in the states that did not pass these mandates, over time. The model also tested whether states issuing these mandates had differential pre-event trends in COVID-19 rates before they were issued. This is a critical assumption of the validity of an event study that must be upheld under testing. In addition, the model allowed us to control for a wide range of time-invariant differences between states and counties, such as population density and socioeconomic and demographic factors, plus time-variant differences between states and counties, such as other mitigation and social distancing policies, in addition to state-level COVID-19 testing rates.

We estimated the effects of face cover mandates on the daily county-level COVID-19 growth rate, which is the difference in the natural log of cumulative COVID-19 cases on a given day minus the natural log of cumulative cases in the prior day, multiplied by 100.[21] This measure gives the daily growth rate in percentage points.

The reference period for estimating the face cover mandate effects was 1–5 days before signing the order. We examined how effects change over five post-event periods: 1–5, 6–10, 11–15, 16–20, and 21 or more days. The model also tested for pre-event trends over the course of 6–10, 11–15, and 16 or more days before signing the mandate. For all counties in the analytical sample, the main model included daily data from March 31 (seven days before the first state signed a face cover mandate) through May 22. The models were estimated by least squares weighted by the county's 2019 population with heteroscedasticity-robust and state-clustered standard errors.

As noted earlier, all of the fifteen states plus Washington, D.C., that mandated face cover use in public also mandated employee mask use. To assess the effects of employee face cover mandates, we employed another event study model that focused solely on the employee face cover mandate as the policy intervention. In this analysis, we excluded the sixteen jurisdictions that enacted both public and employee face cover mandates and focused on the twenty states that enacted an employee-only mandate and the fifteen states with neither a public nor an employee mandate.

LIMITATIONS We were unable to measure face cover use in the community (that is, compliance with the mandate). As such, the estimates represent the intent-to-treat effects of these mandates—that is, their effects as passed and not the individual-level effect of wearing a face mask in public on one's own COVID-19 risk. Related, we did not measure enforcement of the mandates, which might affect compliance. We also did not have data on county-level mandates for wearing face masks in public. In some states without state-level mandates at the time of our study, such as California,[22] Texas,[23] and Colorado,[24] multiple counties had enacted such mandates. These county-level mandates did not bias the intent-to-treat estimates of effects of state-level mandates as actually passed, but they added local-level heterogeneity not directly accounted for in the model. We did examine the robustness of estimates to the exclusion of some of these states. Finally, we were able to examine only confirmed COVID-19 cases. However, there is evidence of a higher infection rate in the community than is reflected in the number of confirmed cases.[25]

Study Results

EFFECTS OF MANDATES FOR FACE COVERING IN PUBLIC Exhibit 1 plots the event study estimates of effects of state mandates for community face covering in public on the county-level daily growth rate of COVID-19 cases, with 95 percent confidence intervals, obtained from the main regression model (in appendix B),[19] using county-level daily data from March 31 through May22; appendix exhibit C1 (column 1) reports the exact estimates. The effects are shown over the course of five periods after signing the orders, relative to the five days before signing (which is the reference period). Also shown

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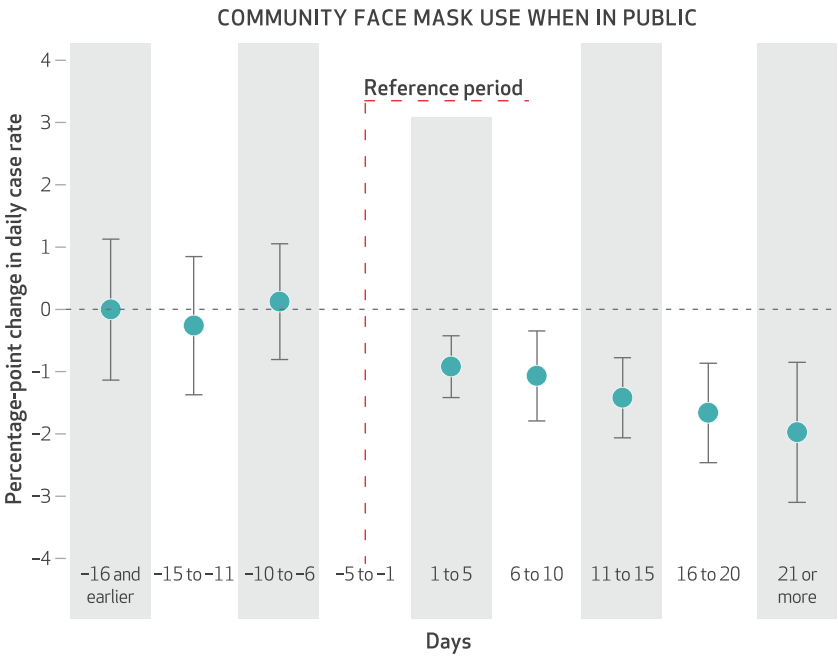
EXHIBIT 1

Event study estimates of the effects of states mandating community face mask use in public on the daily county-level growth rate of COVID-19 cases, 2020



SOURCE Authors' analysis of US county-level COVID-19 case data between March 31 and May 22, 2020. **NOTES** Event study estimates (dots) and 95% confidence intervals (bars) of the effects of states mandating community use of face covers or masks when people are in public on the county-level daily growth rate of COVID-19 cases over different periods before and after the mandate order was signed. The reference period was the first five days before the mandate order was signed. The model controlled for major COVID-19 mitigation policies as time-varying (closure of K–12 schools, county-level or statewide shelter-in-place orders, nonessential business closure, closure of restaurants for dining in, closure of gyms or movie theaters), COVID-19 tests per 100,000 people, county fixed effects, and day fixed effects. The model was estimated by least squares weighted by the county 2019 population, and the standard errors were robust to heteroscedasticity and clustered at the state level.

are estimated differences in daily COVID-19 growth rates between states with and without the mandates over the course of three periods before the reference period.

There was a significant decline in daily COVID-19 growth rate after the mandating of face covers in public, with the effect increasing over time after the orders were signed. Specifically, the daily case rate declined by 0.9, 1.1, 1.4, 1.7, and 2.0 percentage points within 1–5, 6–10, 11–15, 16–20, and 21 or more days after signing, respectively. All of these declines were statistically significant ($p < 0.05$ or less). In contrast, the pre-event trends in COVID-19 case growth rates were small and statistically insignificant.

We also projected the number of averted COVID-19 cases with the mandates for face mask use in public by comparing actual cumulative daily cases with daily cases predicted by the model if none of the states had enacted the public face cover mandate at the time they did (see details in appendix B).[19] The main model estimates suggested that because of these mandates, 230,000–450,000 cases may have been averted by May 22. Estimates of averted cases should be viewed cautiously and only as general approximations.

ROBUSTNESS CHECKS We estimated multiple extensions of the main event study model to assess the robustness of estimates to different model specifications and sample choices. These checks started the event study on March 26; added flexible controls for social distancing measures, state reopening measures, employee face mask use mandates, and county-specific time trends; and allowed time trends to vary by sociodemographic indicators. Other checks used the mandate effective date instead of the signing date, used hyperbolic sine transformation to account for zero cases, included states as the unit instead of counties, included only urban counties, and excluded some states without state-level mandates but with multiple counties having local mandates. The detailed description and results of these robustness checks are in appendix C.[19] The results were robust across these checks; effects were smaller when we used the effective dates instead of the signing dates, which differ by about two to three days, on average, suggesting earlier compliance, and when we used states as the unit of analysis. But the estimates remained meaningful and statistically significant in all checks.

EFFECTS OF EMPLOYEE-ONLY FACE COVER MANDATES As noted earlier, we also directly assessed the effects of states mandating only that certain employees wear face masks. Twenty states issued employee use mandates but not community use mandates. We reestimated the event study model described earlier for an employee-only mandate including those twenty states (issued between April 17 and May 9) and the fifteen states without mandates, and excluding the sixteen jurisdictions that issued both public and employee use mandates. Exhibit 2 plots the event study estimates of changes in county-level daily COVID-19 growth rates with the employee-only face cover mandates and their 95 percent confidence intervals. All pre- and postmandate estimates were small and insignificant. Overall, these results indicate no evidence of declines in daily COVID-19 growth rates with employee-only mandates.

Discussion

Around the world, governments have been fighting COVID-19 spread through a mix of policies and mitigation measures such as school and nonessential business closures and shelter-in-place orders. Some countries have also recommended or mandated widespread community use of face

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masks as a mitigation measure. However, the effectiveness of this measure is highly debated. The debate and uncertainty are fueled by the limited direct empirical evidence available on the magnitude of the effects of widespread face mask use in public on COVID-19 mitigation. There is a critical need for empirical evidence on the magnitude of these effects from natural experiments.[8] This evidence is especially relevant as governments reopen their economies and loosen social distancing restrictions while new infections continue to occur and while there is no vaccine or widely accessible or effective treatments in sight.

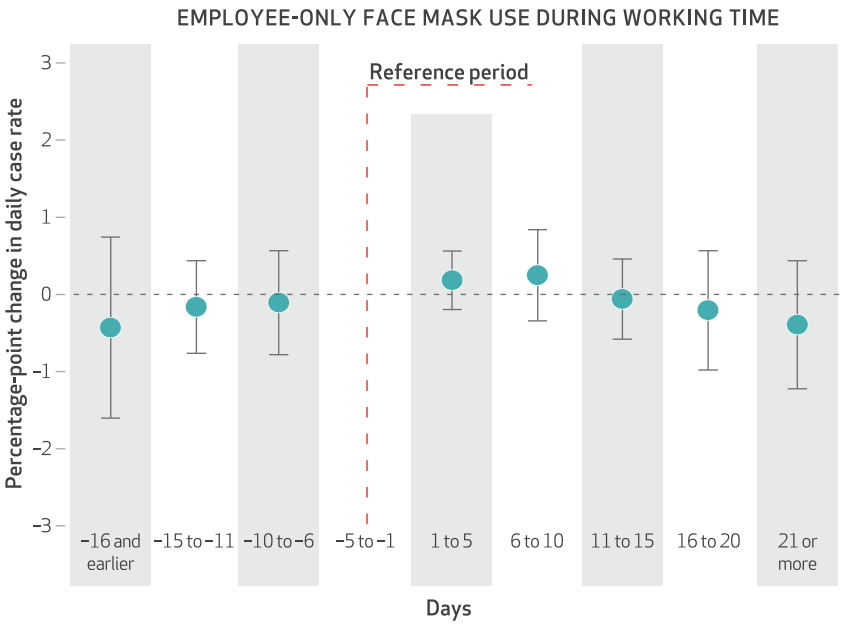
The study provides direct evidence on the effectiveness of widespread community use of face masks from a natural experiment that evaluated the effects of state government mandates in the US for face mask use in public on COVID-19 spread. Fifteen states plus Washington, D.C., mandated face mask use between April 8 and May 15. Using an event study that examined daily changes in county-level COVID-19 growth rates, the study found that mandating public use of face masks was associated with a reduction in the COVID-19 daily growth rate. Specifically, we found that the average daily county-level growth rate decreases by 0.9, 1.1, 1.4, 1.7, and 2.0 percentage points in 1–5, 6–10, 11–15, 16–20, and 21 or more days after signing, respectively.

These estimates are not small; they represent nearly 16 percent to 19 percent of the effects of other social distancing measures (school closures; bans on large gatherings; shelter-in-place orders; and closures of restaurants, bars, and entertainment venues) after similar periods from their enactment.[21] The estimates suggest that the effectiveness of and benefits from these mandates increase over time. By May 22, 2020, the estimates suggest that 230,000–450,000 COVID-19 cases may have been averted on the basis of when states passed these mandates. Again, the estimates of averted cases should be viewed cautiously, as they are sensitive to assumptions and different approaches to transforming the changes in the daily growth rate estimates to cases.

The early declines in the daily growth rate over the course of five days after signing the order are broadly consistent with the timing of the effects of other social distancing measures such as business closures.[21] Although the median incubation period is estimated to be around five days,[26] there is a wide range from 2.2 days (2.5th percentile) to 11.5 days (97.5th percentile), which suggests that for many people, symptoms may appear relatively early. Further, people may become aware of the mandates early through governors' briefings and related media reports, or they may be anticipating them.

EXHIBIT 2

Event study estimates of effects of states mandating only employee use of face masks during working time on daily county-level growth rate of COVID-19 cases



SOURCE Authors' analysis of US county-level COVID-19 case data between March 31 and May 22, 2020. **NOTES** Event study estimates (dots) and 95% confidence intervals (bars) of the effects of states mandating employee use of face covers or masks on the county-level daily growth rate of COVID-19 cases over different periods before and after the mandate order was signed. This model excluded fifteen states plus Washington, D.C., that made the use of face covering mandatory for both the general public and employees. The reference period was the first five days before the mandate order was signed. The model controlled for major COVID-19 mitigation policies as time-varying (closure of K–12 schools, county-level or statewide shelter-in-place orders, nonessential business closure, closure of restaurants for dining in, and closure of gyms or movie theaters), COVID-19 tests per 100,000 people, county fixed effects, and day fixed effects. The model was estimated by least squares weighted by the county 2019 population, and the standard errors were robust to heteroscedasticity and clustered at state level.

There is no evidence of differential pre-mandate COVID-19 trends with respect to issuing these mandates. The estimates represent the intent-to-treat effects of the statewide face cover mandates as passed, conditional on other national and local measures. In that way, the effects are independent of the CDC national guidance to wear face masks that was issued April 3, 2020.[12] These effects were robust to several model checks. The study provides evidence from a natural experiment on the effectiveness of mandating public use of face masks in mitigating the spread of COVID-19. We found no evidence for effects of states mandating employee face mask use, perhaps because many businesses themselves already required their employees to wear masks.[27,28] In that case, mandating employee mask use reinforce what many businesses already choose to do on their own.

Although the intent-to-treat estimates are of interest for understanding the effectiveness of

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these policies in limiting COVID-19 spread at the community and population levels, understanding how their effects change with compliance and enforcement strategies is important for designing effective policies. Our study has built the first step in estimating the overall effect of these policies as enacted. However, these policies vary in their strictness and the consequences of noncompliance. The mandates generally require wearing a face mask in public whenever the social distance cannot be maintained. States such as Delaware, Maryland, Massachusetts, and Maine clarify what "public" areas are (for example, indoor space in retail establishments, outdoor space in busy parking lots and waiting areas for take-out services, semi-enclosed areas such as at public transportation stops, and enclosed spaces such as in taxis and other public transportation). The language on enforcement and penalties for noncompliance also vary. In states such as Delaware, Hawaii, Maryland, and Massachusetts, the face mask orders state that they have the force and effect of law, with a willful violation subject to a criminal offense with penalties. For example, the order in Maryland states that "a person who knowingly and willfully violates this order is guilty of a misdemeanor and on conviction is subject to imprisonment not exceeding one year or a fine not exceeding $5,000 or both."[29] In contrast, the orders of other states such as Connecticut, Maine, and Pennsylvania, although clearly mandating the wearing of a face mask in public, do not appear to clearly specify that violations of the order are subject to criminal offense or penalties. Future work should examine whether and how differences in strictness and enforcement modify the effects of these mandates.

Compliance and enforcement may also differ across contextual factors (such as other social distancing measures, workforce distribution, population demographics, and socioeconomic and cultural factors). In that regard, it is important to clarify that the suggested benefits from mandating face mask use are not substitutes for other social distancing measures; the effects are conditional on the other enacted social distancing measures and how communities are complying with them. It is also important to extend the evidence into additional measures of exposure to the virus in the community as data become available, such as from serological testing for antibodies. Finally, future work can examine effects on deaths, which lag cases and change not only with the number of cases but also with case severity.

Conclusion

The study provides evidence that US states mandating the use of face masks in public had a greater decline in daily COVID-19 growth rates after issuing these mandates compared with states that did not issue mandates. These effects were observed conditional on other existing social distancing measures and were independent of the CDC recommendation to wear face covers issued April 3, 2020. As international and state governments begin to relax social distancing restrictions, and considering the high likelihood of a second COVID-19 wave in the fall and winter of 2020,[30] requiring the use of face masks in public could help in reducing COVID-19 spread. ■

An unedited version of this article was published online June 16, 2020, as a Fast Track Ahead Of Print article. That version is available in the online appendix.

NOTES

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ABSTRACT

Face Masks Considerably Reduce COVID-19 Cases in Germany: A Synthetic Control Method Approach[1]

We use the synthetic control method to analyze the effect of face masks on the spread of Covid-19 in Germany. Our identification approach exploits regional variation in the point in time when face masks became compulsory. Depending on the region we analyse, we find that face masks reduced the cumulative number of registered Covid-19 cases between 2.3% and 13% over a period of 10 days after they became compulsory. Assessing the credibility of the various estimates, we conclude that face masks reduce the daily growth rate of reported infections by around 40%.

JEL Classification: I18, C23

Keywords: COVID-19, public health measures, face masks, synthetic control method, Germany

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1 Introduction

Many countries have experimented with several public health measures to mitigate the spread of Covid-19. One particular measure that has been introduced are face masks. It is of obvious interest to understand the contribution made by such a measure to reducing infections.

The effect of face masks on the spread of infections has been studied for a long time. The usefulness in the clinical context is beyond dispute. There is also considerable evidence that they helped in mitigating the spread of epidemics such as SARS 2003 or influenza (see below). The effect of face masks worn in public on the spread of Covid-19 has not been systematically analyzed so far. This is the objective of this paper.

There is a general perception in Germany that public wearing of face masks reduces incidences considerably. This perception comes mainly from the city of Jena. After face masks were introduced on 6 April 2020, the number of new infections fell almost to zero. Jena is not the only city or region in Germany, however, that introduced face masks. Face masks became compulsory in all federal states between 20 April and 29 April 2020. Six regions made masks compulsory before the introduction at the federal level. These dates lay between 6 April and 25 April (see appendix A and Kleyer et al., 2020, for a detailed overview of regulations in Germany). This leads to a lag between individual regions and the corresponding federal states of between two and 18 days.

We derive findings by employing synthetic control methods (SCM, Abadie and Gardeazabal, 2003, Abadie et al., 2010, Abadie, 2019). Our identification approach exploits the previously mentioned regional variation in the point in time when face masks became compulsory in public transport and sales shops. We use data for 401 German regions to estimate the effect of this public health measure on the development of registered infections with Covid-19. We consider the timing of mandatory face masks as an exogenous event to the local population. Masks were imposed by local authorities and were not the outcome of some process in which the population was involved.[2] We compare the Covid-19 development in various regions to their synthetic counterparts. The latter are constructed as a weighted average of control regions that are similar to the regions of interest. Structural dimensions taken into account include prior Covid-19 cases, their demographic structure and the local health care system.

We indeed find strong and convincing statistical support for the general perception that public wearing of face masks in Jena strongly reduced the number of incidences. We obtain a synthetic control group that closely follows the Covid-19 trend before introduction of mandatory masks in Jena and the difference between Jena and this group is very large after 6 April. Our findings indicate that the early introduction of face masks in Jena has resulted in a reduction of almost 25% in the cumulative number of reported Covid-19 cases after 20 days. The drop is greatest, larger than 50%, for the age group 60 years and above. Our results are robust when we conduct sensitivity checks and apply several placebo tests, e.g. tests for pseudo-treatment effects in similarly sized cities in the federal state of Thuringia and for pseudo-treatment effects in Jena before the treatment actually started. We also test for announcement effects.

Constructing control groups for other single regions is not always as straightforward as for Jena. As a consequence, it is harder to identify the effect of face masks in these regions. When we

[2] This is similar to the setup in Abadie et al. (2010), who study the effect of an increase in the tobacco tax in California. The tobacco tax was decided upon by the state government.

move from single to multiple treatment effects, we find smaller effects. They are still sufficiently large, however, to support our point that wearing face masks is a very cost-efficient measure for fighting Covid-19. When we summarize all of our findings in one single measure (we compare all measures in appendix B.4), we conclude that the daily growth rate of Covid-19 cases in the synthetic control group falls by around 40% due to mandatory mask-wearing relative to the control group.[3]

Concerning the literature (see appendix D for a more detailed overview), the effects of face masks have been surveyed by Howard et al. (2020) and Greenhalgh et al. (2020). Greenhalgh et al. (2020) mainly presents evidence on the effect of face masks during non-Covid epidemics (influenza and SARS). Marasinghe (2020) reports that they "*did not find any studies that investigated the effectiveness of face mask use in limiting the spread of COVID-19 among those who are not medically diagnosed with COVID-19 to support current public health recommendations*".

In addition to medical aspects (like transmission characteristics of Covid-19 and filtering capabilities of masks), Howard et al. (2020) survey evidence on mask efficiency and on the effect of a population. They first stress that "*no randomized control trials on the use of masks <…> has been published*". The study which is "*the most relevant paper*" for Howard et al. (2020) is one that analyzed *"exhaled breath and coughs of children and adults with acute respiratory illness*" (Leung et al., 2020, p. 676), i.e. used a clinical setting. Concerning the effect of masks on community transmissions, the survey needs to rely on pre-Covid-19 studies. We conclude from this literature review that our paper is the first analysis that provides field evidence on the effect of masks on mitigating the spread of Covid-19.

2 Identification, data and implementation

Identification. Our identification approach exploits the regional variation in the point in time when face masks became mandatory in public transport and sales shops. Given the federal structure of Germany, decisions are made by municipal districts (regions in what follows) and federal states. We can exploit differences by, first, identifying six regions (equivalent to the EU nomenclature of territorial units for statistics, NUTS, level 3) which made wearing face masks compulsory before their respective federal states. For all other regions, mandatory mask-wearing followed the decision of the corresponding federal state. Second, as Figure 1 shows, variation across federal states also implies variations across regions.

To identify possible treatment effects from introducing face masks, we apply SCM for single and multiple treated units. Our methodical choice is motivated as follows: First, the original goal of SCM to "*estimate the effects of <…> interventions that are implemented at an aggregate level affecting a small number of large units (such as cities, regions, or countries)*" (Abadie, 2019, p.3) clearly matches with our empirical setup. Compared to standard regression analyses, SCM is particularly well suited for comparative case study analyses with only one treated unit or a very small number thereof (Abadie and Gardeazabal, 2003, Becker et al., 2018). Second, the method is flexible, transparent and has become a widely utilized tool in the policy evaluation literature (Athey and Imbens, 2017) and for causal analyses in related disciplines

[3] The main channel through which masks reduce transmission of SARS-CoV-2 is the reduction in aerosols and droplets, as argued by Prather et al. (2020).

(see, e.g., Kreif et al., 2015, for an overview of SCM in health economics, Pieters et al., 2017, for a biomedical application).[4]

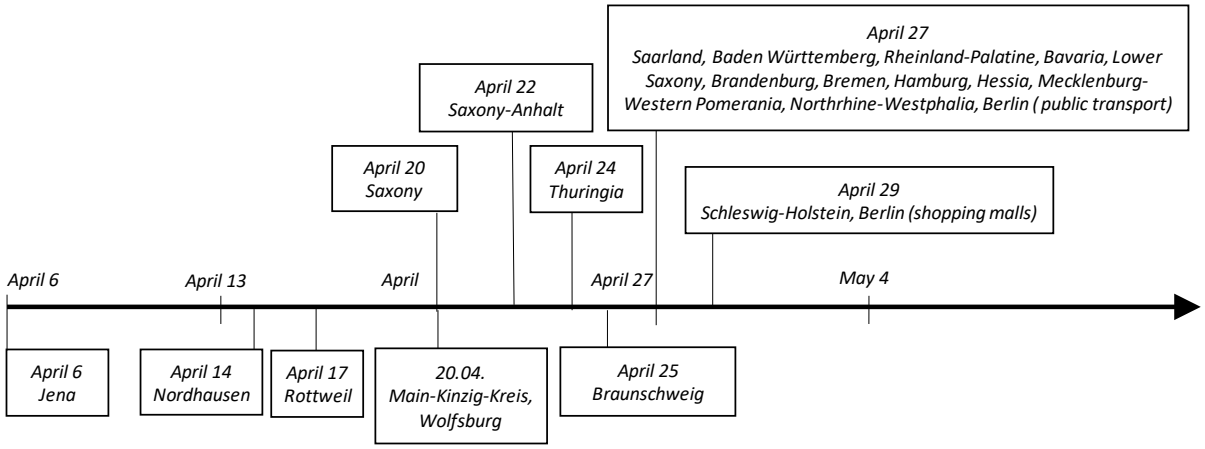

Figure 1: The timing of mandatory mask wearing in federal states (top) and individual regions (below)

SCM identifies synthetic control groups for the treated unit(s) to build a counterfactual. In our case, we need to find a group of regions that have followed the same Covid-19 trend as treated units before mandatory masks in the latter. This control group would then most likely have had the same behavior as treated unit(s) in the absence of the mask obligation. We can then use this group to 'synthesize' the treated unit and conduct causal inference. The synthetic control group is thereby constructed as an estimated weighted average of all regions in which masks did not become compulsory earlier on. Historical realizations of the outcome variable and several other predictor variables that are relevant in determining outcome levels allow us to generate the associated weights, which result from minimizing a pre-treatment prediction error function (see Abadie and Gardeazabal, 2003, Abadie et al., 2010 and Abadie, 2019 for methodical details).

Data. We use the official German statistics on reported Covid-19 cases from the Robert Koch Institute (RKI, 2020). The RKI collects the data from local health authorities and provides updates on a daily basis. Using these data (available via API), we build a balanced panel for 401 NUTS Level 3 regions and 95 days spanning the period from January 28 to May 1, 2020 (38,095 observations). We use the cumulative number of registered Covid-19 cases in each district as main outcome variable.[5] We estimate overall effects for this variable together with disaggregated effects by age groups (persons aged 15-34 years, 35-59 years and 60+ years). As an alternative outcome variable, we also use the cumulative incidence rate. Table 1 shows summary statistics for both variables for our sample period.

Table 1 also presents our other predictor variables. We focus on factors that are likely to describe the regional number and dynamics of reported Covid-19 cases. Obviously, past values

[4] Friedson et al. (2020) employ the SCM to estimate the effect of the shelter-in-place order for California in the development of Covid-19. The authors find *inter alia* that around 1600 deaths from Covid-19 were avoided by this measure during the first four weeks.

[5] We are aware of the existence of hidden infections. As it appears plausible to assume that they are proportional to observed infections across regions, we do not believe that they affect our results. We chose the date of reporting (as opposed to date of infections) because not all reported infections include information about the date of infection.

of (newly) registered Covid-19 cases are important to predict the regional evolution of Covid-19 cases over time in an autoregressive manner. In addition, we argue that a region's demographic structure, such as the overall population density and age structure, and its basic health care system, such as the regional endowment with physicians and pharmacies per population, are important factors for characterizing the local context of Covid-19. Predictor variables are obtained from the INKAR online database of the Federal Institute for Research on Building, Urban Affairs and Spatial Development. We use the latest year available in the database (2017). We consider it likely that regional demographic structures only gradually vary over time such that they can be used to measure regional differences during the spread of Covid-19 in early 2020.

Table 1: Summary Statistics of Covid-19 indicators (outcome variables) and predictors characterizing the regional demographic structure and basic health care system

	Mean	**S.D.**	**Min.**	**Max.**
PANEL A: Data on registered Covid-19 cases				
[1] Newly registered cases per day	4.13	10.66	0	310
[2] Cumulative number of cases	120.86	289.07	0	5795
[3] Cum. cases [2] per 100,000 inhabitants	59.87	106.80	0	1,530.32
PANEL B: Regional demographic structure and local health care system				
Population density (inhabitants/km^2)	534.79	702.40	36.13	4,686.17
Population share of highly educated* individuals (in %)	13.07	6.20	5.59	42.93
Share of females in population (in %)	50.59	0.64	48.39	52.74
Average age of females in population (in years)	45.86	2.11	40.70	52.12
Average age of males in population (in years)	43.17	1.83	38.80	48.20
Old-age dependency ratio (persons aged 65 years and above per 100 of population age 15-64)	34.34	5.46	22.40	53.98
Young-age dependency ratio (persons aged 14 years and below per 100 of population age 15-64)	20.54	1.44	15.08	24.68
Physicians per 10,000 of population	14.58	4.41	7.33	30.48
Pharmacies per 100,000 of population	27.01	4.90	18.15	51.68
Settlement type (categorial variable$^{\$}$)	2.59	1.04	1	4

Notes: * = International Standard Classification of Education (ISCED) Level 6 and above; $ = categories are based on population shares and comprise 1) district-free cities *(kreisfreie Großstädte)*, 2) urban districts *(städtische Kreise)*, 3) rural districts *(ländliche Kreise mit Verdichtungsansätzen)*, 4) sparsely populated rural districts *(dünn besiedelte ländliche Kreise)*.

Implementation. The implementation of the SCM is organized as follows: As baseline analysis, we focus on the single treatment case for the city of Jena for three reasons. First, as shown in Figure 1, Jena was the first region to introduce face masks in public transport and sales shops on April 6. This results in a lead time of 18 days relative to mandatory face masks in the surrounding federal state Thuringia on April 24. By April 29, all German regions had introduced face masks (exact dates are provided in appendix A). A sufficiently long lag between mandatory face masks in the treated unit vis-à-vis the sample of control regions is important for effect identification.

Second, the timing of the introduction of face masks in Jena is -by and large- not affected by other overlapping public health measures related to the Covid-19 spread. Since March 22 the German economy had been in a general "lock down" coordinated among all federal states. Only from April 20 onwards has the economy been gradually reopening. Third, Jena is in various ways a representative case for studying the Covid-19 development: On April 5, which is one day before face masks became compulsory in Jena, the cumulative number of registered Covid-19 cases in Jena was 144. This is very close to the median of 155 for Germany. Similarly, the cumulative number of Covid-19 incidences per 100,000 inhabitants was 126.9 in Jena compared to a mean of 119.3 in Germany (compare Figure A1).

In our baseline configuration of the SCM, we construct the synthetic Jena by including the number of cumulative Covid-19 cases (measured one and seven days before the start of the treatment) and the number of newly registered Covid-19 cases (in the last seven days prior to the start of the treatment) as autoregressive predictor variables. The chosen period shall ensure that the highly non-linear short-run dynamics of regional Covid-19 cases are properly captured. We use cross-validation tests to check the sensitivity of the SCM results when we allow for a shorter training period in the pre-treatment phase by imposing longer lags. The autoregressive predictors are complemented by the cross-sectional data on the region's demographic and basic health care structure.

Although the case study of Jena can be framed in a clear identification strategy, the Covid-19 spread in a single municipality may still be driven by certain particularities and random events that may prevent a generalization of estimated effects. We therefore also test for treatment effect in districts that introduced face masks after Jena but still before they became compulsory in the corresponding federal state. More importantly, however, we apply a multiple treatment approach that takes all regions as treated units which introduced face masks by April 22. This results in 32 regions from Saxony and Saxony-Anhalt. All other regions apart from Thuringia introduced face masks on April 27. We employ this delay to study the effects of mandatory masks up to May 1st. We end on May 1st as we would expect that differences across treated and non-treated regions should disappear 5-7 days after April 27. This delay results from a median incubation time of 5.2 days (Linton et al., 2020 and Lauer et al., 2020) and around 2 days accounting for reporting to authorities (as assumed e.g. in Donsimoni et al., 2020a, b).

Although SCM appears to be a natural choice for our empirical identification strategy, we are well aware of the fact that its validity crucially depends on important practical requirements including the availability of a proper comparison group, the absence of early anticipation effects or interference from other events (Cavallo et al., 2013, Abadie, 2019). In the implementation of the single and multiple treatment SCM we check for these pitfalls through sensitivity and placebo tests. We deal with these issues in our baseline case study for Jena as follows:

1. We have screened the introduction and easing of public health measures, as documented in Kleyer et al. (2020), to ensure that no interference takes place during our period of study. This is the case at least until April 20 when exit strategies from public health measures started.
2. We make sure that the regions used to create the synthetic control, i.e. the donor pool, are not affected by the treatment (Campos et al., 2015). We eliminate the two immediate geographical neighbors of Jena from the donor pool to rule out spillover effects. We also exclude those regions for which anticipation effects may have taken place because face masks became compulsory in quick succession to Jena.

3. We account for early anticipation effects in Jena. Specifically, we take the announcement that face masks will become compulsory one week before their introduction as an alternative start of the treatment period.
4. We apply cross-validation tests to check for sensitivities related to changes in historical values in the outcome variables used as predictors. We also run placebo-in-time tests to check whether effects actually occurred even before the start of the treatment.
5. We test for the sensitivity of the results when changing the donor pool and run comprehensive placebo-in-space tests as a mode of inference in the SCM framework.

Inference thereby relies on permutation tests and follows the procedures suggested by Cavallo et al. (2013) and applied, for example, by Eliason and Lutz (2018) or Hu et al. (2018). For both the single and multiple treatment applications we estimate placebo-treatment effects for each district in which masks did not become compulsory early on. These placebo treatments should be small, relative to the treated regions. We calculate significance levels for the test of the hypothesis that the mask obligation did not significantly affect reported Covid-19 cases. This provides us with *p*–values for each day, which capture the estimated treatment effect on reported Covid-19 cases from placebo regions. The *p*-values are derived from a ranking of the actual treatment effect within the distribution of placebo treatment effects. We follow the suggestion in Galiani and Quistorff (2017) and compute adjusted *p*-values taking the pre-treatment match quality of the placebo treatments into account.[6]

3 The effects of face masks on Covid-19

Baseline results for Jena. Panel A in Figure 2 shows the SCM results for the introduction of face masks in Jena on April 6. The visual inspection of the development of cumulative Covid-19 cases shows that the fit of the synthetic control group is very similar to Jena before the treatment.[7] The difference in the cumulated registered Covid-19 cases between Jena and its corresponding synthetic control unit after the start of the treatment can be interpreted as the treatment effect on the treated.

The figure clearly shows a gradually widening gap in the cumulative number of Covid-19 cases between Jena and the synthetic control unit. The size of the effect 20 days after the start of the treatment (April 26) amounts to a decrease in the number of cumulative Covid-19 cases of 23%. For the first 10 days, the decrease amounts to 13%. Expressed differently, the daily growth rate of the number of infections decreases by 1.32 percentage points per day (see appendix B.4 for computational details and an overview of all measures). If we look at the estimated differences by age groups, Table A2 in the appendix indicates that the largest effects are due to the age group of persons aged 60 years and above. Here the reduction in the number of registered cases is even larger than 50%. For the other two age groups we find a decrease between 10 and 20%.

[6] We conduct all estimations in STATA using "Synth" and "Synth Runner" packages (Abadie at al., 2020, Galiani and Quistorff, 2017). Data and estimation files can be obtained from the authors upon request.

[7] The pre-treatment root mean square prediction error (RMSPE) of 3.145 is significantly below a benchmark RMSPE of 6.669, which has been calculated as the average RMSPE for all 401 regions in the pre-treatment period until April 6. This points to the relatively good fit of the synthetic control group for Jena in this period.

If we consider a median incubation of 5.2 days plus a potential testing and reporting lag of 2-3 days, the occurrence of a gradually widening gap between Jena and its synthetic control three to four days after the mandatory face masks seems fast. One might conjecture that an announcement effect played a role. As shown in appendix B.7, online searches for (purchasing) face masks peaked on April 22, when it was announced that face masks would become compulsory in all German federal states.[8] A smaller peak (70% of the April 22 peak) of online searches appeared on March 31. This is one day after Jena announced that masks would become compulsory on April 6. The announcement was accompanied by a campaign "Jena zeigt Maske" to communicate the necessity to wear face masks in public[9] and was widely discussed all over Germany.

Panel B in Figure 2 therefore plots the results when we set the start of the treatment period to the day of the announcement on 30 March. The visual inspection of the figure shows the existence of a small anticipation effect (which is mainly driven by the relative development of Covid-19 age group 15-34 years (Panel B in Figure A2). Yet, the gap to the synthetic control significantly widens only approximately 10 days after the announcement. As this temporal transmission channel appears plausible against the background of incubation times and given that no other intervention took place around this time in Jena or the regions in the synthetic control group, we take this as first evidence for a face mask-effect in the reduction of Covid-19 infections. Appendix B.6 shows similar SCM results for the incidence rate (overall and by age groups). We find a reduction of approximately 30 cases per 100,000 of population.

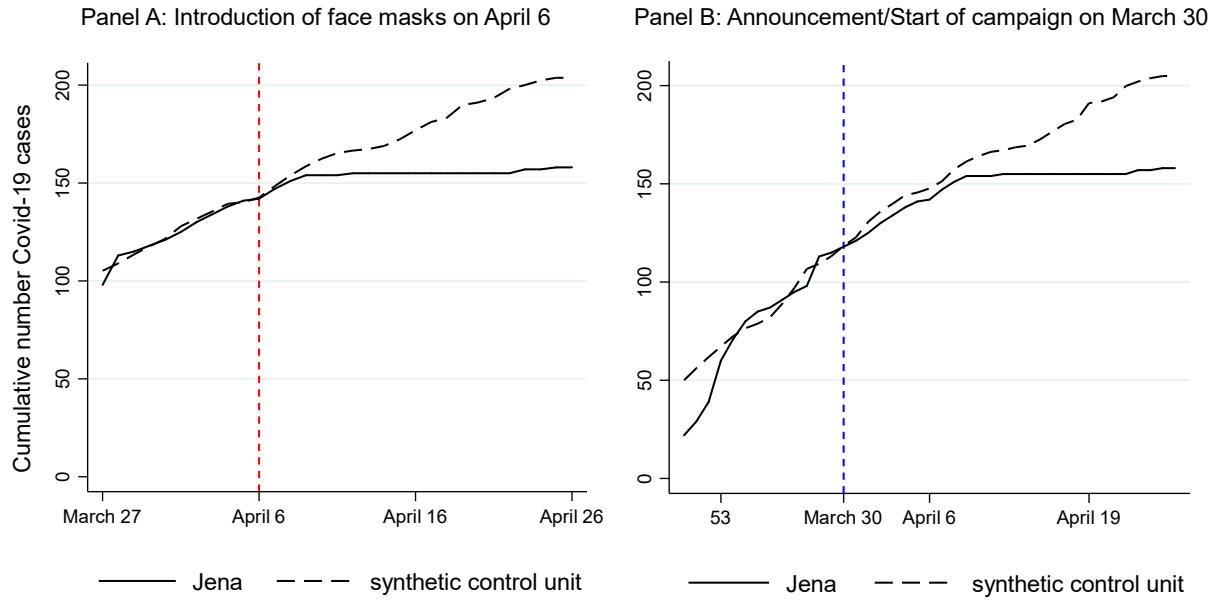

Figure 2: Treatment effects of mandatory face masks in Jena on April 6 and start of campaign on March 30 (see Table A3 and appendix B.2 for details)

[8] See https://www.tagesschau.de/inland/corona-maskenpflicht-103.html. Last accessed May 05, 2020.

[9] See https://www.jenaer-nachrichten.de/stadtleben/13069-jena-zeigt-maske-kampagne-f%C3%BCr-mund-schutz-startet. Last accessed May 05, 2020.

Obviously, the estimated differences in the development of Jena vis-à-vis the synthetic Jena is only consistently estimated if our SCM approach delivers robust results. Accordingly, we have applied several tests to check for the sensitivity of our findings.

Cross-validation and placebo-in-time test. One important factor is that our results are not sensitive to changes in predictor variables. We therefore perform cross-validation checks by modifying the length of the training and validation periods before the start of the treatment. Panel A in Figure 3 shows that lagging the autoregressive predictor variables further in time only slightly changes our results. Importantly, we do not find a systematic downward bias of our baseline specification (cumulative number of reported Covid-19 cases: one and seven days before start of treatment; number of newly registered Covid-19 cases: last seven days before start of treatment) compared to an alternative specification. The latter trains the synthetic control on the basis of information on cumulative Covid-19 cases 7 and 14 days prior to the treatment together with the development of newly register cases between day 7 and 14 prior to the treatment. Given that regional Covid-19 cases developed very dynamically and non-linearly in this period, this is an important finding in terms of the robustness of our results.

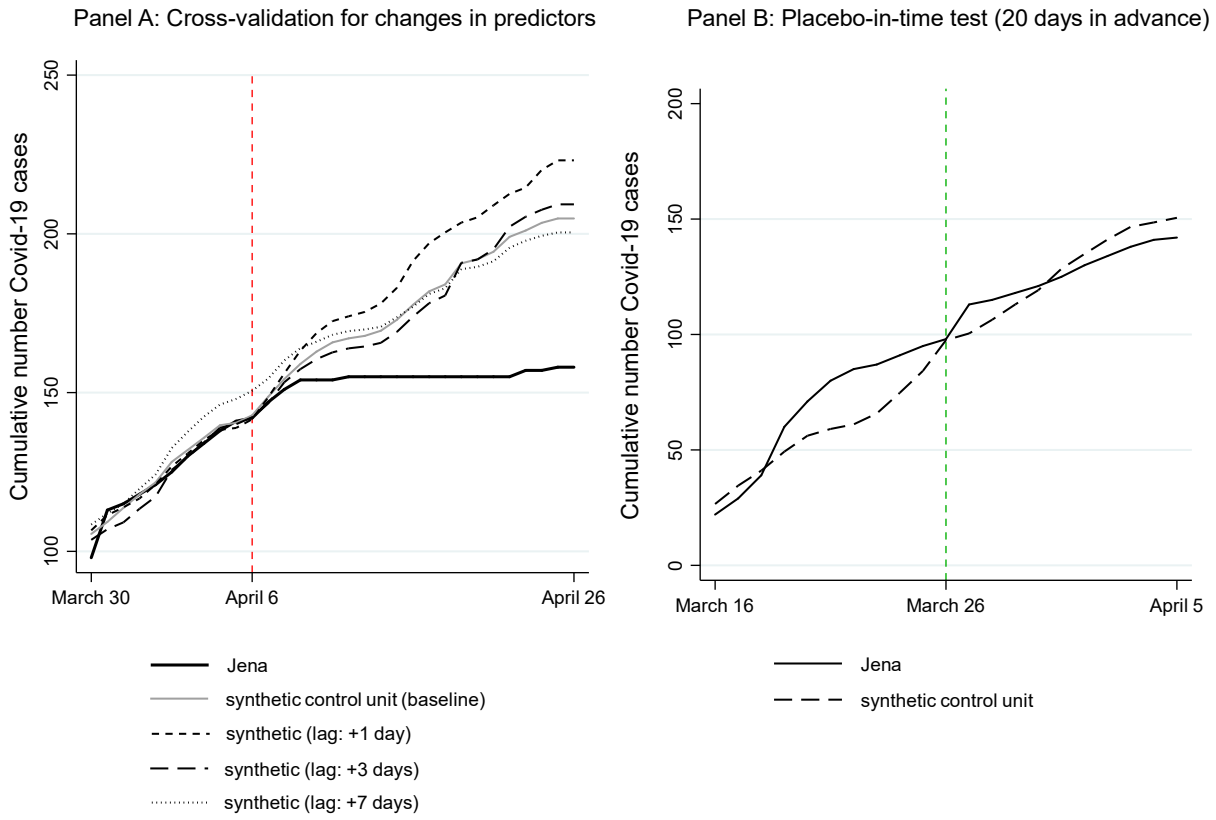

Figure 3: Cross-validation for changes in predictor variables and placebo-in-time test

Notes: In Panel A the baseline specification for the synthetic control group uses historical values of the outcome variable in the following way: i) number of cumulative Covid-19 cases (measured one and seven days before the start of the treatment), ii) the number of newly registered Covid-19 cases (in the last seven days prior to the start of the treatment); the alternative specifications lag these values by 1, 3 and 7 days.

Another important factor for the validity of the results is that we do not observe an anticipation effect for Jena prior to the announcement day. We test for a pseudo-treatment in Jena over a period of 20 days before the introduction of face masks. This period is equally split into a pre-

and pseudo post-treatment period. As Panel B in Figure 3 shows, there is no strong deviation from the path of the synthetic control group. This result needs to be interpreted with some care as the regional variation of Covid-19 cases in Germany is very heterogeneous the longer we go back in time. This is indicated by the generally lower fit of the synthetic control group in matching the development in Jena in mid-March when the absolute number of Covid-19 cases was still low.

Changing the donor pool. In addition, we also check for the sensitivity of the results when changing the donor pool. This may be important as our baseline specification includes the region of Heinsberg in the donor pool used to construct the synthetic Jena (with a weight of 4.6%; compare Table A3). As Heinsberg is one of the German regions which was significantly affected by the Covid-19 pandemic during the Carnival season, this may lead to an overestimation of the effects of face masks. Accordingly, appendix B.8 presents estimates for alternative donor pools. Again, we do not find evidence for a significant bias in our baseline specification. By tendency, the treatment effect becomes larger, particularly if we compare Jena only to other regions in Thuringia (to rule out macro-regional trends) and to a subsample of larger cities (*kreisfreie Städte*). Both subsamples exclude Heinsberg. We also run SCM for subsamples excluding Thuringia (to rule out spillover effects) and for East and West Germany (again in search for specific macro regional trends). Generally, these sensitivity tests underline the robustness of the estimated treatment effect for Jena.

Placebo-in-space tests. A placebo test in space checks whether other cities that did not introduce face masks on April 6 have nonetheless experienced a decline in the number of registered Covid-19 cases. If this had been the case, the treatment effect may be driven by other latent factors rather than face masks. Such latent factors may, for instance, be related to the macro-regional dynamics of Covid-19 in Germany. Therefore, appendix B.9 reports pseudo-treatment effects for similarly sized cities in Thuringia assuming that they have introduced face masks on April 6 although –in fact– they did not. As the figure shows, these cities show either a significantly higher or similar development of registered Covid-19 compared to their synthetic controls. This result provides further empirical support for a relevant effect in the case of Jena.

As a more comprehensive test, we also ran placebo-in-space tests for all other regions that did not introduce face masks on April 6 or closely afterwards. Again, we estimate the same model on each untreated region, assuming it was treated at the same time as Jena. The empirical results in Figure 4 indicate that the reduction in the reported number of Covid-19 cases in Jena clearly exceeds the trend in most other regions – both for the overall sample in Panel A and the subsample of large cities (*kreisfreie Städte*) in Panel B.

As outlined above, one advantage of this type of placebo-in-space-test is allows us to conduct inference. Accordingly, Panel C and Panel D report adjusted *p*-values that indicate the probability if the treatment effect for Jena was observed by chance given the distribution of pseudo-treatment effects in the other German regions (see Galiani and Quistorff, 2017). For both samples, the reported *p*-values indicate that the reduction in the number of Covid-19 cases in Jena did not happen by chance but can be attributed to the introduction of face masks, at the latest - roughly two weeks after the start of the treatment. This timing is again in line with our above argument that a sufficiently long incubation time and testing lags need to be considered in the evaluation of treatment effects.

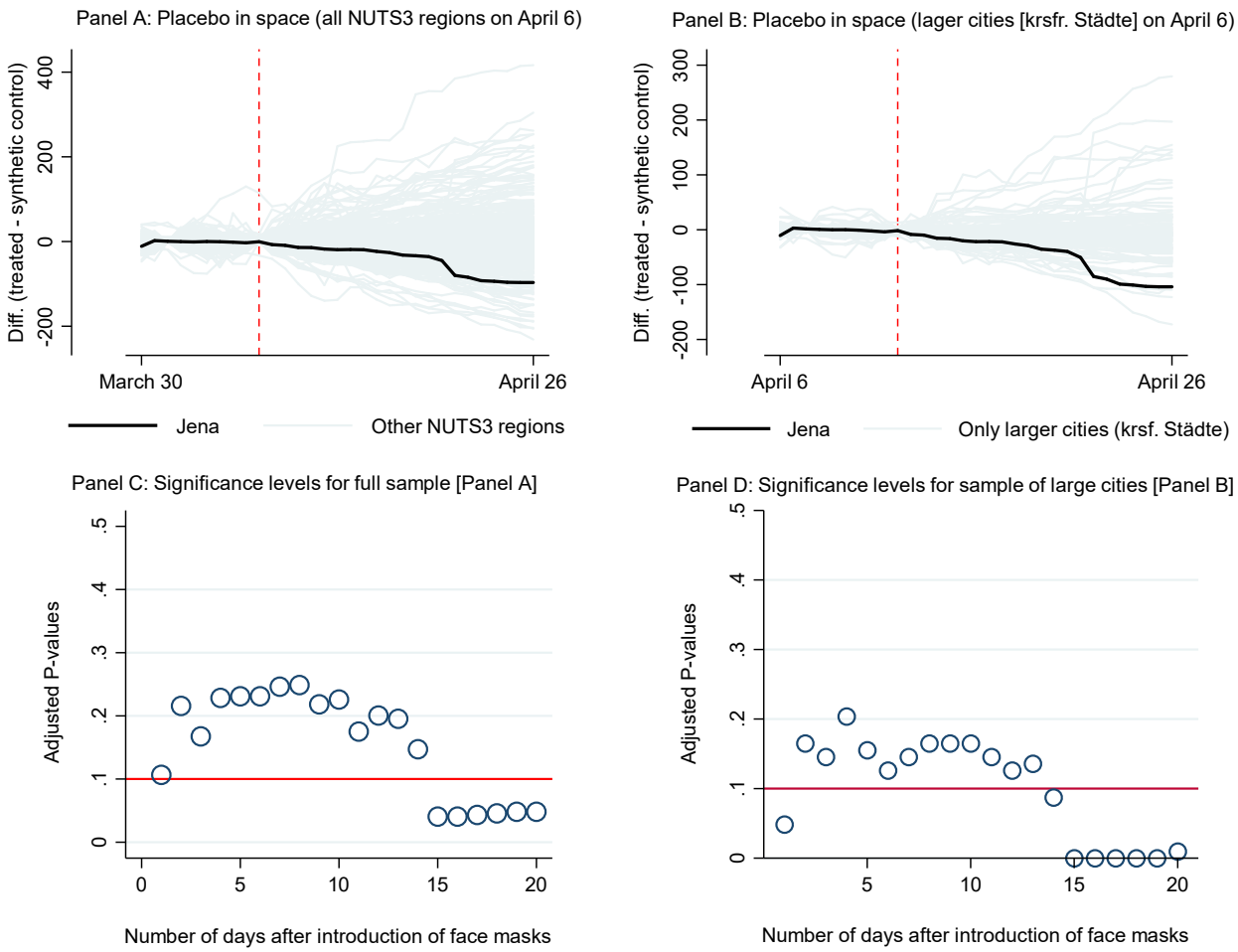

Figure 4: Comprehensive placebo-in-space tests for the effect of face masks on Covid-19 cases

Notes: Graphs exclude the following regions with a very large number of registered Covid-19 cases: Hamburg (2000), Berlin (11000), Munich (9162), Cologne (5315) and Heinsberg (5370). In line with Abadie et al. (2010), we only include placebo effects in the pool for inference if the match quality (pre-treatment RMSPE) of the specific control regions is smaller than 20 times the match quality of the treated unit. *P*-values are adjusted for the quality of the pre-treatment matches (see Galiani and Quistorff, 2017).

Treatment in other districts. Jena may be a unique case. We therefore also study treatment effects for other regions that have antedated the general introduction of face masks in Germany. Further single unit treatment analyses are shown in appendix C. Multiple unit treatments are studied in two ways. The first sample covers all 401 regions and 32 treated units. The second focused on the subsample of 105 larger cities (*kreisfreie Städte*), of which 8 are treated units. Treated regions introduced face masks by April 22. The multiple treatment approach, visible in Figure 5, points to a significant face mask-effect in the reduction of Covid-19 infections. The adjusted *p*-values indicate that the estimated treatment effects are not random.

Face masks may have made a particular difference in the spread of Covid-19, particularly in larger cities with higher population density and accordingly higher intensity of social interaction.[10] Over a period of 10 days, we observe an average reduction of 12.3 cases between treated and control regions. Relative to the average number of cumulative Covid-19 cases on May 1 in control regions (295.6), this amounts to a reduction of 4.2% of cases. The daily growth

[10] This is perfectly in line with Prather et al. (2020) given the reduction in aerosols and droplets via using masks.

rate of the number of infections correspondingly shrinks by 0.42 percentage points. For the entire sample, the reduction in the daily growth rate is estimated to be 0.23 percentage points (see again appendix B.4 for an overview of all measures).

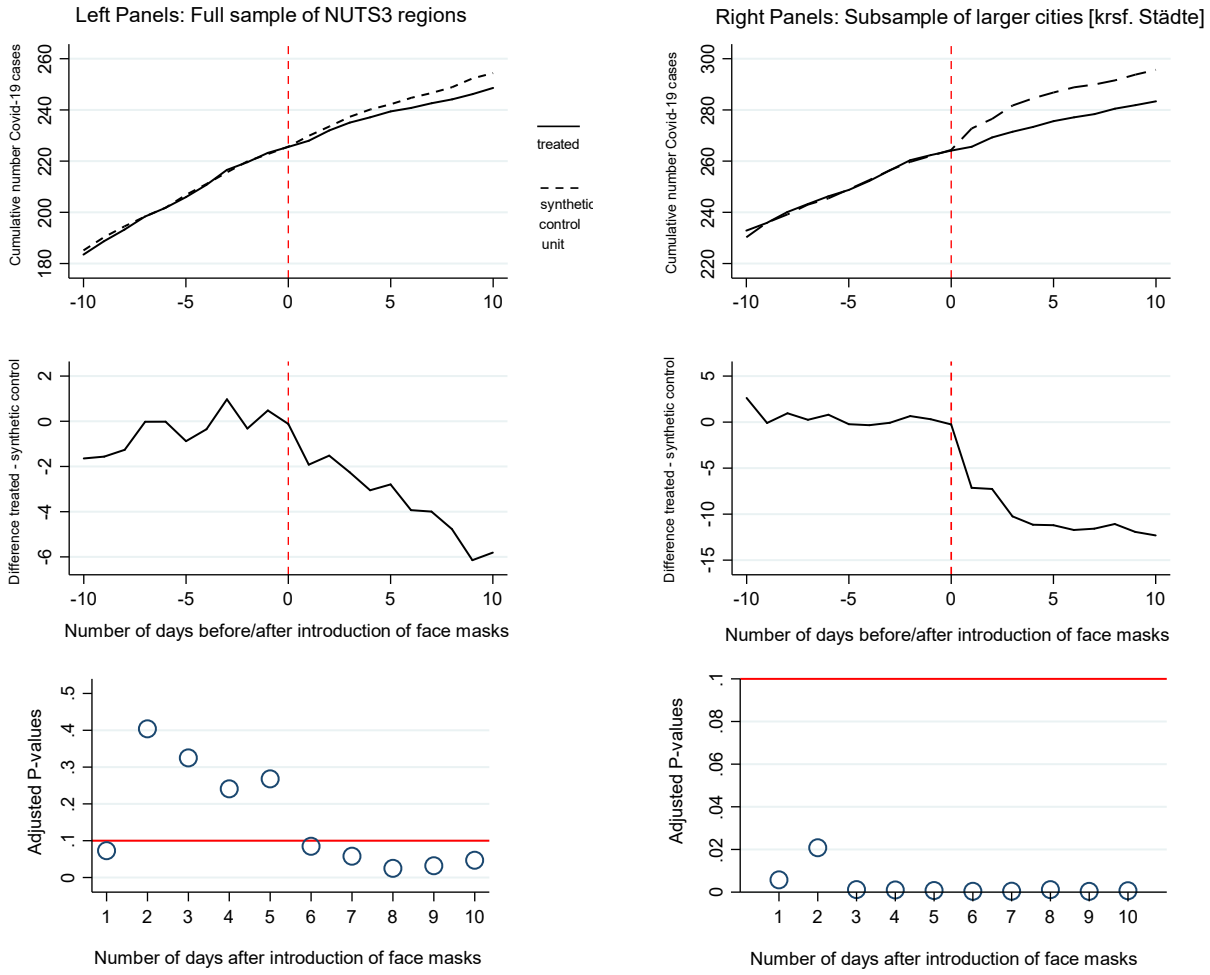

Figure 5: Average treatment effects for introduction of face masks (multiple treated units)

Notes Statistical inference for adjusted *p*-values has been conducted on the basis of a random sample of 1,000,000 placebo averages.

4 Conclusion

We set out by analyzing the city of Jena. The introduction of face masks on 6 April reduced the number of new infections over the next 20 days by almost 25% relative to the synthetic control group. This corresponds to a reduction in the average daily growth rate of the total number of reported infections by 1.32 percentage points. Comparing the daily growth rate in the synthetic control group with the observed daily growth rate in Jena, the latter shrinks by around 60% due to the introduction of face masks. This is a sizeable effect. Wearing face masks apparently helped considerably in reducing the spread of Covid-19. Looking at single treatment effects for all other regions puts this result in some perspective. The reduction in the growth rate of infections amounts to 20% only. By contrast, when we take the multiple treatment effect for larger cities into account, we find a reduction in the growth rate of infections by around 40%.

What would we reply if we were asked what the effect of introducing face masks would have been if they had been made compulsory all over Germany? The answer depends, first, on which of the three percentage measures we found above is the most convincing and, second, on the point in time when face masks are made compulsory. The second aspect is definitely not only of academic interest but would play a major role in the case of a second wave.

We believe that the reduction in the growth rates of infections by 40% to 60% is our best estimate of the effects of face masks. The most convincing argument stresses that Jena introduced face masks before any other region did so. It announced face masks as the first region in Germany while in our post-treatment period no other public health measures were introduced or eased. Hence, it provides the most clear-cut experiment of its effects. Second, as stated above, Jena is a fairly representative region of Germany in terms of Covid-19 cases. Third, the smaller effects observed in the multiple treatment analysis may also result from the fact that –by the time that other regions followed the example of Jena– behavioral adjustments in Germany's population had also taken place. Wearing face masks gradually became more common and more and more people started to adopt their usage even when it was not yet required.

We should also stress that 40 to 60% might still be a lower bound. The daily growth rates in the number of infections when face masks were introduced was around 2 to 3%. These are very low growth rates compared to the early days of the epidemic in Germany, where daily growth rates also lay above 50% (Wälde, 2020). One might therefore conjecture that the effects might have been even greater if masks had been introduced earlier.

We simultaneously stress the need for more detailed analyses. First, Germany is only one country. Different norms or climatic conditions might change the picture for other countries. Second, we have ignored spatial dependencies in the epidemic diffusion of Covid-19. This might play a role. Third, there are various types of face masks. We cannot identify differential effects since mask regulations in German regions do not require a certain type. This calls for further systematic causal analyses of the different health measure implemented to fight the spread of Covid-19. Our results provide some initial empirical evidence on this important matter.

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Supplementary Appendix
for

Face Masks Considerably Reduce Covid-19 Cases in Germany

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A synthetic control method approach

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A. Timing of introduction of mandatory face masks

Table A1: Overview of dates when masks became compulsory in federal states and districts

Federal State	Public transport	Sales shops	Individual NUTS3 region	Introduction of face masks	Difference in days to state
Baden-Wurttemberg	27.04.2020	27.04.2020	LK Rottweil	17.04.2020	10
Bavaria	27.04.2020	27.04.2020			
Berlin	27.04.2020	29.04.2020			
Brandenburg	27.04.2020	27.04.2020			
Bremen	27.04.2020	27.04.2020			
Hamburg	27.04.2020	27.04.2020			
Hesse	27.04.2020	27.04.2020	Main-Kinzig-Kreis	20.04.2020	7
Mecklenburg-West Pomer.	27.04.2020	27.04.2020			
Lower Saxony	27.04.2020	27.04.2020	Wolfsburg	20.04.2020	7
			Braunschweig	25.04.2020	2
North Rhine-Westphalia	27.04.2020	27.04.2020			
Rheinland-Pfalz	27.04.2020	27.04.2020			
Saarland	27.04.2020	27.04.2020			
Saxony	20.04.2020	20.04.2020			
Saxony-Anhalt	22.04.2020	22.04.2020			
Schleswig-Holstein	29.04.2020	29.04.2020			
Thuringia	24.04.2020	24.04.2020	Jena	06.04.2020	18
			Nordhausen	14.04.2020	10

Notes: A comprehensive overview of all public health measures introduced in German federal states and individual regions is given in Kleyer et al. (2020).

B. Background and additional estimates for SCM application to Jena

This appendix presents supporting findings for the comparative case study of Jena.

B.1. Covid-19 cases and cumulative incidence rate in Jena and Germany on April 5

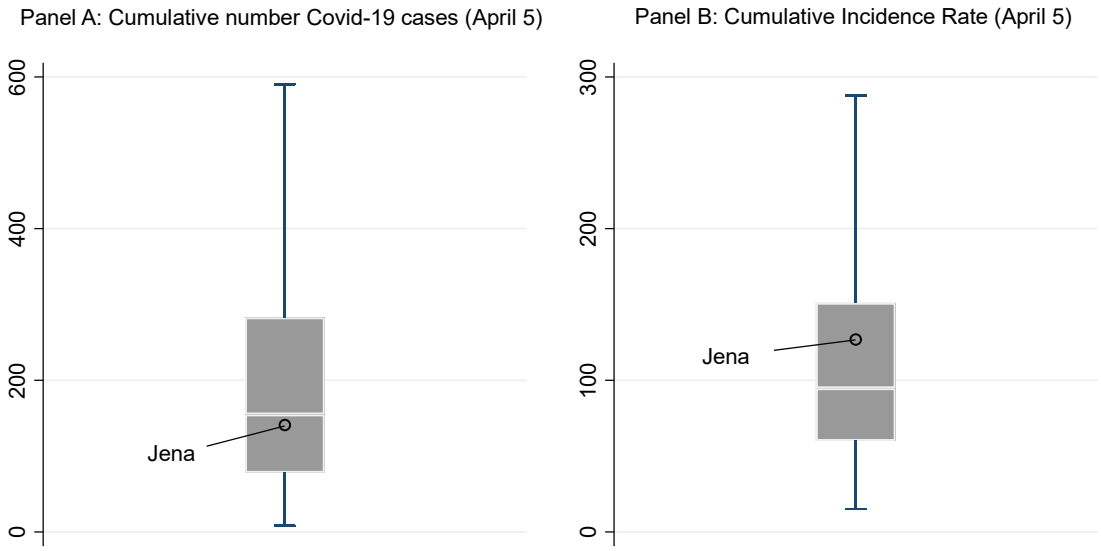

Figure A1: Box plots for distribution of Covid-19 cases across German NUTS3 regions (April 5)

B.2. Evaluation of pre-treatment predictor balance and prediction error (RMSPE)

This appendix shows the balancing properties of the SCM approach together with the root mean square percentage error (RMSPE) as a measure for the quality of the pre-treatment prediction.

Table A2: Pre-treatment predictor balance and RMSPE for SCM in Figure 2

Treatment:	**Introduction of face masks**		**Announcement/ start of campaign**	
	Jena	Synthetic control group	Jena	Synthetic control group
Cumulative number of registered Covid-19 cases (one and seven days before start of treatment, average)	129.5	129.2	93	92.7
Number of newly registered Covid-19 cases (last seven days before the start of the treatment, average)	3.7	3.8	5	5.2
Population density (Population/km^2)	38.4	22.8	968.1	947.9
Share of highly educated population (in %)	968.1	1074.3	38.4	26.3
Share of female in population (in %)	50.1	50.1	50.1	50.1
Average age of female population (in years)	43.5	43.7	43.5	43.9
Average age of male population (in years)	40.5	40.6	40.5	40.8
Old-age dependency ratio (in %)	32.1	29.3	32.1	29.8
Young-age dependency ratio (in %)	20.3	19.6	20.3	19.5
Physicians per 10,000 of population	20.5	19.8	20.5	20.8
Pharmacies per 100,000 of population	28.8	28.7	28.8	28.6
Settlement type (categorial variable)	1	1.3	1	1.9
RMSPE (pre-treatment)	**3.145**		**4.796**	

Notes: Donor pool includes all other German NUTS3 regions except the two immediate neighboring regions of Jena (Weimarer Land, Saale-Holzland-Kreis) as well as the regions Nordhausen and Rottweil since the latter regions introduced face masks in short succession to Jen on April 14 and April 17.

B.3. Selected control regions and their associated sample weights

Table A3: Distribution of sample weights in donor pool for synthetic Jena

Introduction of face masks (Panel A in Figure 2)		
ID	**NUTS 3 region**	**Weight**
13003	Rostock	0.326
6411	Darmstadt	0.311
3453	Cloppenburg	0.118
7211	Trier	0.117
6611	Kassel	0.082
5370	Heinsberg	0.046

Note: Donor pools corresponds to SCM estimation in Panel A of Figure 2. Sample weights are chosen to minimize the RMSPE ten days prior to the start of the treatment.

B.4. Growth rates

Jena has 142 registered cases on April 6 compared to an estimated number of 143 cases in the synthetic control group. On April 26 Jena counts 158 cases and the synthetic control group reports 205 (again estimated) cases. The daily growth rate in Jena is denoted by x_{Jena} and can be computed from $142\ [1+x_{Jena}]^{20} = 158$. The daily growth rate in the control group is denoted by $x_{control}$ and can be computed from $143\ [1+x_{control}]^{20} = 205$. Hence, the introduction of the face mask is associated with a decrease in the number of infections of $x_{control} - x_{Jena}$ percentage points per day.

Table A4: Summary of treatment effects of face mask introduction in Germany

	Single Treatment (Jena)	Multiple treatments (all districts)	Multiple treatments (cities)
Percentage change in cumulative number of Covid-19 cases over 20 days	-22.9%	n.a.	n.a.
Absolute change in cumulative number of Covid-19 cases over 10 days	-23	-5.8	-12.3
Percentage change in cumulative number of Covid-19 cases over 10 days	-12.8%	-2.3%	-4.2%
Difference in daily growth rates of Covid-19 cases in percentage points	-1.32%	-0.23%	-0.42%
Reduction in daily growth rates of Covid-19 cases in percent	60.1%	18.94%	37.28%

These numbers are computed in an Excel-file available on the web pages of the authors.

B.5. SCM results by age groups

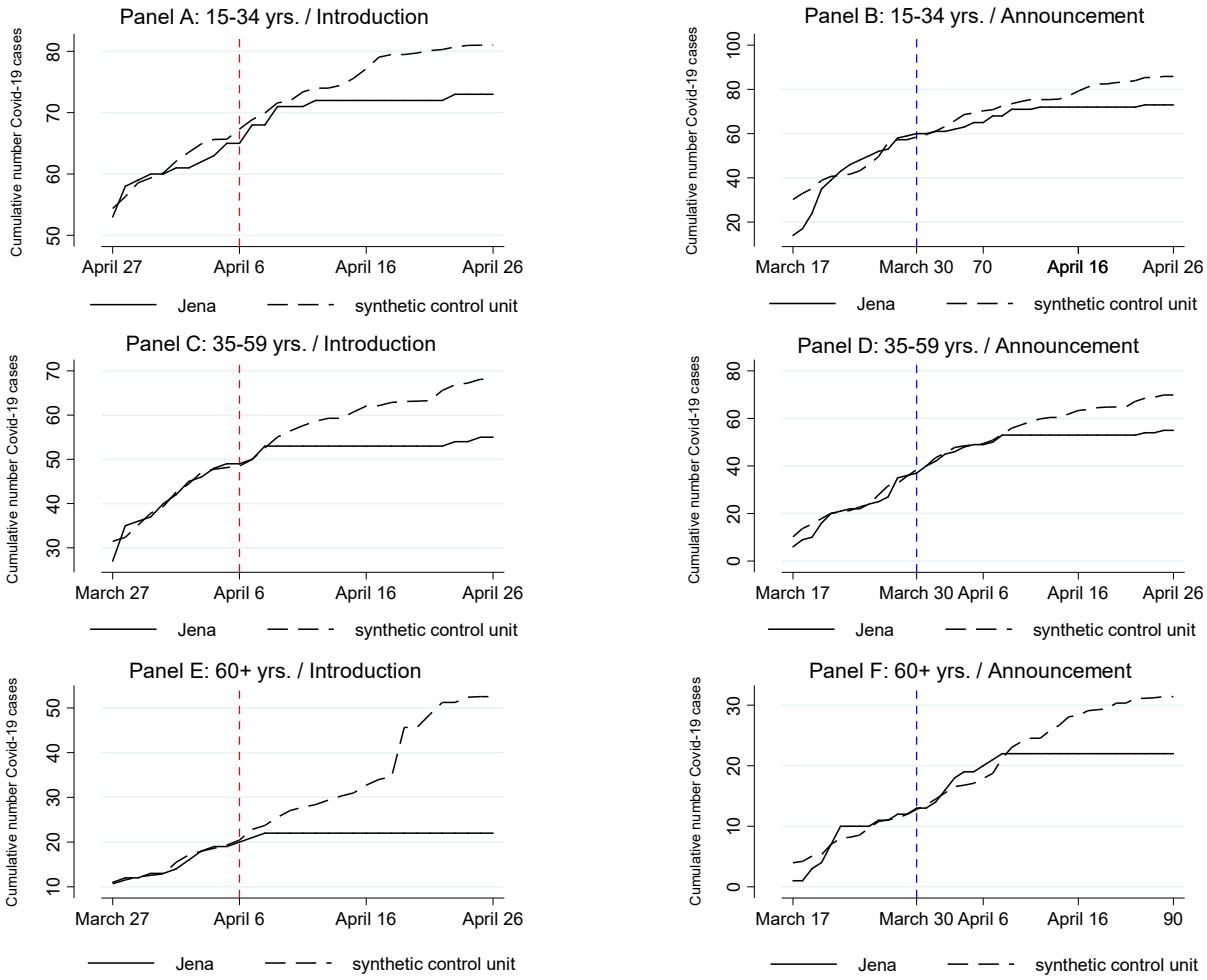

Figure A2: Treatment effects for introduction and announcement of face masks in Jena

Notes: Predictor variables are chosen as for overall specification shown in Figure 2.

Table A5: Sample weights in donor pool for synthetic Jena (cumulative Covid-19 cases; by age groups)

Age Group 15-34 years			**Age Group 35-59 years**			**Age Group 60 years and above**		
ID	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**
1001	Flensburg	0.323	6411	Darmstadt	0.528	6411	Darmstadt	0.522
7211	Trier	0.207	16055	Weimar	0.16	16055	Weimar	0.244
13003	Rostock	0.184	14511	Chemnitz	0.15	7316	Neustadt a.d. Weinstraße	0.068
5370	Heinsberg	0.142	8221	Baden-Baden	0.07	9562	Erlangen	0.06
3453	Cloppenburg	0.107	6434	Hochtaunus-kreis	0.062	3356	Osterholz	0.056
6413	Offenbach am Main	0.038	8435	Bodenseekreis	0.029	5515	Münster	0.027
			5370	Heinsberg	0.001	9188	Starnberg	0.022

Note: Donor pools corresponds to SCM estimations in Figure A2. Sample weights are chosen to minimize the RMSPE ten days prior to the start of the treatment.

B.6. Effects on cumulative number of infections per 100,000 inhabitants

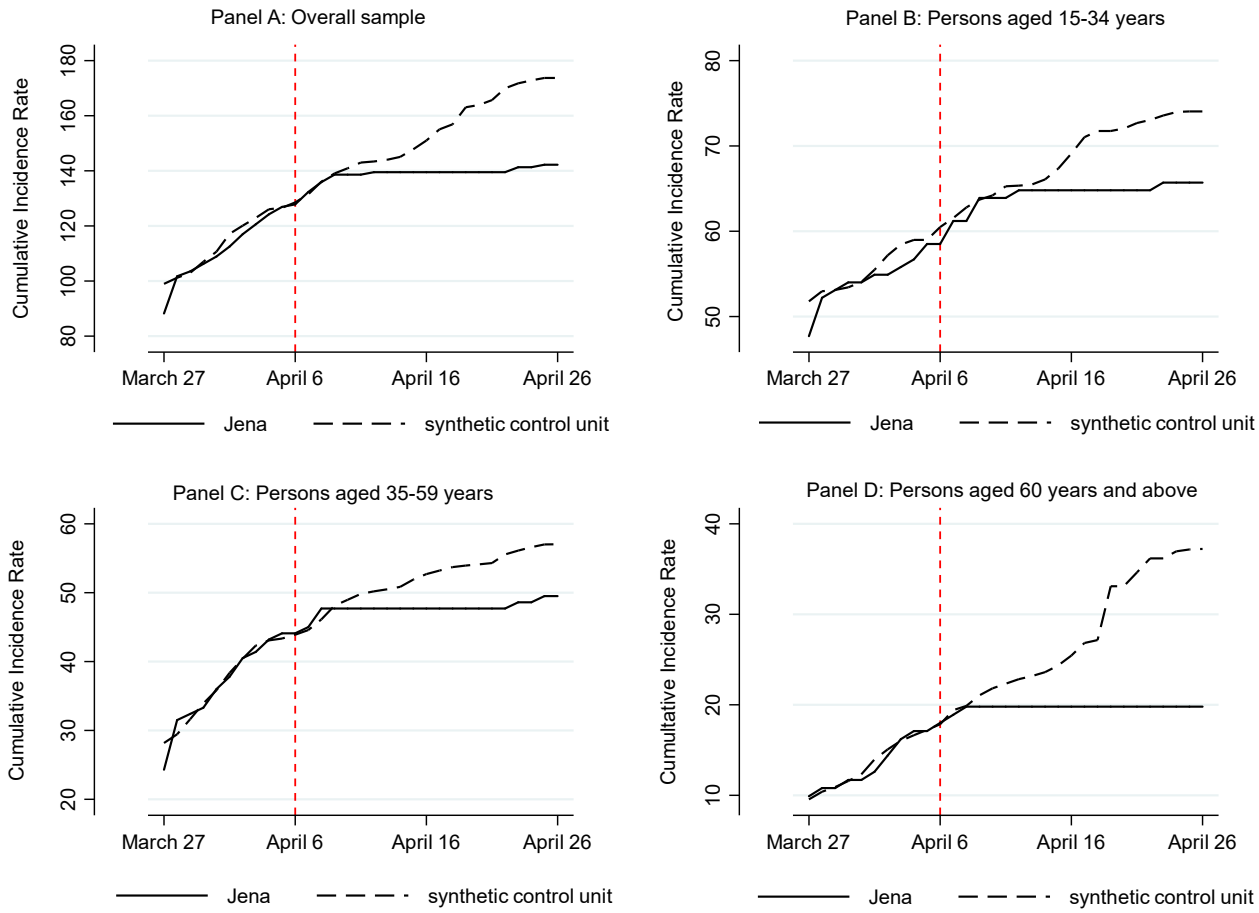

Figure A3: Treatment effects for introduction of face masks on cumulative incidence rate

Notes: See Table 1 for a definition of the incidence rate. Predictor variables are chosen as for overall specification shown in Figure 2.

Table A6: Sample weights in donor pool for synthetic Jena (cumulative incidence rate)

ID	NUTS 3 region	Weight
6411	Darmstadt	0.46
15003	Magdeburg	0.171
5370	Heinsberg	0.133
13003	Rostock	0.093
5515	Münster	0.066
11000	Berlin	0.035
12052	Cottbus	0.032
6611	Kassel	0.011

Note: Donor pools corresponds to SCM estimation in Figure A3. Sample weights are chosen to minimize the RMSPE ten days prior to the start of the treatment.

Table A7: Sample weights in donor pool for synthetic Jena (cumulative incidence rate; by age groups)

Age Group 15-34 years			Age Group 35-59 years			Age Group 60 years and above		
ID	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**
5370	Heinsberg	0.377	6411	Darmstadt	0.419	6411	Darmstadt	0.448
13003	Rostock	0.288	14511	Chemnitz	0.184	14612	Dresden	0.313
1001	Flensburg	0.14	14612	Dresden	0.154	9188	Starnberg	0.071
6611	Kassel	0.138	8221	Heidelberg	0.138	16054	Suhl	0.069
11000	Berlin	0.058	9188	Starnberg	0.088	5515	Münster	0.06
			5370	Heinsberg	0.016	8221	Heidelberg	0.039

Note: Donor pools corresponds to SCM estimations in Figure A3. Sample weights are chosen to minimize the RMSPE ten days prior to the start of the treatment.

B.7. Google trends and announcement effects

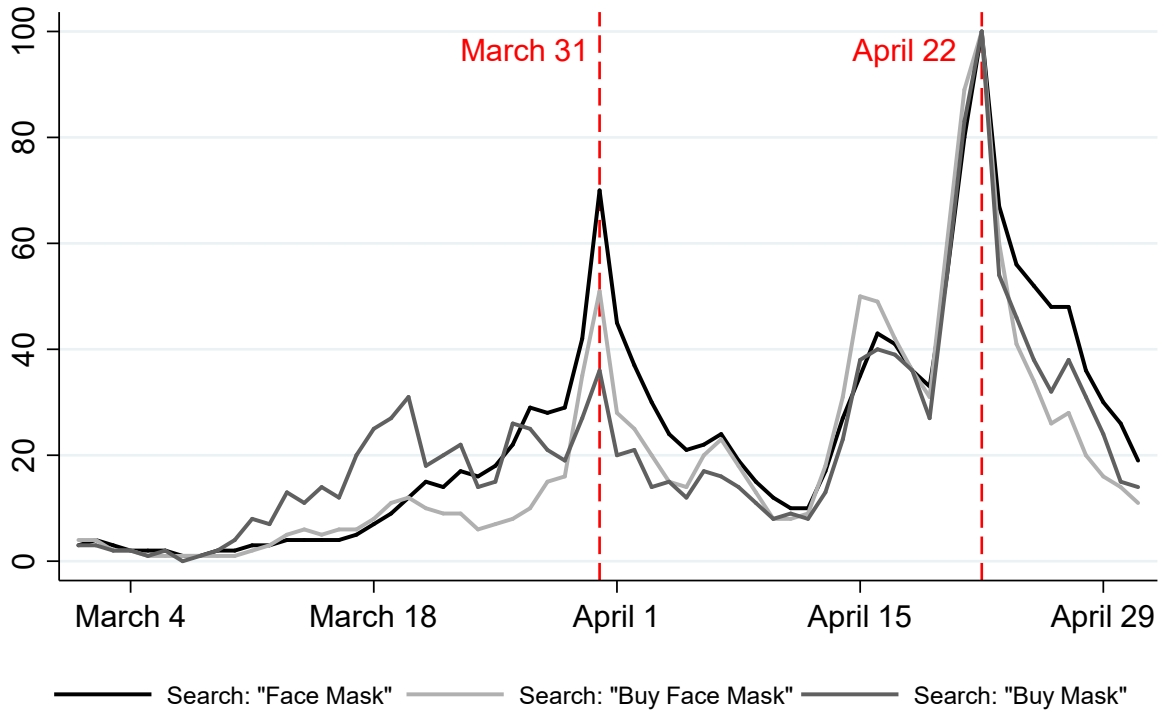

Figure A4: Online search for face masks and purchase options according to Google Trends

Note: Online search for keywords (in German) as shown in the legend as Face Mask ("Mund.-Nasen-Schutz"), Buy Face Mask ("Mundschutz kaufen") and Buy mask ("Maske kaufen"); alternative keywords show similar peaks but with a lower number of hits; based on data from Google Trends (2020).

B.8. Changes in donor pool for synthetic Jena

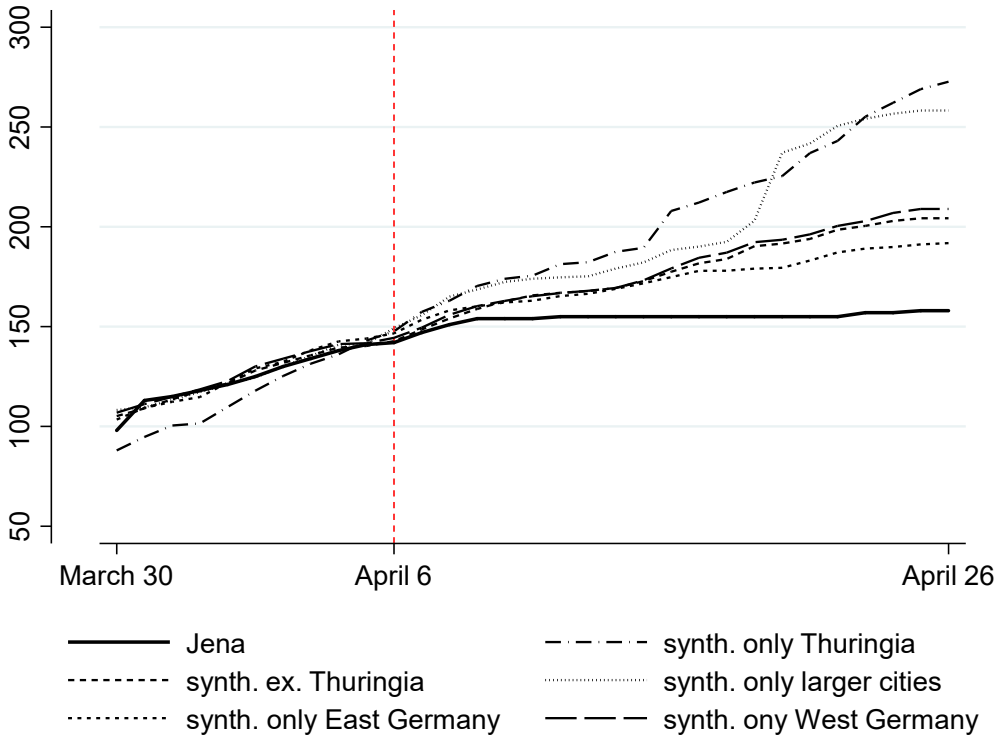

Figure A5: Treatment effects for changes in donor pool used to construct synthetic Jena

Notes: See main text for a detailed definition of the respective donor pools. Predictor variables are chosen as for overall specification shown in Figure 2.

Table A8: Sample weights for alternative donor pools used to construct synthetic Jena

Only Thuringia			**Excluding Thuringia**			**Only larger cities**		
ID	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**
16076	Greiz	0.533	13003	Rostock	0.318	6411	Darmstadt	0.504
16051	Erfurt	0.467	6411	Darmstadt	0.302	13003	Rostock	0.304
			7211	Trier	0.129	5113	Essen	0.192
			3453	Cloppenburg	0.122			
			6611	Kassel	0.083			
			5370	Heinsberg	0.046			
Only East Germany			**Only West Germany**					
ID	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**			
16051	Erfurt	0.865	6411	Darmstadt	0.242			
14612	Dresden	0.124	3402	Emden	0.198			
11000	Berlin	0.011	6611	Kassel	0.169			
			7211	Trier	0.168			
			4012	Bremerhaven	0.167			
			5370	Heinsberg	0.057			

Note: Donor pools corresponds to SCM estimations in Figure A5. Sample weights are chosen to minimize the RMSPE ten days prior to the start of the treatment.

B.9. Place-in-space tests for other major cities in Thuringia

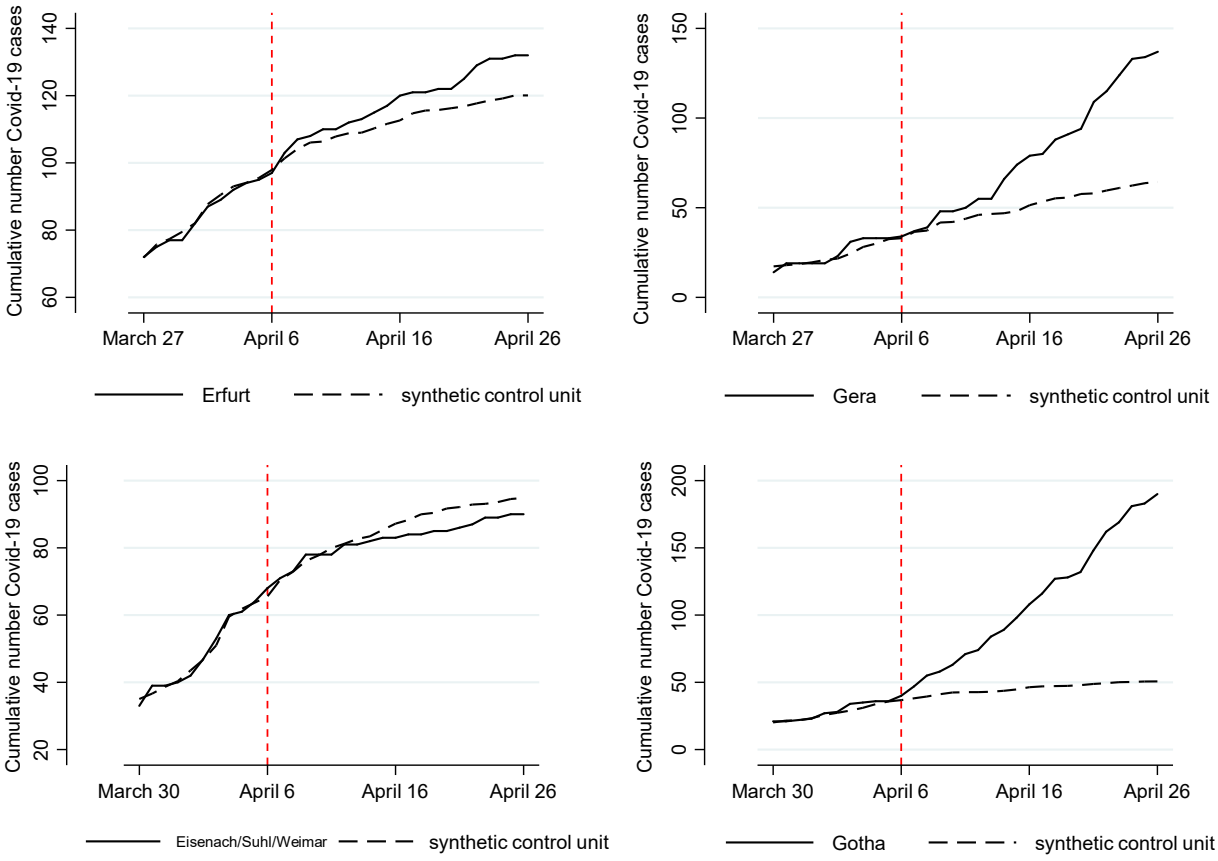

Figure A6: Placebo tests for the effect of face masks in other cities in Thuringia on April 6.

Notes: For the placebo tests in the other cities in Thuringia the same set of predictors as for Jena (Figure 2) has been applied. The reported regions cover all *kreisfreie Städte* plus Gotha (*Landkreis*). The cities Weimar, Suhl and Eisenach have been aggregated since the number of reported Covid-19 is low in these cities.

Table A9: Sample weights in donor pool for synthetic control groups (other cities in Thuringia)

Erfurt			Gera		
ID	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**
13003	Rostock	0.28	15001	Dessau-Roßlau	0.501
16055	Weimar	0.244	16054	Suhl	0.222
3356	Osterholz	0.212	7318	Speyer	0.162
7313	Landau in der Pfalz	0.154	8231	Pforzheim	0.061
6413	Offenbach am Main	0.078	7311	Frankenthal (Pfalz)	0.046
5370	Heinsberg	0.029	8211	Baden-Baden	0.005
5515	Münster	0.004	9662	Schweinfurt	0.003
			14521	Erzgebirgskreis	0.001
Weimar/Suhl/Eisenach			**Gotha**		
ID	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**
15001	Dessau-Roßlau	0.263	15081	Altmarkkreis	0.23
12052	Cottbus	0.236	16077	Altenburger Land	0.164
13004	Schwerin	0.202	15086	Jerichower	0.161
9361	Amberg	0.177	3402	Emden	0.111
14626	Görlitz	0.069	16071	Weimarer Land	0.108
9363	Weiden i.d. Opf.	0.036	16074	Saale-Holzland-Kreis	0.063
14521	Erzgebirgskreis	0.008	16061	Eichsfeld	0.058
9184	München	0.005	16070	Ilm-Kreis	0.055
6411	Darmstadt	0.005	3453	Cloppenburg	0.027
			15003	Magdeburg	0.017
			4012	Bremerhaven	0.007

Note: Donor pools corresponds to SCM estimations in Figure A6. Sample weights are chosen to minimize the RMSPE ten days prior to the start of the treatment.

C. The effect in other German cities and regions (single treatment analyses)

In addition to Jena, we test for treatment effects in Nordhausen, Rottweil, Main-Kinzig-Kreis, and Wolfsburg (compare Figure 1). We ignore Braunschweig here as the introduction became effective only two days in advance of its federal state.

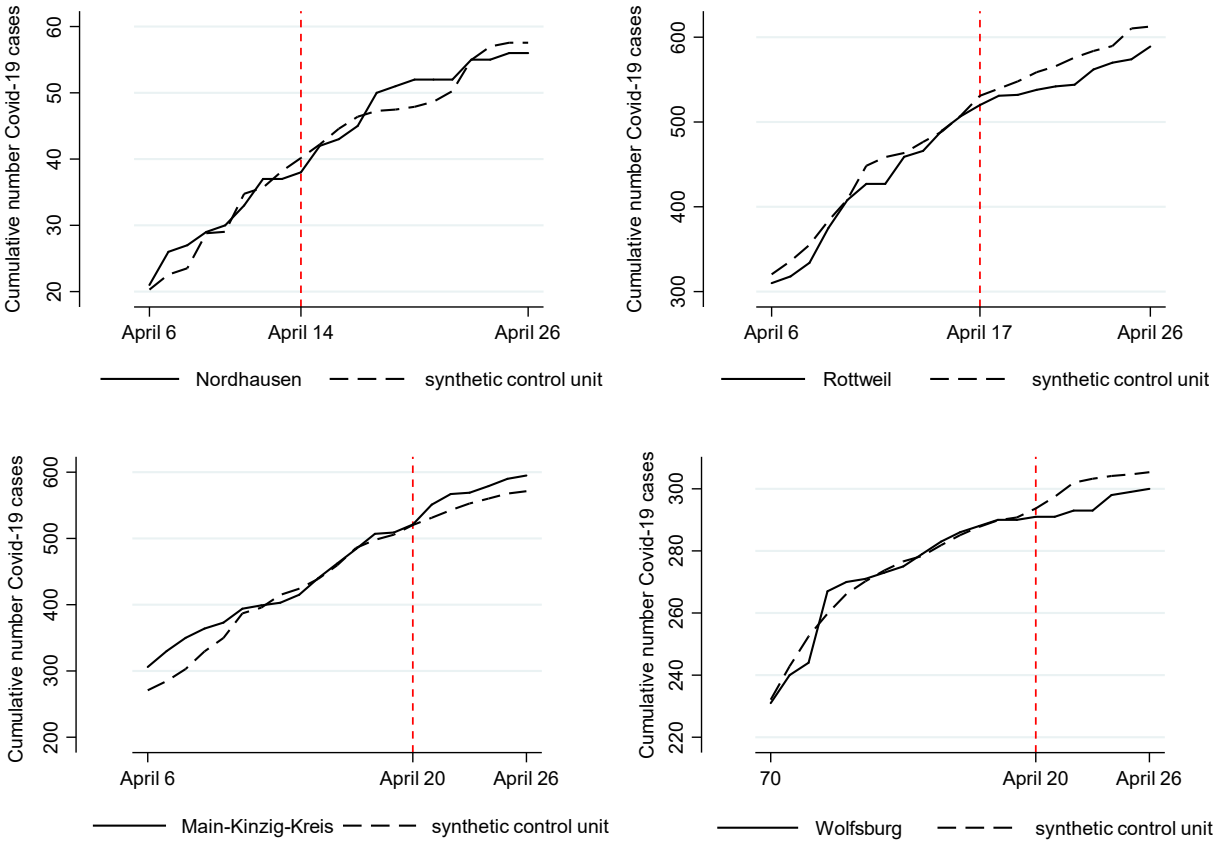

Figure A7: Treatment effects for introduction of face masks in other cities

Notes: Nordhausen (Thuringia, April 14, top left), Rottweil (Baden Württemberg, April 17, top right), Wolfsburg (Lower Saxony, April 20, middle left), Main-Kinzig-Kreis (Hessia, April 20, middle right). Predictor variables are chosen as for overall specification shown in Figure 2.

As the figure shows, the result is 2:1:1. Rottweil and Wolfsburg display a positive effect of mandatory mask wearing, just as Jena. The results in Nordhausen are very small or unclear. In the region of Main-Kinzig, it even seems to be the case that masks increased the number of cases relative to the synthetic control group. As all of these regions introduced masks after Jena, the time period available to identify effects is smaller than for Jena. The effects of mandatory face masks could also be underestimated as announcement effects and learning from Jena might have induced individuals to wear masks already before they became mandatory. Finally, the average pre-treatment RMSPE for these four regions (7.150) is larger than for the case of Jena (3.145). For instance, in the case of the region of Main-Kinzig it is more than three times as high (9.719), which indicates a lower pre-treatment fit. The obtained treatment effects should then be interpreted with some care as the pre-sample error could also translate into the treatment period. In order to minimize the influence of a poor pre-treatment fit for some individual regions, the main text therefore compares the results in Jena mainly with a multiple unit treatment approach.

Table A10: Sample weights in donor pool for synthetic controls (other treated NUTS3 regions)

	Nordhausen			**Rottweil**	
ID	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**
16069	Hildburghausen	0.228	8327	Tuttlingen	0.324
6636	Werra-Meißner-Kreis	0.209	5966	Olpe	0.216
16064	Unstrut-Hainich-Kreis	0.168	8136	Ostalbkreis	0.2
16054	Suhl	0.109	16071	Weimarer Land	0.063
3402	Emden	0.093	14521	Erzgebirgskreis	0.06
12073	Uckermark	0.071	3102	Salzgitter	0.043
12053	Frankfurt (Oder)	0.07	16061	Eichsfeld	0.035
3354	Lüchow-Dannenberg	0.051	9187	Rosenheim	0.031
			9279	Dingolfing-Landau	0.025
			3455	Friesland	0.003
	Main-Kinzig-Kreis			**Wolfsburg**	
ID	**NUTS 3 region**	**Weight**	**ID**	**NUTS 3 region**	**Weight**
8136	Ostalbkreis	0.193	8212	Karlsruhe	0.357
1062	Stormarn	0.168	8221	Heidelberg	0.189
5966	Olpe	0.113	8211	Baden-Baden	0.158
6433	Groß-Gerau	0.105	10046	St. Wendel	0.128
9473	Coburg	0.092	14511	Chemnitz	0.071
5562	Recklinghausen	0.063	5117	Mülheim an der Ruhr	0.059
7313	Landau in der Pfalz	0.059	5315	Köln	0.028
9171	Altrötting	0.056	15003	Magdeburg	0.007
7338	Rhein-Pfalz-Kreis	0.047	9663	Würzburg	0.004
6437	Odenwaldkreis	0.041			
8236	Enzkreis	0.041			
3159	Göttingen	0.023			

Note: Donor pools corresponds to SCM estimations in Figure A7. Sample weights are chosen to minimize the RMSPE ten days prior to the start of the treatment.

D. A brief survey of public health measures against Covid-19

Our approach goes in line with various studies that have already tried to better understand the effect of public health measures on the spread of Covid-19 (Barbarossa et al., 2020, Hartl et al., 2020, Donsimoni et al., 2020, Dehning et al., 2020, Gros et al., 2020, Adamik et al, 2020). However, these earlier studies all take an aggregate approach in the sense that they look at implementation dates for a certain measure and search for subsequent changes in the national incidence. There are some prior analyses that take a regional focus (Khailaie et al. 2020) but no attention is paid to the effect of policy measures.[11]

There are also many cross-country analyses, both in a structural SIR (susceptible, infectious and removed) sense (Chen and Qiu, 2020) and with an econometric focus on forecasting the end of the pandemic (Ritschl, 2020). Others draw parallels between earlier pandemics and Covid-19 (Barro et al., 2020). These studies do not explicitly take public health measures into account. Some studies discuss potential effects of public health measures and survey general findings (Wilder-Smith et al. 2020, Anderson et al., 2020, Ferguson et al, 2020) but do not provide direct statistical evidence on specific measures.

The synthetic control method (SCM) has been applied by Friedson et al. (2020) to estimate the effect of the shelter-in-place order for California, USA, in the development of Covid-19. The authors find *inter alia* that around 1600 deaths from Covid-19 have been avoided by this measure during the first four weeks. The effects of face masks have been surveyed by Howard et al. (2020) and Greenhalgh et al. (2020). Greenhalgh et al. (2020) mainly presents evidence on the effect of face masks during non-Covid epidemics (influenza and SARS). Marasinghe (2020) reports that they "*did not find any studies that investigated the effectiveness of face mask use in limiting the spread of COVID-19 among those who are not medically diagnosed with COVID-19 to support current public health recommendations*".

In addition to medical aspects (like transmission characteristics of Covid-19 and filtering capabilities of masks), Howard et al. (2020) survey evidence on mask efficiency and on the effect of a population. They first stress that "*no randomized control trials on the use of masks <…> has been published*". The study which is "*the most relevant paper*" for Howard et al. (2020) is one that analyzed *"exhaled breath and coughs of children and adults with acute respiratory illness*" (Leung et al., 2020, p. 676), i.e. used a clinical setting. Concerning the effect of masks on community transmissions, the survey needs to rely on pre-Covid-19 studies.

We conclude from this literature review that our paper is the first analysis that provides field evidence on the effect of masks on mitigating the spread of Covid-19.

[11] In a short note, Hartl and Weber (2020) apply panel methods based on time dummies to understand the relative importance of various public health measures. They employ data at the federal state level and not at the regional level. As a detailed model description is not available, an appreciation of results is difficult at this point.

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- "Mask Mandate Effectiveness" via *Resolve to Save Lives* Weekly Science Review: https://preventepidemics.org/covid19/science/weekly-science-review/october-3-9/
    - **Main message:** Enforceable policies and mandates to promote health behaviors can be highly effective when they are evidence-based and implemented with the health of the population and the greater good in mind. Mask mandates to mitigate spread of the virus that causes COVID-19 have been enacted differently across and within countries. Although the magnitude of the effect can be difficult to measure, comparisons between settings with and without mandates suggest that mask mandates, together with other mitigation measures, contribute to control the COVID-19 pandemic. Enforceable mask mandates are one strategy leaders can use to reduce the spread of COVID-19 and protect the health of their residents.

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RESEARCH LETTER

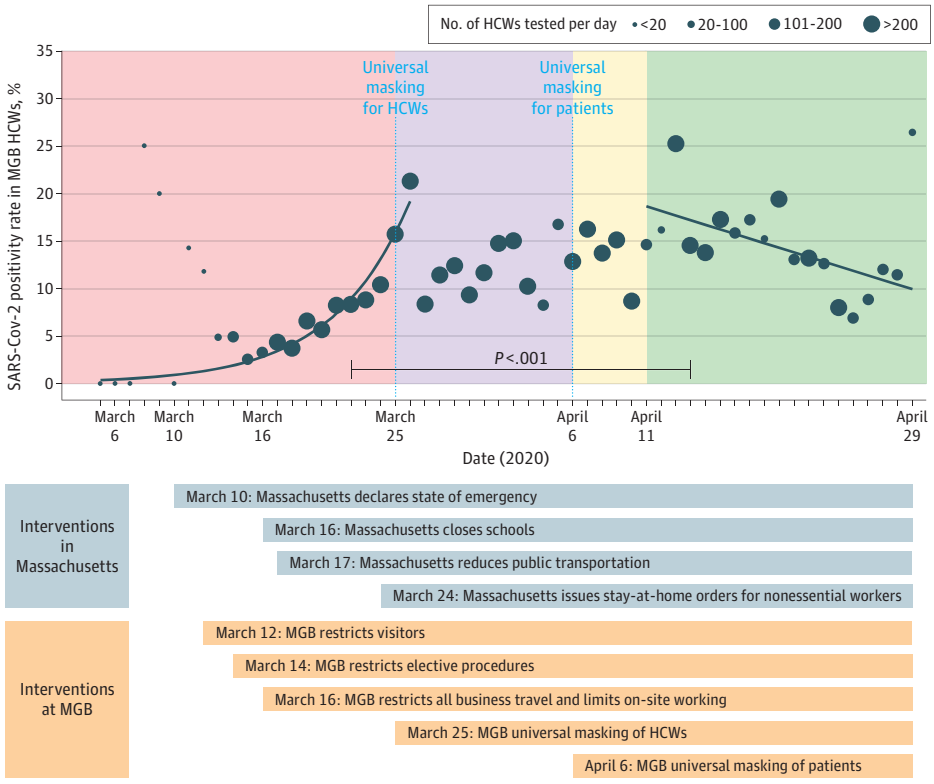
Association Between Universal Masking in a Health Care System and SARS-CoV-2 Positivity Among Health Care Workers

The coronavirus disease 2019 (COVID-19) pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has severely affected health care workers (HCWs).[1] As a result, hospital systems began testing HCWs[2] and implementing infection control measures to mitigate workforce depletion and prevent disease spread.[3] Mass General Brigham (MGB) is the largest health care system in Massachusetts, with 12 hospitals and more than 75 000 employees. In March 2020, MGB implemented a multipronged infection reduction strategy involving systematic testing of symptomatic HCWs and universal masking of all HCWs and patients with surgical masks.[4] This study assessed the association of hospital masking policies with the SARS-CoV-2 infection rate among HCWs.

Editorial

Methods | The institutional review board of MGB approved the study and waived informed consent. Using electronic medical records, we identified HCWs providing direct and indirect patient care who were tested for SARS-CoV-2 with reverse transcriptase–polymerase chain reaction between March 1 and April 30, 2020. The primary criterion for testing HCWs in our health care system was having symptoms consistent with SARS-CoV-2 infection. Information on the job description of each HCW was obtained by linking their record to the MGB Occupational Health Services and Human Resources databases.

Figure. Temporal Trend in Percentage Positivity of SARS-CoV-2 Testing Among HCWs



HCW indicates health care worker; MGB, Mass General Brigham; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2. All dates given are for the year 2020. The size of each data marker is proportional to the total number of SARS-CoV-2 tests performed each day over the time of the study period (x-axis), while the position of each data marker along the y-axis shows the percentage of daily test results that were positive among HCWs. The horizontal bars below the x-axis represent the timing of key interventions implemented in the state of Massachusetts and at MGB. The dotted lines represent the implementation dates of hospital policies. The study period is divided into 3 phases: a preintervention period before implementation of universal masking of HCWs (pink), which includes March 26, the day after implementation of universal masking for HCWs, to account for HCWs who became symptomatic after business hours on March 25 and were tested on March 26; a transition period until implementation of universal masking of patients (purple) plus an additional lag period (yellow); and the intervention period (green). For the preintervention and intervention periods, daily tests were fitted by weighted nonlinear regression (curves). The change in overall slope was compared between the 2 curves to determine any statistically significant changes in trend (as shown by the *P* value).

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We identified 3 phases during the study period: a preintervention period before implementation of universal masking of HCWs (March 1-24, 2020); a transition period until implementation of universal masking of patients (March 25-April 5, 2020) plus an additional lag period to allow for manifestations of symptoms (April 6-10, 2020), as previously defined[5]; and an intervention period (April 11-30, 2020). Positivity rates included the first positive test result for all HCWs in the numerator and HCWs who never tested positive plus those who tested positive that day in the denominator. For each HCW, any tests subsequent to their first positive test result were excluded. Using weighted nonlinear regression, we fit the best curve for the preintervention and intervention periods (based on R^2 value). The number of daily tests was used as the weight such that days with more tests had more weight in determining the curve. The overall slope of each period was calculated using linear regression to estimate the mean trend, regardless of curve shape. The change in overall slope between the preintervention and intervention periods was compared to determine any statistically significant change in mean trend, using a 2-sided $\alpha = .05$. The analysis was conducted using R version 4.0 (R Foundation).

Results | Of 9850 tested HCWs, 1271 (12.9%) had positive results for SARS-CoV-2 (median age, 39 years; 73% female; 7.4% physicians or trainees, 26.5% nurses or physician assistants, 17.8% technologists or nursing support, and 48.3% other). During the preintervention period, the SARS-CoV-2 positivity rate increased exponentially from 0% to 21.32%, with a weighted mean increase of 1.16% per day and a case doubling time of 3.6 days (95% CI, 3.0-4.5 days). During the intervention period, the positivity rate decreased linearly from 14.65% to 11.46%, with a weighted mean decline of 0.49% per day and a net slope change of 1.65% (95% CI, 1.13%-2.15%; $P < .001$) more decline per day compared with the preintervention period (**Figure**).

Discussion | Universal masking at MGB was associated with a significantly lower rate of SARS-CoV-2 positivity among HCWs. This association may be related to a decrease in transmission between patients and HCWs and among HCWs. The decrease in HCW infections could be confounded by other interventions inside and outside of the health care system (Figure), such as restrictions on elective procedures, social distancing measures, and increased masking in public spaces, which are limitations of this study. Despite these local and statewide measures, the case number continued to increase in Massachusetts throughout the study period,[6] suggesting that the decrease in the SARS-CoV-2 positivity rate in MGB HCWs took place before the decrease in the general public. Randomized trials of universal masking of HCWs during a pandemic are likely not feasible. Nonetheless, these results support universal masking as part of a multipronged infection reduction strategy in health care settings.

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Author Contributions: Dr Bhatt had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Drs Wang and Ferro contributed equally to this article.
Concept and design: Wang, Ferro, Hashimoto, Bhatt.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Wang, Ferro.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Wang, Zhou.
Administrative, technical, or material support: Wang, Ferro, Hashimoto.
Supervision: Hashimoto, Bhatt.

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Science Agenda Development and Update

Greg Armstrong
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Joanne Cono
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Brandi Limbago
Sam Posner
Henry Walke

October 19, 2020

Background and Current Status

- Request to develop a Science Agenda
  - Build on what had been previously done
  - Other research agendas (NIAID, DHS, WHO, Published Literature)
  - 1-3 year time horizon
- Related products in development
  - Internal document for internal decision making
  - Project tracking and reporting
  - Priority Questions

Status and Purpose of the Internal Document

- Review
  - Agency Leadership
  - Team B
  - IM Leadership
  - Task Forces
- Purpose
  - Support internal decision making
  - Document and prioritize emerging issues
  - Identify priority areas

Document Structure

- Six Priority Areas
  - COVID-19 disease detection, burden and impact
  - Transmission of SARS-CoV-2
  - Natural history of SARS-CoV-2 infection
  - Protection in healthcare and non-healthcare work settings
  - Prevention, mitigation, and intervention strategies
  - Social, behavioral, and communication science
- Objectives for each Priority Area
- Specific Activities

PRIORITY AREA I. COVID-19 DISEASE DETECTION, BURDEN, AND IMPACT

- Objective 1. Develop new, or modify existing, methods of epidemiologic surveillance for COVID-19
- Objective 2. Develop and optimize testing for SARS-CoV-2
- Objective 3. Utilize viral genomics to advance understanding of COVID-19 and mitigate its impact
- Objective 4. Use mathematical modeling and other technological tools to forecast COVID-19 trends and measure the impact of interventions across a range of populations
- Objective 5. Assess and limit the impact of COVID-19 on healthcare services and public health programs in domestic and international settings

PRIORITY AREA II. TRANSMISSION OF SARS-CoV-2

- **Objective 1. Refine understanding of SARS-CoV-2 transmission modes**
- **Objective 2. Identify host and virus factors associated with person-to-person transmission**
- **Objective 3. Assess and characterize transmission of SARS-CoV-2 across a spectrum of healthcare settings**
- **Objective 4. Evaluate transmission of SARS-CoV-2 in non-healthcare workplace and community settings/populations**
- **Objective 5. Evaluate zoonotic and reverse zoonotic transmission of SARS-CoV-2**

PRIORITY AREA III. NATURAL HISTORY OF SARS-CoV-2 INFECTION

- **Objective 1. Define the spectrum and clinical course of SARS-CoV-2 infection**
- **Objective 2. Characterize the immune response in infected persons**

PRIORITY AREA IV. PROTECTION IN HEALTHCARE AND NON-HEALTHCARE WORK SETTINGS

- **Objective 1. Improve and assess the effectiveness of personal protective equipment**
- **Objective 2. Assess strategies to reduce transmission of SARS-CoV-2 in healthcare and non-healthcare work settings**

PRIORITY AREA V. PREVENTION, MITIGATION, AND INTERVENTION STRATEGIES

- Objective 1. Evaluate individual- and community-level strategies to limit infection with SARS-CoV-2
- Objective 2. Evaluate strategies to limit infection with SARS-CoV-2 in specialized settings or select populations
- Objective 3. Develop methods to detect SARS-CoV-2 in the environment
- Objective 4. Identify the most effective methods for contact tracing, testing, and monitoring
- Objective 5. Evaluate travel-related interventions
- Objective 6. Optimize the acceptability, coverage, safety, and effectiveness of COVID-19 vaccines

PRIORITY AREA VI. SOCIAL, BEHAVIORAL, AND COMMUNICATION SCIENCE

- Objective 1. Understand where people receive information about the pandemic
- Objective 2. Optimize uptake of recommended behaviors and actions
- Objective 3. Enhance CDC communication products and information tools
- Objective 4. Assess the social, behavioral, and mental health impacts of the pandemic

Proposed list of priority questions that need to be answered by October 2020

- How can schools mitigate risks when reopening?
- How can workplaces mitigate risks when reopening?
- How to prevent and control COVID-19 in congregate and critical infrastructure settings?
- How can racial/ethnic disparities in COVID-19 impact be addressed?
- What are the best practices for contact tracing?
- What are the relative roles of aerosol vs. droplet vs. fomite transmission in COVID-19?
- Can the effectiveness of face coverings be documented and improved?
- How effective are other non-pharmaceutical interventions?
- What is the role of superspreaders and superspreading events?
- What is the extent of protection afforded by immune response to infection?

New questions to be addressed by January 2021

- How well are prevention and control strategies performing in schools, congregate settings, and critical infrastructure settings?
- Can the effectiveness of masks worn in community settings, for source control or protection, be documented and improved?
- How can adherence to mitigation recommendations (masks, social distancing, hand hygiene) be improved?
- How can racial/ethnic disparities in COVID-19 be assessed and addressed?
- What are best practices for increasing vaccine confidence in the general population, and what strategies are needed to ensure early vaccine uptake in groups that may be prioritized for vaccination, such as healthcare personnel and essential workers, and in racial and ethnic minority communities?
- How can we ensure we are actively monitoring the safety and effectiveness of vaccines in a consistent manner across different vaccines ?

New questions to be addressed by January 2021

- How do antigen assays antigen perform relative to presence of transmissible virus, including in asymptomatic individuals? How should these tests be complemented by other testing strategies?
- Is there enough evidence to support reducing the quarantine period, with or without testing? With or without a mask?
- What are the health impacts of infection with special consideration for long-term sequelae, pediatric populations, and persons with co-morbidities?
- What is the duration of protection afforded by immune response to infection and immunization and can we identify correlates of protection?
- Can the relationship of duration, distance, mask use, and environmental factors (ventilation, temperature, humidity) on risk of transmission be better defined to inform public health practice (e.g. whom to quarantine and test or how to prioritize various prevention approaches)?

Thank you for your interest

For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Subject: Embargoed: MMWR Early Release Preview for October 6, 2020
Date: Tuesday, October 6, 2020 10:01:01 AM
Attachments: image001.png
image006.png
MMWR ER COVID-19 Incidence After Mitigation Measures - October 6, 2020.pdf

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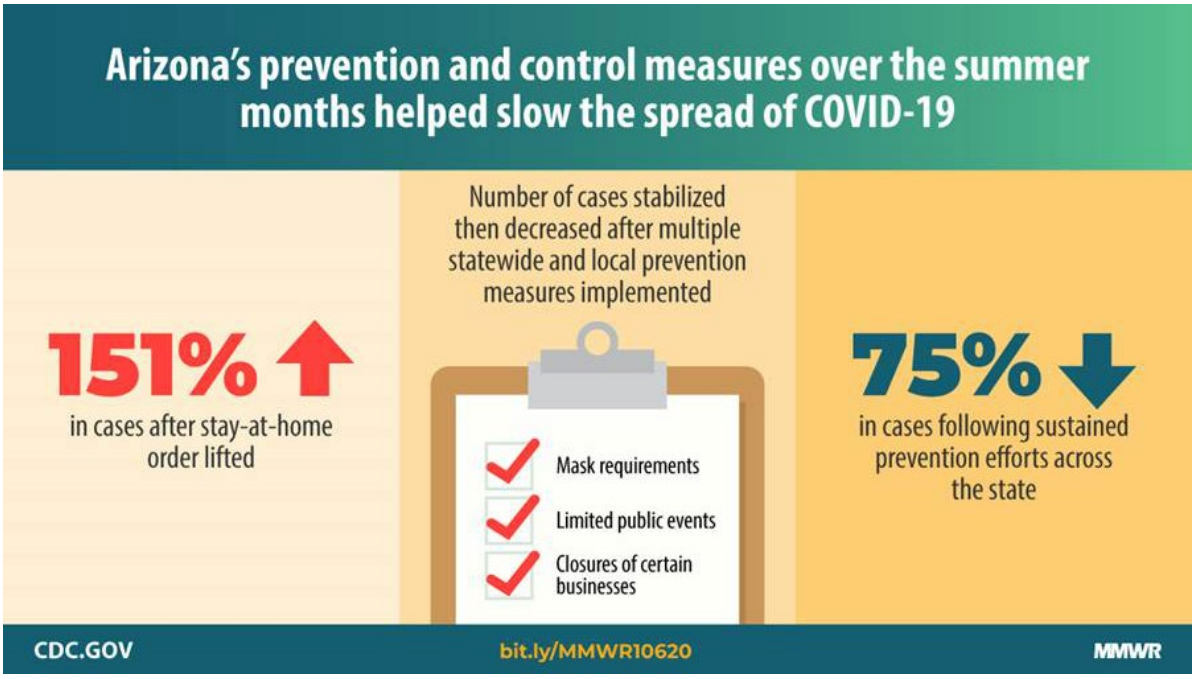

Trends in COVID-19 Incidence After Implementation of Mitigation Measures — Arizona, January 22-August 7, 2020
Link when live: https://www.cdc.gov/mmwr/volumes/69/wr/mm6940e3.htm?s_cid=mm6940e3_w

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The *MMWR* Weekly COVID-19 Briefing is a weekly podcast to update readers on the latest scientific information from CDC's COVID-19 response. In each episode, *MMWR* Editor-in-Chief Dr. Charlotte Kent provides an overview of the latest scientific information published in *MMWR*. New episodes are posted every Monday. Subscribe on Apple Podcasts, Stitcher, Spotify, and Google Play.

This week, MMWR published a series of reports describing the role that young adults have played in the spread of COVID-19. This issue also looked at COVID-19 among school-aged children and CDC deployments to work with health agencies in state, tribal, local, and territorial areas.

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Trends in COVID-19 Incidence After Implementation of Mitigation Measures — Arizona, January 22–August 7, 2020

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Mitigating the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), requires individual, community, and state public health actions to prevent person-to-person transmission. Community mitigation measures can help slow the spread of COVID-19; these measures include wearing masks, social distancing, reducing the number and size of large gatherings, pausing operation of businesses where maintaining social distancing is challenging, working from or staying at home, and implementing certain workplace and educational institution controls (*1*–*4*). The Arizona Department of Health Services' (ADHS) recommendations for mitigating exposure to SARS-CoV-2 were informed by continual monitoring of patient demographics, SARS-CoV-2 community spread, and the pandemic's impacts on hospitals. To assess the effect of mitigation strategies in Arizona, the numbers of daily COVID-19 cases and 7-day moving averages during January 22–August 7, 2020, relative to implementation of enhanced community mitigation measures, were examined. The average number of daily cases increased approximately 151%, from 808 on June 1, 2020 to 2,026 on June 15, 2020 (after stay-at-home order lifted), necessitating increased preventive measures. On June 17, local officials began implementing and enforcing mask wearing (via county and city mandates),* affecting approximately 85% of the state population. Statewide mitigation measures included limitation of public events; closures of bars, gyms, movie theaters, and water parks; reduced restaurant dine-in capacity; and voluntary resident action to stay at home and wear masks (when and where not mandated). The number of COVID-19 cases in Arizona peaked during June 29–July 2, stabilized during July 3–July 12, and further declined by approximately 75% during July 13–August 7. Widespread implementation and enforcement of sustained community mitigation measures informed by state and local officials' continual data monitoring and collaboration can help prevent transmission of SARS-CoV-2 and decrease the numbers of COVID-19 cases.

ADHS supports surveillance and investigation efforts of local public health departments, compiles surveillance and investigation information across counties, and provides infrastructure statewide to support infectious disease surveillance. Data on laboratory-confirmed and probable (*5*) COVID-19 cases (based on the Council of State and Territorial Epidemiologists case definitions)† were collected in the centralized Medical Electronic Disease Surveillance Intelligence System (MEDSIS),§ which is used by state, tribal, and county public health agencies to report human-based diseases in Arizona. Information was submitted to or entered into MEDSIS by health care providers, laboratories, local health departments, tribal entities, and ADHS. Multiple laboratory tests submitted for a single patient were combined into a single record. Specimen collection date was used for confirmed cases, and symptom onset date was used for probable cases.

Temporal trends were examined by comparing the number of daily COVID-19 cases (as of September 1)¶ and 7-day moving averages before, during, and after implementation of enhanced community mitigation measures, defined as the following: limitations on persons' time away from their place of residence

*Mandates and ordinances varied and were county- and city-specific. Enforcement types included educating persons on the dangers of COVID-19 spread, issuing fines to persons and businesses who refused to comply with mandates, and loss of licenses for businesses not enforcing rules or mandates.

†https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/positionstatement2020/Interim-20-ID-02_COVID-19.pdf.

§https://azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-services/index.php#medsis-faqs.

¶https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/covid-19/dashboards/index.php.

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except for essential activities; certain business closures and service limitations (e.g., occupancy limitations, curbside pickup, and delivery of goods); enhanced sanitation practices**; social distancing, employee mask wearing, and symptom screenings for all businesses operating a physical location; limitations on the occurrence and size of public events; and local mandates enforcing mask use. The 7-day moving average was calculated after the cumulative case count exceeded 20 cases and is presented to describe COVID-19 trends.

On March 11, 2020, Arizona declared a public health state of emergency to prepare for, prevent, respond to, and mitigate the spread of SARS-CoV-2. Additional guidance was provided to local officials, businesses, communities, and individual persons to implement social distancing and close schools statewide (March 15); postpone and limit large gatherings to fewer than 50 persons; recommend telework options; restrict access to congregate settings; require restaurants to provide dine-out options only; and close all bars, gyms, and movie theaters in counties with confirmed COVID-19 cases (March 19) (Table). Based on Arizona data and CDC guidance (*1*,*2*), ADHS also recommended limiting persons' time away from their place of residence except for essential activities (i.e., stay-at-home order, "Stay Home, Stay Healthy, Stay Connected")†† (March 31).

During April 1–May 15, the 7-day moving average of daily cases ranged from 154 to 443 (Figure). During April 29–May 11, Arizona initiated a phased approach for retail shops and stores, cosmetologists, and barbers to reopen and operate, and for restaurants to resume dine-in services; the stay-at-home order ended May 15.

Average daily cases increased 151% from June 1 (808) to June 15 (2,026), necessitating an increased focus on preventive measures by businesses, communities, and individual persons. Updated guidance from state officials provided local governments the authority to implement mask policies (June 17) and enforcement measures tailored to local public health needs (local policies were applicable to approximately 85% of the total Arizona population). Before June 17, mask wearing had not been widely mandated or enforced. Arizona limited organized public events to fewer than 50 persons (with some exceptions); closed bars, gyms, movie theaters, and water parks and recreational tubing facilities (June 29); and limited restaurants' indoor dining to <50% capacity, with at least 6 feet of separation between patrons (July 9). The 7-day moving average of daily cases peaked during

** Based on guidance from ADHS, CDC, and the Department of Labor, and Occupational Safety and Health Administration to limit and mitigate the spread of COVID-19, including promoting healthy hygiene practices; and intensifying cleaning, disinfection and ventilation practices.

†† https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-admin-orders; https://azgovernor.gov/executive-orders.

TABLE. Public policies to implement and enforce COVID-19 community mitigation measures and dates of issue/reissue* — Arizona, March 11–August 7, 2020

Mitigation measure	Date of issue/reissue
Declaration of emergency	Mar 11
School closure (on-site learning)	Mar 15
Limits on senior living facilities visitation	Mar 19
Expanded availability and coverage for telemedicine for persons, pets, and animals	Mar 25, Apr 1
Deferred requirements to renew driver license	Mar 20
Stay-at-home order	Mar 30–May 15
Business/Service closures	
Bars	Mar 19, Jun 29, Jul 23
Movie theaters	Mar 19, Jun 29, Jul 23
Indoor gyms and fitness clubs	Mar 19, Jun 29, Jul 23
Restaurants, on-site dining	Mar 19
Pools	Mar 19
Water parks and recreational tubing facilities	Jun 29, Jul 23
Business/Service limits (requirements)	
All businesses operating a physical location (enhanced sanitation,† social distancing, employee mask wearing, symptom screenings)	Jun 17
Retail (limited capacity, social distancing, enhanced sanitation)	Apr 29
Barbers and cosmetologists (employee mask wearing, spaced appointments, enhanced sanitation)	May 4
Restaurants (social distancing, limited capacity, employee mask wearing, patron mask wearing [when not eating or drinking], employee screening, enhanced sanitation)	May 4, Jul 9
Public pools (e.g., at hotels; limited capacity)	Jun 29, Jul 23
Private pools in public areas (e.g., multihousing complexes; limited capacity)	Jun 29, Jul 23
Public events (<50 persons)	Mar 15, Jun 29, Jul 23
Wearing masks (mandatory)	
Local officials able to mandate and enforce wearing masks	Jun 17
Yuma County	Jun 18
Maricopa County	Jun 19
Pima County	Jun 19
Santa Cruz County	Jun 19
Coconino County	Jun 20
>40 other cities/tribal communities	Jun 17–25§

Abbreviation: COVID-19 = coronavirus disease 2019.

* Issue dates are the dates the issuing official signed the order implementing the mandatory mitigation measure. In some instances, mitigation measures were effective either immediately or within 1 to 3 days of issue. https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-admin-orders; https://azgovernor.gov/executive-orders.

† Based on guidance from the Arizona Department of Health Services, CDC, Department of Labor, and Occupational Safety and Health Administration (OSHA) to limit and mitigate the spread of COVID-19 including promoting healthy hygiene practices; and intensifying cleaning, disinfection and ventilation practices.

§ Other tribal communities with mask mandates (issued June 18–23) included Fort McDowell Yavapai Nation, Gila River Indian Community, Navajo Nation, Salt-River Pima-Maricopa Indian Community, Tohono O'Odham Nation. Other cities with mask mandates (issued June 17–25) included Avondale, Bisbee, Buckeye, Carefree, Casa Grande, Chandler, Clarkdale, Clifton, Coolidge, Cottonwood, Douglas, Flagstaff, Fountain Hills, Gila Bend, Gilbert, Glendale, Globe, Goodyear, Guadalupe, Jerome, Kingman, Litchfield Park, Mammoth, Mesa, Miami, Nogales, Oro Valley, Paradise Valley, Payson, Peoria, Phoenix, San Luis, Sedona, Scottsdale, Somerton, Superior, Surprise, Tempe, Tolleson, Tucson, Youngtown, Yuma. Several other tribal communities and cities encouraged but did not mandate wearing masks.

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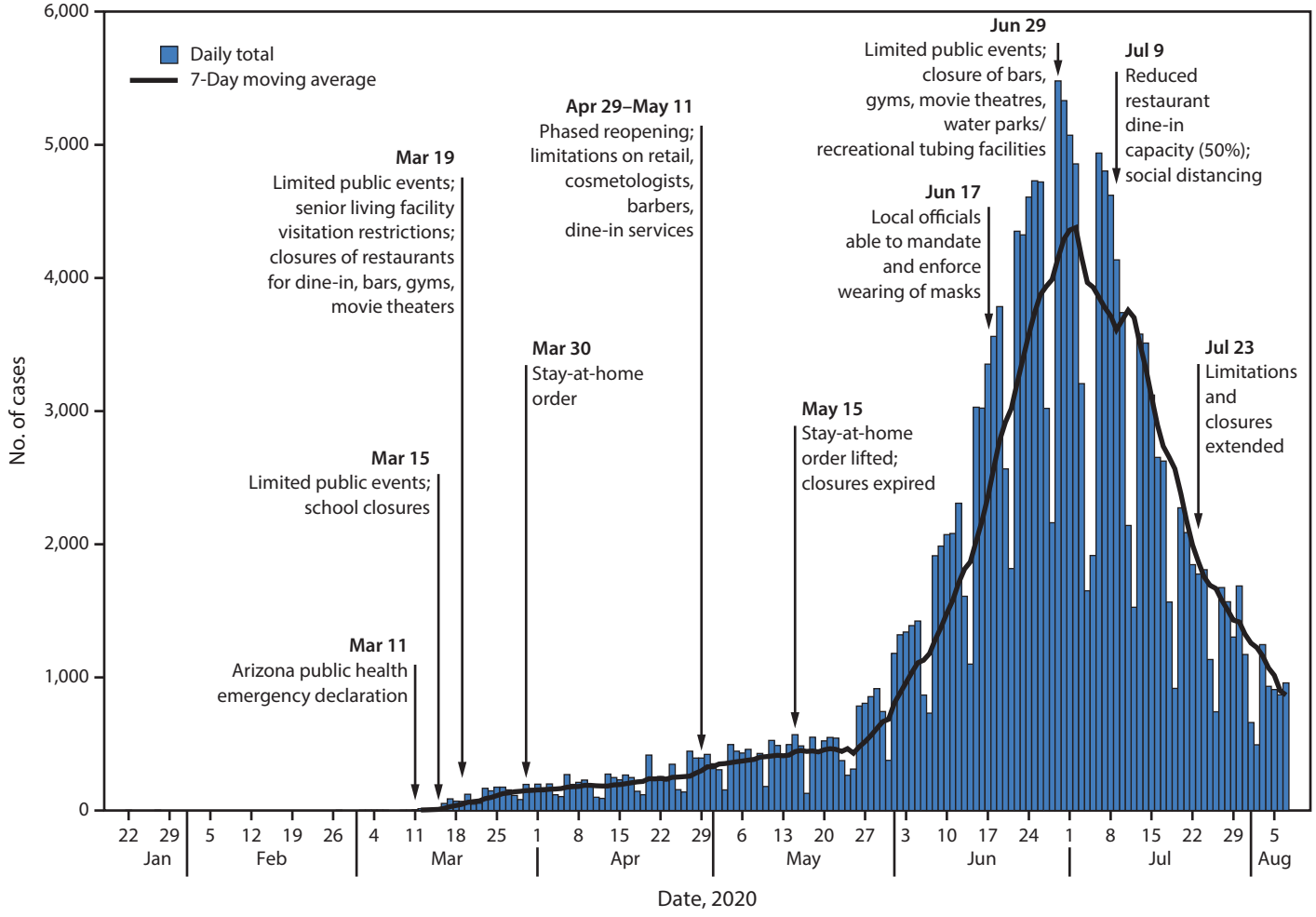
FIGURE. Selected community mitigation measures* and COVID-19 case counts† and 7-day moving averages§ — Arizona, January 22–August 7, 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

* Issue dates are the dates the issuing official signed the order implementing the mandatory mitigation measure. In some instances, mitigation measures were effective either immediately or within 1 to 3 days of issue. https://www.azdhs.gov/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/index.php#novel-coronavirus-admin-orders; https://azgovernor.gov/executive-orders.

† As of September 1, 2020. Specimen collection date was used for confirmed cases, and symptom onset date was used for probable cases.

§ Plotting of 7-day moving average began when cumulative case count exceeded 20 cases.

June 29–July 2 (range = 4,148–4,377), stabilized during July 3–12 (range = 3,609–4,160), and subsequently decreased 75% from July 13 (3,506) to August 7 (867). Mitigation measures put in place in June were extended through August to further limit transmission.

Discussion

Quantitative data on the effectiveness of community mitigation measures at suppressing the spread of COVID-19 are limited. The primary goal of implementing widespread enhanced mitigation measures in Arizona was to protect and save lives and maintain capacity in the health care system. A combination of voluntary and enforceable measures is more effective than any single measure (*6*). Mitigation measures mandated through public policy can effectively increase social distancing (*7*), and wearing masks has prevented transmission of SARS-CoV-2 (*8*). In Arizona, decreases in daily COVID-19 cases were observed after widespread sustained community mitigation measures that promoted social distancing, limited large gatherings, paused operations of businesses where mask use and social distancing were difficult to maintain, mandated and enforced mask wearing, and promoted voluntary resident actions to stay at home and wear masks (when and where not mandated). The number of COVID-19 cases stabilized and began to decrease approximately 2 weeks after local officials began mandating mask wearing (throughout several counties

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and cities) and enhanced sanitation practices. Additional declines in case counts were associated with implementation of statewide limitations and closures sustained throughout July and extended into August.

The findings in this report are subject to at least four limitations. First, the relationship between mitigation measures and changes in case counts are temporal correlations and should not be interpreted to infer causality. Other factors that might have influenced the rate of change (e.g., travel restrictions, neighboring state mitigation measures, and individual choices to reduce movement before implementation of mandates) cannot be ruled out. Second, health centers run by tribal entities and federal health facilities (i.e., Indian Health Service, Veteran's Administration, and Department of Defense) in the state are requested but not required to comply with state reporting rules. Many of these health centers and federal health facilities complied with reporting, but the completeness of reporting by these entities is unknown. Third, adherence to mitigation measures was not assessed, nor could the extent to which each individual measure affected the number of incident COVID-19 cases be established. Finally, Arizona might not be representative of other U.S. states, and community mitigation measures might have a different impact in more populous or densely populated states; thus, these findings are not necessarily generalizable to other settings.

Enhanced mitigation measures should be implemented by communities and persons to slow COVID-19 spread, particularly before a vaccine or therapeutic treatment becomes widely available. State, local, and tribal officials are best positioned to continually monitor data and collaborate to determine the level and types of enhanced mitigation required. Mitigation measures, including mask mandates, that are implemented and enforced statewide appear to have been effective in decreasing the spread of COVID-19 in Arizona.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

Summary

What is already known about this topic?

Community mitigation measures can help slow the spread of COVID-19.

What is added by this report?

The number of COVID-19 cases in Arizona stabilized and then decreased after sustained implementation and enforcement of statewide and locally enhanced mitigation measures, beginning approximately 2 weeks after implementation and enforcement of mask mandates and enhanced sanitations practices began on June 17; further decreases were observed during July 13–August 7, after statewide limitations and closures of certain services and businesses.

What are the implications for public health practice?

Widespread implementation and enforcement of sustained community mitigation measures, including mask wearing, informed by state and local officials' continual data monitoring and collaboration can help prevent transmission of SARS-CoV-2 and decrease the numbers of COVID-19 cases.

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From: Centers for Disease Control and Prevention
To: Young, Dorthy
Subject: Field Notes: King County Monitors the Ongoing Economic, Social, and Health Effects of COVID-19
Date: Tuesday, March 2, 2021 7:44:35 AM

Field Notes

King County Monitors the Ongoing Economic, Social, and Health Effects of COVID-19

Community mitigation strategies used to slow pandemics—such as physical distancing policies, mask mandates, avoiding crowds, hand washing or using hand sanitizers, business and school closures, and travel restrictions—can reduce the spread of disease but have other effects on individual health and community well-being. As the local health jurisdiction tasked with protecting the health of its residents, Public Health—Seattle & King County (PHSKC) needed to quickly develop ways to monitor and evaluate the ongoing social and economic impacts of the COVID-19 mitigation response. The first COVID-19 case diagnosed in the United States came through the international airport in King County, Washington, in January 2020, with additional community-acquired cases

diagnosed among King County residents in February 2020. As cases began to increase, state and local governments enacted strategies designed to prevent person-to-person spread of the novel coronavirus.

In population health assessments, King County often performs better than the US average but continues to face stark health disparities by race/ethnicity, location, and income. COVID-19 is no exception. With support from CDC, PHSKC incorporated aspects of CDC's approach to evaluating COVID-19 community mitigation strategies to track various social, emotional, and economic impacts on the King County community since April 2020.

For more information about this story and to read other highlights from the field, visit Field Notes on CDC's Public Health Professionals Gateway.

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From:	Kate Heyer
To:	McLaughlin, Joseph B (HSS); David Lakey, MD; Shah, Nirav; Dobbs, Thomas E; ScottHarris; jose.romero@arkansas.gov; kristen.ehresmann@state.mn.us; Randall Mayer; Jeff Stover; Terry Dwelle; manisha.juthani@ct.gov
Cc:	Griffin, Jenny; Patricia Vinson; Grace Lee; Marcus Plescia; Meredith Allen; Andy Baker-White; Ericka McGowan; Carolyn McCoy
Subject:	Follow up from 11/16 ASTHO IDPC call
Date:	Tuesday, November 23, 2021 3:24:10 PM
Attachments:	image001.png IDPC Meeting Notes_11.22.2021.docx DRAFT - Public Health Authority Policy Statement.002.docx

Good afternoon,

Thank you for participation in last week's IDPC call. Attached please see notes from the call and an updated draft of the *Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease* policy statement.

- Since we met last week, we have been fortunate to gain a new IDPC member! **Dr. Manisha Juthani (SHO-CT)** has agreed to serve on the IDPC and plans to join us on our next call. Please join me in welcoming her to our group.
- *Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease* policy statement: Andy incorporated edits from our call in the attached draft. **If you are interested in meeting with Andy as a small group to wordsmith the draft, please let me know and I'll work to propose a few dates and times for that conversation.**
- As I mentioned during the call, Alyssa Boyea from our staff will be also be sending a request for your feedback to the questionnaire to assess public opinion on rebuilding trust and confidence in public health after the Thanksgiving holiday.
- Additionally, CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) will soon be updating its Data Security and Confidentiality Guidelines. The purpose of the document is to recommend standards for all NCHHSTP programs that, when adopted, will facilitate the secure collection, storage, and use of data while maintaining confidentiality. NCHHSTP has requested that ASTHO provide concrete examples and feedback on what needs to be updated in these guidelines. Please share anything you think should be added, removed, or reframed within these guidelines with me by **December 15.**

Lastly, the next IDPC call is scheduled for **February 15, 2022 at 12PM ET**. An agenda and call-in information will be sent closer to the call. Please send any suggested agenda topics to me.

Thank you all for your continued support of the IDPC and have a wonderful Thanksgiving.

Kate

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PUBLIC HEALTH AUTHORITY TO PREVENT AND CONTROL THE SPREAD OF COMMUNICABLE AND INFECTIOUS DISEASE

POSITION

The Association of State and Territorial Health Officials (ASTHO) supports the establishment of robust public health legal authorities to facilitate the timely and adequate response to communicable and infectious disease outbreaks. These legal authorities are often exercised without the need of an emergency declaration and may allow, among other things, the abatement of nuisances, investigation of the causes of disease, institution of quarantine measures, ordering individuals or groups to isolate, conducting contact tracing and case investigations, collecting data, temporarily limiting or canceling public events, temporarily restricting or closing venues, and requiring vaccination verification for certain conduct and activities (e.g., school attendance). Beyond their use in the response to the historic pandemic caused by the novel coronavirus, in the past, these powers have been routinely exercised for more commonly experienced disease outbreaks, such as mumps and measles. Additionally, other societal sectors, such as business, education, cultural, and religion often depend on public health to stop the spread of infectious disease, prevent widespread disruptions, and quell public anxiety and fear. Maintaining these state and territorial legal authorities are key to being prepared for communicable and infectious disease outbreaks both now and in the future.

Summary of Recommendations:

- Ensure public health authority that can respond to future disease outbreaks without undue delay.
- Support public health authority that is guided by data and science.
- Ensure public health authority that protects the public's interest and well-being.

BACKGROUND

Establishing and using legal authority to control the spread of infectious disease dates to before the founding of the country. For example, colonial governments implemented isolation and quarantine precautions for incoming ships to prevent the introduction and spread of smallpox and other contagions.[1] These powers and activities were seen not only as a way of protecting the health of the local communities but also protective of trade and commerce.[2] As the scientific understanding of communicable and infectious disease grew, new tools such as contact tracing, disease investigation, data collection, and vaccines were added to public health's legal authority and practice. During the current pandemic public health authority has been used, with evidenced benefit, to slow the spread of the coronavirus by limiting the size of gatherings, encouraging social distancing, temporarily closing high-risk venues, and requiring the use of face coverings in certain places.[3,4,5,6,7,8,9]

Despite the successes in exercising public health authority, grave questions and negative perceptions about the role and use of public health powers in response to the pandemic and, by implication, future infectious disease outbreaks have arisen. Over the last year, the critical attitude toward the pandemic response has led to the rolling back of public health authority in several jurisdictions.[10] The reductions in public health legal authority will conceivably make it more difficult to respond to future disease outbreaks. As state and territorial policy makers continue to address the many issues related to the current pandemic, they are encouraged to consider these potential impacts and costs.

RECOMMENDATIONS

With regards to state and territorial public health authority to prevent and control the spread of communicable and infectious disease, ASTHO recommends:

- Ensuring public health legal authority that is appropriate and necessary for the prevention and control of future communicable and infectious disease outbreaks. Highly contagious illnesses, like measles, can be effectively contained through the public health measures and activities that are being questioned and criticized during the COVID-19 pandemic. We are unsure how the next major disease outbreak will spread and public health authority must be ready and able to respond to future diseases. Public health authority to implement non-medical and medical interventions swiftly and adeptly must be maintained and the creation of administrative burdens that delay public health action, endangers the public well-being, and leaves communities vulnerable to infectious disease outbreaks, should be avoided.
- Supporting evidence-based laws and policies for the identification, prevention, and control of communicable and infectious diseases. Public health authority should align with present and future diseases that public health agencies are obligated and required to confront and the authority should also be exercised in a manner that addresses the identifiable, known characteristics of the disease outbreak.
- Ensuring that public health legal authority properly and adequately balances a public health agency's obligations and requirements to protect the public's health and well-being with the rights of individuals. Laws and policies that undermine and encumber a public health agency's obligations or arbitrarily limit the agency's authority, impede disease prevention and control. Public health authority that is reasonable and aligned with the preventing and controlling the spread of infectious disease should be established and maintained.

APPROVAL DATES

Prevention Policy Committee Approval:
Board of Directors Approval:
Policy Expires:

ASTHO membership supported the development of this policy, which was subsequently approved by the ASTHO Board of Directors. Be advised that the statements are approved as a general framework on the issue at a point in time. Any given state or territorial health official must interpret the issue within the current context of his/her jurisdiction and therefore may not adhere to all aspects of this Policy Statement.

---

[1] Parmet WE. "Health Care and the Constitution: Public Health and the Role of the State in the Framing Era." *Hastings Const. L.Q.* 1993. 20(2):267-335. Available at https://repository.uchastings.edu/hastings_constitutional_law_quaterly/vol20/iss2/1. Accessed 10-12-2021.

[2] Id.

[3] Castillo R, Staguhn E, Weston-Farber E. "The effect of state-level stay-at-home orders on COVID-19 infection rates." *Am. Journal of Infection Control*. 2020. 48(8):958-960. Available at https://doi.org/10.1016/j.ajic.2020.05.017. Accessed 9-28-2021.

[4] Moreland A, Herlihy C, Tynan MA, et al. "Timing of State and Territorial COVID-19 Stay-at-Home Orders and Changes in Population Movement — United States, March 1–May 31, 2020." *Morb Mortal Wkly Rep.* 2020. 69:1198–1203. Available at http://dx.doi.org/10.15585/mmwr.mm6935a2. Accessed 9-28-2021.

[5] Lyu W, Wehby G. “Comparison of Estimated Rates of Coronavirus Disease 2019 (COVID-19) in Border Counties in Iowa Without Stay-at-Home Order and Border Counties in Illinois with a Stay-at-Home Order.” *JAMA Netw. Open.* 2020. 3(5):1-7. Available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766229?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=051820. Accessed 9-28-2021.

[6] Cheng V, Wong S, Chaung, V, et al. “The role of community-wide wearing of face masks for control of coronavirus disease 2019 (COVID-19) epidemic due to SARS-CoV-2.” *J. of Infection*. 2020. 81(1):107-114. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7177146/. Accessed 10-25-2021.

[7] Guy GP Jr., Lee FC, Sunshine G, et al. “Association of State-Issued Mask Mandates and Allowing On-Premises Restaurant Dining with County-Level COVID-19 Case and Death Growth Rates — United States, March 1–December 31, 2020.” *Morb Mortal Wkly Rep*. 2021. 70:350–354. Available at http://dx.doi.org/10.15585/mmwr.mm7010e3. Accessed 9-28-2021.

[8] Howard J, Huang A, Li Z, et al. “An evidence review of face masks against COVID-19." *Proc. Natl. Acad. Sci.* 2021. 118 (4):1-12. Available at: https://doi.org/10.1073/pnas.2014564118. Accessed 9-28-2021.

[9] Dasgupta S, Kassem AM, Sunshine G, et al. “Differences in rapid increases in county-level COVID-19 incidence by implementation of statewide closures and mask mandates — United States, June 1–September 30, 2020.” *Ann Epidemiol*. 2021. 57:46-53. Available at https://doi.org/10.1016/j.annepidem.2021.02.006. Accessed 9-28-2021.

[10] Weber L, Barry-Jester AM. “Over Half of States Have Rolled Back Public Health Powers in Pandemic.” *Kaiser Health News*. Sept. 15, 2021. Available at https://khn.org/news/article/over-half-of-states-have-rolled-back-public-health-powers-in-pandemic/. Accessed 11-1-2021.

November 16, 2021 | 12 – 1 p.m. ET

IDPC Meeting

Attending

- Jose Romero
- Scott Harris
- Thomas Dobbs
- Randy Mayer
- Joe McLaughlin
- Kris Ehresmann
- Jeff Stover
- Carolyn McCoy
- Kate Heyer
- Grace Lee
- Andy Baker-White
- Meredith Allen
- Ericka McGown
- Marcus Plescia

Meeting Notes

- Carolyn McCoy (ASTHO) provided an update on her discussion between staff in Rep. Rosa De Lauro's office from the Appropriations Committee with Dr. Dobbs on flexible funding.
    - ASTHO has been tracking three key issues:
        - Bipartisan Infrastructure Bill was signed into law.
        - Build Back Better Act, which is awaiting a score from the Congressional Budget Office (CBO) before being sent to members of Congress who will move on a vote.
            - The House may take it to the floor this week, despite parts of the CBO scoring estimates not coming out until the end of this week.
            - ASTHO is keeping track of this proposal because 7.5 billion is allocated for PH preparedness in the proposal.
        - The Fiscal Year 2022 Fiscal Appropriations process is underway.
            - Dr. Dobbs spoke to Senate Appropriations y staff. There is $1 billion proposed in the House, $600 million proposed in the Senate for flexible funding for PH infrastructure.
    - Federal funding runs out on Dec 3rd, and it is largely acknowledged that there is a need for a short-term continuing resolution. There is a question on how long this funding will last and if it will go into the 2022 election year. Likely fiscal fallout from not raising the debt ceiling would be catastrophic.

Andy Baker-White (ASTHO) shared the draft of the ***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease*** policy statement

- IDPC members discussed some edits that could be made on the list of recommendations.
    - State health officials shared that they have gotten far less resistance on isolation/quarantine mandates directed towards individuals compared to broader

PH-based population-based interventions (mask and vaccine mandates, school closures, etc.)

- Members emphasized the need to make sure that the recommendations section needs to be concise as some may not read the rest of the statement.
- Members expressed appreciation for the statement striking a balance between protecting individual rights and ensuring the public wellbeing. Many people do not recognize their obligation to protecting community health, so making this statement stronger would be a suggestion.
    - Joe McLaughlin said that CSTE has a public health law subcommittee, and it be helpful to reach out to them for some collaboration.
        - ASTHO has a steering committee of attorneys to who can also provide feedback.
    - Dr. Dobbs said many people don't respect the individual liberties of people who want to be safe during the pandemic. The pandemic has allowed those who are reckless to rob freedoms from people who want to live safely.

- The ***Preparing for the Next Pandemic/Public Health Crisis*** white paper was presented to the IDPC to gather feedback and edits.
    - The pandemic has highlighted how the PH sector has received a lot of funding, but that it is not always at the right time or for the right activities. Action-based flexible funding is necessary.
    - Members expressed a need for an all-hazards preparedness and response plan that is more nimble, more useful, less cumbersome, and easy for all those in the workforce to access and execute a pandemic response plan.
        - The white paper should acknowledge the role of misinformation during a pandemic response. Communications have been a challenge, especially for those whose first language was English. It's important to think about non-English speaking populations when planning for and throughout a response.
        - Ensuring judicious use of FEMA funds, proposing requiring a 100% federal match, and increasing surveillance capacity were all discussed as additional recommendations to the white paper.
    - Depoliticization of public health is vital in future pandemic responses. State leaders should be trained to be prepared to navigate political environments early and frequently in their work at a health agency. Legislators must support state health departments and the science.
    - There is a critical need to instill and boost trust in public health.
        - Mandates are challenging to explain when you're trying to increase trust in public health because they further emphasize and exacerbate public health fears of government overreach.
        - Emphasizing that PH is prevalent in everyday life, not just during a pandemic, is crucial for boosting the public's education on the role of PH.
            - State health agencies should emphasize that we train for PH responses through everyday PH initiatives.

- Another white paper is currently being drafted by MIT. It may be useful to reference this document, specifically on using technology for surveillance. Having an IT infrastructure is part of the PH infrastructure.
- Members emphasized that now, during the COVID-19 pandemic, is the most important time to get ahead of PH fear and mistrust.
- Members discussed ways to build back trust in public health. Members discussed whether the IDPC believes that a year from now there is going to be this level of mistrust. He wanted more perspective on trust as an issue going into the future, or if mistrust is just an issue now.
    - Dr. Dobbs said that they are using their roles as leaders to promote other important PH topics, because PH is broader than a pandemic.
    - Jeff Stover said VA is doing some marketing on a "PH Reality Campaign". Using the environment of the COVID-19 pandemic right now serves as platform to educate people on what PH really is.

- Next topics for future IDPC calls:
    - Trust in public health institutions.
    - Negative test reporting, contact tracing (for conditions outside of COVID such as STDs and TB), frequency of case reporting, and what the markers are for COVID becoming endemic.

Action Items

- Andy Baker-White will incorporate the IDPC's suggested edits in the draft of the policy statement. Any members who wish to send proposed edits via e-mail can e-mail kheyer@astho.org or reach out to set up a time for a call with Andy
- ASTHO will incorporate the IDPC's suggestions into the white paper and consider whether to engage public health attorneys to review. The ASTHO team will also solicit feedback from the ASTHO Preparedness Policy Committee and provide a draft back for IDPC review.

astho™

From:	Kate Heyer
To:	Dobbs, Thomas E; David Lakey, MD; ScottHarris; Joe Mclaughlin; jose.romero@arkansas.gov; kristen.ehresmann@state.mn.us; Randall Mayer; Jeff Stover; Terry Dwelle; Shah, Nirav
Cc:	Griffin, Jenny; Peggie Lawrence; Patricia Vinson
Subject:	Follow Up from August ASTHO IDPC call
Date:	Friday, September 10, 2021 8:27:12 AM
Attachments:	image001.png IDPC meeting notes August 2021.docx

Hello, IDPC members,

Attached are the notes and suggested action items from the August IDPC call. I ask that you please not distribute the notes outside of this group.

I will send a draft of the *Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease* policy statement when it is ready.

Given the preference for a quarterly meeting, we will plan to hold the next call on **November 16 at 12PM ET**. An Outlook invitation is forthcoming.

Thank you again and please do not hesitate to reach out with any questions or discussion items for the next call.

Kate

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IDPC Meeting – August 17, 2021

Attendees: Thomas Dobbs (MS, IDPC Chair), Scott Harris (AL), Jose Romero (AR), Terry Dwelle (Alumni-ND), David Lakey (Alumni-TX), Randy Mayer (NASTAD Rep – IA), Joe McLaughlin (CSTE Rep - AK)

Key Takeaways:

- State legislatures are receiving a lot of pushback on issuing policies relating to vaccine mandates, mask mandates, school reopening, and other public health measures. There has been conflict and confusion between the roles of state legislative bodies and state health officials on authority to implement public health measures in many states.
- Communication remains a barrier between national, state, and local levels, which further elevates confusion amidst the pandemic.
- There is a dire need to critically think about and reevaluate the future of pandemic response. The COVID-19 pandemic has been a heavily politicized topic in public health. Public health must move towards working with politicians, and state legislatures must publicly show support for state health officials, striving to reach a compromise between both parties.
- Misbeliefs on the COVID-19 pandemic are far entrenched in many communities across the country. It is important to utilize both horizontal and vertical communicators to transform communities. Joining forces with healthcare providers (especially private physicians), increasing transparency within the CDC, ensuring continued healthcare access, engaging academic medical centers, and utilizing community healthcare workers are all ways to bridge gaps. It is vital to engage all stakeholders to ensure no one is working within a silo.
- ***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease policy statement*** discussion**:** ASTHO supports state and territorial frameworks that establish a robust authority on the response to disease outbreak.
    - Recommendations:
        - Public health powers should be such that they facilitate timely, flexible responses to disease outbreak.
            - Legislative oversight must allow for timely and flexible responses
        - Legal frameworks must be reliable and reasonable so that they can be aligned with the disease(s) that need to be prevented or managed.
        - Any sort of public health authority to direct the mitigation of the disease is to be guided by data and science.
        - This legal framework is to prepare and respond to future unknown outbreaks.
    - SHOs had some thoughts on the policy statement and recommendations. The state legislature should be involved in these conversations. This policy statement should separate the daily activities that stop daily outbreaks from historic events that have tremendous economic impacts on the state. SHOs would also like to hear something about the balance of individual rights and the importance on why states have an interest in preventing disease.

Action Items:

- ASTHO will develop the first draft of the policy statement to disseminate for review and comment.
- ASTHO staff will reach out to invite Dr. Jay Butler (CDC) and/or Dr. John Auerbach (CDC) for a discussion with the IDPC on a future call about bridging science and politics in public health to generate consistent messages across the political spectrum.
- ASTHO's ID Guiding Principles need to be updated, approved, and in a policy statement format by September 2022. ASTHO staff will add detail about delineating federal vs. state responsibilities for pandemic response for committee review.

Proposed Activities for Future IDPC Engagement:

- Continue discussing options for SHOs to take more proactive action with governors when they propose or implement actions that do not support public health goals. Strategies should include advance relationship-building before a pandemic emerges. Additional efforts should also be focused on engaging private physicians—to assist with depoliticizing future responses. Included in this is reiterating the role of the SHO: SHOs *should* be a bridge between politics and science.
- Consider sharing state public health leaders' experiences working to increase the credibility of public health during the COVID response via ASTHO's *Public Health Review Morning Edition* podcast. Note: this is an outlet we can use to share innovative ideas or to discuss public health priorities across any public health topic area.

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From: Kate Heyer
To: Dobbs, Thomas E
Cc: Griffin, Jenny
Subject: Follow up from the August ASTHO IDPC meeting
Date: Wednesday, September 8, 2021 3:17:05 PM
Attachments: image001.png
IDPC_meeting_notes_August_2021.docx

Hi Dr. Dobbs,

Attached please see the high-level notes and proposed action items from the August IDPC call. I have 2 comments in the document that I would appreciate your thoughts on before I distribute to the committee. Please let me know if you approve of the notes and any thoughts about the proposed action items.

Also, would you like to plan for the next IDPC call to be held on November 16 at 11AM CT/12PM ET? That would fit the quarterly cadence the members requested and is in the same time block as our August call. If that does not work, I will send a Doodle poll for scheduling.

Best, Kate

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Attendees: Thomas Dobbs (MS, IDPC Chair), Scott Harris (AL), Jose Romero (AR), Terry Dwelle (Alumni-ND), David Lakey (Alumni-TX), Randy Mayer (NASTAD Rep – IA), Joe McLaughlin (CSTE Rep - AK)

Key Takeaways:

- State legislatures are receiving a lot of pushback on issuing policies relating to vaccine mandates, mask mandates, school reopening, and other public health measures. There has been conflict and confusion between the roles of state legislative bodies and state health officials on authority to implement public health measures in many states.
- Communication remains a barrier between national, state, and local levels, which further elevates confusion amidst the pandemic.
- There is a dire need to critically think about and reevaluate the future of pandemic response. The COVID-19 pandemic has been a heavily politicized topic in public health. Public health must move towards working with politicians, and state legislatures must publicly show support for state health officials, striving to reach a compromise between both parties.
- Misbeliefs on the COVID-19 pandemic are far entrenched in many communities across the country. It is important to utilize both horizontal and vertical communicators to transform communities. Joining forces with healthcare providers (especially private physicians), increasing transparency within the CDC, ensuring continued healthcare access, engaging academic medical centers, and utilizing community healthcare workers are all ways to bridge gaps. It is vital to engage all stakeholders to ensure no one is working within a silo.
- ***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease policy statement*** discussion**:** ASTHO supports state and territorial frameworks that establish a robust authority on the response to disease outbreak.
    - Recommendations:
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            - Legislative oversight must allow for timely and flexible responses
        - Legal frameworks must be reliable and reasonable so that they can be aligned with the disease(s) that need to be prevented or managed.
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        - This legal framework is to prepare and respond to future unknown outbreaks.
    - SHOs had some thoughts on the policy statement and recommendations. The state legislature should be involved in these conversations. This policy statement should separate the daily activities that stop daily outbreaks from historic events that have tremendous economic impacts on the state. SHOs would also like to

hear something about the balance of individual rights and the importance on why states have an interest in preventing disease.

Action Items:

- ASTHO will develop the first draft of the policy statement to disseminate for review and comment.
- ASTHO staff will reach out to invite Dr. Jay Butler (CDC) and/or Dr. John Auerbach (CDC) for a discussion with the IDPC on a future call about bridging science and politics in public health.

Commented [KH1]: Dr. Dobbs, can you provide any additional detail about this request to help me frame my outreach?

Proposed Activities for Future IDPC Engagement:

- Consider options for SHOs to take more proactive action with governors when they propose or implement actions that do not support public health goals. Would include advance relationship-building before a pandemic emerges. Additional efforts should also be focused on engaging private physicians—to assist with depoliticizing future responses. Included in this is reiterating the role of the SHO: SHOs *should* be a bridge between politics and science.
- Develop a framework for future pandemic response, delineating federal vs. state responsibilities.
- Consider sharing described by Joe McLaughlin to increase the credibility of public health by reaching out via routine ECHOs with healthcare providers, scientists, and the media during the COVID response via Public Health Review Morning Edition podcast. Note: this is an outlet we can use to share innovative ideas or to discuss public health priorities across any public health topic area.

Commented [KH2]: Since the ID Guiding Principles need to be updated, approved, and in the policy statement format by September 2022, this could be the best place to address this.

Also, see here: https://jnslp.com/wp-content/uploads/2020/12/The-Roles-of-the-State-and-Federal-Governments-in-a-Pandemic_2.pdf

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From:	Craig, Jim
To:	Adcox-Green, Ashley; Boxx, Robert; Byers, Paul; Craft, Christy; Darnell, Tim; Hall, David; Horn, Marshall; Jennings, Twyla; Parker, Melissa; Sharlot, Liz; Taylor, Kathryn; William McLeod; Vaughn1, Wayne; Ware, Daphne; Williams, Alisa; Young, Dorthy
Subject:	FW: CDC COVID-19 Weekly Digest of Resources: 1/30 - 2/5
Date:	Monday, February 8, 2021 6:26:06 PM
Attachments:	2021-02-05-Science-Update_Final_Public.pdf ELC_EnhancingDetectionExpansion_FAQs_2Feb2021.pdf Fact Sheet_12-things-jurisdictions-need-to-know-about-vaers_Feb2021.pdf

FYSA

From: Green, Jamilla (CDC/DDID/NCEZID/DPEI) <qwq7@cdc.gov>
Sent: Monday, February 8, 2021 5:02 PM
To: Byers, Paul <Paul.Byers@msdh.ms.gov>; Craig, Jim <Jim.Craig@msdh.ms.gov>; Jefferson, Randy (CDC/DDID/NCHHSTP/DSTDP) <ryj8@cdc.gov>; Ware, Daphne <Daphne.Ware@msdh.ms.gov>; Vaughn, Wayne <Wayne.Vaughn@msdh.ms.gov>
Cc: CDC IMS 2019 NCOV Response HDTF 4/6 Regional Support TM <eocevent438@cdc.gov>
Subject: CDC COVID-19 Weekly Digest of Resources: 1/30 - 2/5

Good afternoon Mississippi Colleagues,

Here is your weekly digest of CDC resources.

CDC COVID-19 Science Update: See the latest science update, released on 2/5/2021, attached to this email. Previous science updates can be viewed at ***https://www.cdc.gov/library/covid19*.**

MMWR Articles: Below are links to recent COVID MMWR articles

- **February 5, 2021 (Early Release)** Observed Face Mask Use at Six Universities — United States, September–November 2020
- **February 5, 2021 (Early Release)** Decline in COVID-19 Hospitalization Growth Rates Associated with Statewide Mask Mandates — 10 States, March–October 2020
- **February 5, 2021** Sexual Orientation Disparities in Risk Factors for Adverse COVID-19–Related Outcomes, by Race/Ethnicity — Behavioral Risk Factor Surveillance System, United States, 2017–2019
- **February 5, 2021** Decreases in Young Children Who Received Blood Lead Level Testing During COVID-19—34 Jurisdictions, January–May 2020
- **February 5, 2021** Racial and Ethnic Disparities in the Prevalence of Stress and Worry, Mental Health Conditions, and Increased Substance Use Among Adults During the COVID-19 Pandemic — United States, April and May 2020
- **February 5, 2021** Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program — United States, December 14, 2020–January 14, 2021
- **February 5, 2021** Early COVID-19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program — United States, December 2020–January 2021

*Older MMWR COVID-19 Reports can be viewed at https://www.cdc.gov/mmwr/Novel_Coronavirus_Reports.html

CDC Website Updates: Please find updated CDC website pages for 1/30-2/5

Response Website Updates (1/30/21-2/5/21)

- Cases in the U.S. Friday, February 05, 2021
- Overall US COVID-19 Vaccine Distribution and Administration Update as of Fri, 05 Feb 2021 06:00:00 EST Friday, February 05, 2021
- COVID-19 Science Update released: February 5, 2021 Edition 75 Friday, February 05, 2021
- Vaccination Considerations for Persons with Disabilities Friday, February 05, 2021
- COVID-19 Vaccination for Communities Friday, February 05, 2021
- Requirement for Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States Friday, February 05, 2021
- Information for School Nurses and Other Healthcare Personnel (HCP) Working in Schools and Child Care Settings Friday, February 05, 2021
- Guidance for SARS-CoV-2 Point-of-Care Testing Friday, February 05, 2021
- Toolkit for Correctional and Detention Facilities Friday, February 05, 2021
- eCR Now: COVID-19 Electronic Case Reporting Friday, February 05, 2021
- COVID-19 Questions and Answers: For People Who Use Drugs or Have Substance Use Disorder Friday, February 05, 2021
- More Resources about COVID-19 Friday, February 05, 2021
- Protecting Seafood Processing Workers from COVID-19 Friday, February 05, 2021
- Communication Toolkit Friday, February 05, 2021
- Manufacturing Workers and Employers Friday, February 05, 2021
- Meat and Poultry Processing Workers and Employers Friday, February 05, 2021
- COVIDView Weekly Summary Friday, February 05, 2021
- COVID-19 Travel Recommendations by Country Friday, February 05, 2021
- Cases, Data, and Surveillance Friday, February 05, 2021
- Community, Work, and School Friday, February 05, 2021
- CDC Readiness and Planning Tool: To Prevent the Spread of COVID-19 in Primary and Secondary Schools in Low Resource Non-U.S. Settings Thursday, February 04, 2021
- COVID-19 Vaccine Information for Specific Groups Thursday, February 04, 2021
- US COVID-19 Cases Caused by Variants Thursday, February 04, 2021
- Workplaces and Businesses Thursday, February 04, 2021
- Wear Face Masks on Public Transportation Conveyances and at Transportation Hubs Thursday, February 04, 2021
- Federal Register Notice: Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19 Thursday, February 04, 2021
- Investigating the Impact of COVID-19 during Pregnancy Thursday, February 04, 2021
- Toolkit for People with Disabilities Thursday, February 04, 2021
- Print Resources Thursday, February 04, 2021
- How to Protect Yourself & Others Thursday, February 04, 2021
- ACIP Live Meeting Archive - January 27, 2021 Wednesday, February 03, 2021
- Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination Wednesday, February 03, 2021
- Federal Retail Pharmacy Partnership Program for COVID-19 Vaccination FAQs Wednesday, February 03, 2021
- Pharmacies Participating in the Federal Retail Pharmacy Program Wednesday, February 03, 2021
- Global Clinical Mitigation Wednesday, February 03, 2021
- Science Briefs Wednesday, February 03, 2021
- When Vaccine is Limited, Who Gets Vaccinated First? Wednesday, February 03, 2021

- Vaccines Wednesday, February 03, 2021
- Previous COVID-19 Forecasts: Cases Wednesday, February 03, 2021
- COVID-19 Forecasts: Cases Wednesday, February 03, 2021
- COVID-19 One-Stop Shop Toolkits Wednesday, February 03, 2021
- People with Certain Medical Conditions Wednesday, February 03, 2021
- Considerations for Public Beaches Wednesday, February 03, 2021
- Crew Disembarkations through Commercial Travel Wednesday, February 03, 2021
- Previous COVID-19 Forecasts: Hospitalizations Wednesday, February 03, 2021
- COVID-19 Forecasts: Hospitalizations Wednesday, February 03, 2021
- Daily Activities and Going Out Wednesday, February 03, 2021
- Operating schools during COVID-19: CDC's Considerations Wednesday, February 03, 2021
- Previous Forecasts of Total Deaths Wednesday, February 03, 2021
- COVID-19 Forecasts: Deaths Wednesday, February 03, 2021
- Community Mitigation Wednesday, February 03, 2021
- Staffing Resources Wednesday, February 03, 2021
- Coronavirus Disease 2019 (COVID-19) Wednesday, February 03, 2021
- What Aircraft Maintenance Workers Need to Know about COVID-19 Wednesday, February 03, 2021
- Information for Health Departments on Reporting Cases of COVID-19 Wednesday, February 03, 2021
- Interim Guidance for Health Departments: COVID-19 Vaccination Implementation for People Experiencing Homelessness Tuesday, February 02, 2021
- Global Community Mitigation Tuesday, February 02, 2021
- New Variant of Virus that Causes COVID-19 Detected Tuesday, February 02, 2021
- Testing and International Air Travel Tuesday, February 02, 2021
- Know Your Travel Risk Tuesday, February 02, 2021
- Know When to Delay your Travel to Avoid Spreading COVID-19 Tuesday, February 02, 2021
- Travel during the COVID-19 Pandemic Tuesday, February 02, 2021
- Returning to Work Tuesday, February 02, 2021
- Research Use Only CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay Real-Time RT-PCR Primers and Probes Tuesday, February 02, 2021
- CDC's Diagnostic Multiplex Assay for Flu ***and*** COVID-19 and Supplies Tuesday, February 02, 2021
- COVID-19 in Newly Resettled Refugee Populations Tuesday, February 02, 2021
- Agriculture Workers and Employers Tuesday, February 02, 2021
- Test for Past Infection Tuesday, February 02, 2021
- What Airline Catering Kitchen Workers Need to Know about COVID-19 Tuesday, February 02, 2021
- COVID-19 Employer Information for Transit Maintenance Workers Tuesday, February 02, 2021
- What Airline Customer Service Representatives and Gate Agents Need to Know about COVID-19 Tuesday, February 02, 2021
- Use of Masks to Help Slow the Spread of COVID-19 Tuesday, February 02, 2021
- K-12 Schools and Childcare Programs Tuesday, February 02, 2021
- Travelers Returning from Cruise Ship and River Cruise Voyages Tuesday, February 02, 2021
- After You Travel Tuesday, February 02, 2021
- Travel: Frequently Asked Questions and Answers Tuesday, February 02, 2021
- Frequently Asked Questions Tuesday, February 02, 2021
- Travel Tuesday, February 02, 2021
- COVID-19 Graphics and Buttons Monday, February 01, 2021

Considerations for Public Pools, Hot Tubs, and Water Playgrounds During COVID-19 Monday, February 01, 2021

- Air Travel Toolkit for Airline Partners Monday, February 01, 2021
- Road Travel Toolkit for Transportation Partners Monday, February 01, 2021
- General Business Frequently Asked Questions Monday, February 01, 2021
- What to Know About HIV and COVID-19 Monday, February 01, 2021
- Information for Laboratories about Coronavirus (COVID-19) Monday, February 01, 2021
- Information for Healthcare Professionals about Coronavirus (COVID-19) Monday, February 01, 2021
- What Paratransit Operators Need to Know about COVID-19 Saturday, January 30, 2021
- What Transit Station Workers Need to Know about COVID-19 Saturday, January 30, 2021
- What Bus Transit Operators Need to Know about COVID-19 Saturday, January 30, 2021
- What Rail Transit Operators Need to Know about COVID-19 Saturday, January 30, 2021
- Personal and Social Activities Saturday, January 30, 2021
- Protect Yourself When Using Transportation Saturday, January 30, 2021
- How to Select, Wear, and Clean Your Mask Saturday, January 30, 2021
- How to Wear Masks Saturday, January 30, 2021
- What Rideshare, Taxi, Limo, and other Passenger Drivers-for-Hire Need to Know about COVID-19 Saturday, January 30, 2021

*Daily website updates are now viewable at https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html

Updates on the Federal Retail Pharmacy Program for COVID-19 Vaccination

The initial phased implementation of the program will begin with select retail pharmacies administering COVID-19 vaccine across the country as early as Thursday, February 11. The program will be implemented incrementally, based on the available supply of COVID-19 vaccines. As the vaccine supply increases, the program aims to expand the number of participating pharmacy locations ultimately providing COVID-19 vaccines in all 40,000 retail pharmacy locations nationwide. Allocations to support the Federal Retail Pharmacy Program are separate from weekly allocations provided to jurisdictions. What jurisdictions see in their weekly allocation will remain stable.

Eligibility Criteria for Vaccination

The Federal pharmacy partners will administer vaccine to individuals according to state-selected eligibility criteria. Pharmacy partners have developed screening questionnaires specific to each jurisdiction's criteria and will finalize them based on the survey results to help ensure eligibility prior to vaccination. After launch, immunization program managers will be able to update eligibility criteria weekly using an application in Tiberius, the centralized system used by the federal government to support vaccine distribution efforts. Information about how to use this new Tiberius application will be sent to immunization programs this week.

Program Data and Monitoring

By Friday, CDC will provide a list of the retail locations that will be providing COVID-19 vaccine in each jurisdiction as part of the initial phased implementation of the program.

All pharmacy partners enrolled in the Federal Retail Pharmacy Program are required to report inventory daily to VaccineFinder and patient administration information to the jurisdiction's IIS as

well as directly to CDC's Data Clearing House. Jurisdictions will have access to patient administration data submitted by all pharmacies in their jurisdiction. Jurisdictions will also have access to information in Tiberius-specific to pharmacy programs.

Information will include details on stores that will be receiving vaccine, store-level supply information, and administration/uptake information as it becomes available. Jurisdictions will also be provided points of contacts for pharmacy partners to facilitate coordination with partners.

Communications Support
CDC has developed a **toolkit of materials** to help jurisdictions and partners describe and communicate about the implementation of the Federal Retail Pharmacy Program. We hope these materials will assist in providing clear and consistent information about the program goals and parameters.

The toolkit includes the attached materials for your use and reference:

- Frequently Asked Questions about the Program for Jurisdictions and Pharmacy Partners
- Key communication messages for jurisdictions and pharmacy partners
- A One-Page Fact Sheet on the Federal Retail Pharmacy Program (to share with partners or members of the community)

Upcoming Trainings/Webinars/Jurisdictional Calls

- Below is a link to a series of accredited education about COVID-19 vaccine in general, safety, and administration considerations.
    - Vaccine Courses, Broadcasts, Webcasts and Self Study Training | CDC
- Tiberius users can access the training video on submitting transfer requests at the following link: https://protect-ows.hhs.gov/workspace/compass/view/ri.compass.main.folder.c95b290c-2561-4cd1-85f7-e31dac51d34b [protect-ows.hhs.gov

Upcoming NACCHO Webinars:
Tuesday, February 9 at 12 pm ET: COVID-19 Action in the Biden Era: A Fireside Chat with Dr. Fauci

Upcoming CDC Foundation Webinar:
February 24 at 1:00-2:00 pm EST - Updates and Resources from CDC and Ad Council
During this session,

- Anne Schuchat, principal deputy director at the CDC, will provide an update on vaccine distribution.
- A representative from the Ad Council will present messaging content and guidance for local public health officials
- Judy Monroe, president, and CEO of the CDC Foundation, will moderate an audience Q&A.

Georgia Tech Center for Design and Inclusive Innovation Webinar:
February 10 at 2:00 pm EST

- Guidance for Businesses and Employers Considering the Needs of People with Disabilities during COVID-19

CDC COVID-19 Partner Update Webinar

- COVID-19 Information for Essential Workplaces
- February 8 at 3:00 PM ET

NEW Pharmacy/LTCF Office Hours

- Office Hours will now be held twice a week on Tuesdays and Fridays from 4 - 4:30 pm ET. Please find the call-in information below:

Microsoft Teams meeting

Join on your computer or mobile app

Click here to join the meeting

Or call in (audio only)

+1 404-718-3800,,561828018# United States, Atlanta

(888) 994-4478,,561828018# United States (Toll-free)

Phone Conference ID: 561 828 018#

Find a local number | Reset PIN

Learn More | Meeting options

Upcoming National Vaccine Advisory Committee (NVAC) Meeting

- February 4-5, 1:00-5:45 PM
- Live webcast link and agenda found here

COVID-19 Resources

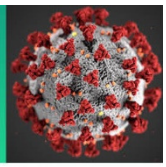
- Vaccine Confidence Consultations from Vaccine Task Force
  - This email serves as an entry point to many vaccine confidence consultation options offered by CDC. Vaccine confidence and communications experts will receive emails from providers and public health professionals and then set up brief calls to understand needs, tailor support, and provide further technical assistance in data collection, creation of communication products and more to promote community vaccine confidence for COVID-19 vaccines. They can be contacted at confidenceconsults@cdc.gov
- ELC Enhancing Detection Expansion FAQ (attached)
  - Developed by the ELC Team, this FAQ answers common questions about Enhancing Detection Expansion funding for jurisdictions. More information can be found on the ELC Website.
- Factsheet: 12 Things Jurisdictions Need to Know about VAERS (attached)
  - A factsheet developed by VTF on how to report adverse events following vaccination to the Vaccine Adverse Events Reporting System (VAERS)
- The COVID State-Profiles Report (aka Governors Report) is now posted publicly at COVID Data Tracker, and will be updated weekly. As a reminder, Community Profile Report has been posted publicly since December, and is updated daily. There is also a public facing version of the **T**herapeutics Distribution Location Tool**.**
- COVID-19 Vaccination Communication Toolkits for Community- Based Organizations and Essential Workers
  - COVID-19 vaccines will be available to essential workers and other community members soon. CDC has designed two toolkits to help build confidence in this new vaccine. The toolkits will help community-based organizations (CBOs) and employers to educate community members and workers about COVID-19 vaccines, raise awareness about the benefits of vaccination, and address common questions and concerns.

Thank you,

Jamilla Green, DrPH, MPH, CPH

Health Department Liaison (Region 4: KY, MS)
Health Department Section
State, Tribal, Local, and Territorial Support Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
qwq7@cdc.gov

COVID-19 Science Update



From the Office of the Chief Medical Officer, CDC COVID-19 Response, and the CDC Library, Atlanta, GA.
Intended for use by public health professionals responding to the COVID-19 pandemic.

***** Available on-line at https://www.cdc.gov/library/covid19 *****

Section headings in the COVID-19 Science Update align with the CDC Science Agenda for COVID-19.

Detection, Burden, and Impact

PEER-REVIEWED

Antigen-based testing but not real-time polymerase chain reaction correlates with severe acute respiratory syndrome coronavirus 2 viral culture. Pekosz *et al.* Clinical Infectious Diseases (January 20, 2021).

Key findings:

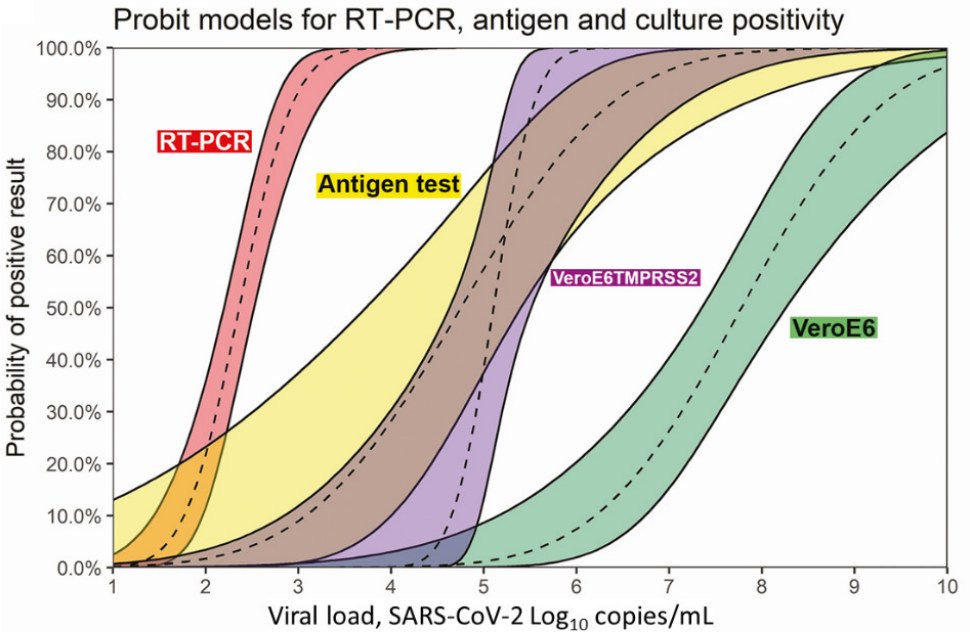
- The BD Veritor antigen test had a higher positive predictive value (PPV) (90.0%, 95% CI 76.3%-97.6%) than the Quidel Lyra RT-PCR SARS-CoV-2 test (73.7%, 95% CI 60.8%-85.3%) relative to positive viral culture.
- Viral culture using VeroE6TMPRSS2 cells, which are susceptible to infection by influenza and coronaviruses, correlated better with antigen tests compared with VeroE6 cells (Figure).

Methods: RT-PCR and antigen tests were compared with SARS-CoV-2 viral cultures from 38 adult patients sampled within 7 days of symptom onset across 21 US localities in June 2020. Probability of positivity and viral loads were fit with probit models for each testing method. *Limitations*: Correlations may be valid only for samples taken within 7 days from symptom onset; small sample of symptomatic adults.

Implications: Point-of-care antigen tests might minimize the spread of SARS-CoV-2 by identifying infectious adults in areas of high community transmission.

MS-DOH-21-1816-A-000479

Figure.



Note: Adapted from Pekosz *et al.* Modelled probability distributions of each SARS-CoV-2 test type, **RT-PCR**, **antigen**, and viral cultures (**VeroE6TMPRSS2** and **VeroE6**), across log-transformed viral load. As viral load increases, the probability of any test producing a positive result increases. Licensed under CC BY-NC-ND 4.0.

PREPRINT (NOT PEER-REVIEWED)

Predictive power of SARS-CoV-2 wastewater surveillance for diverse populations across a large geographical range. Melvin *et al.* medRxiv (January 25, 2021).

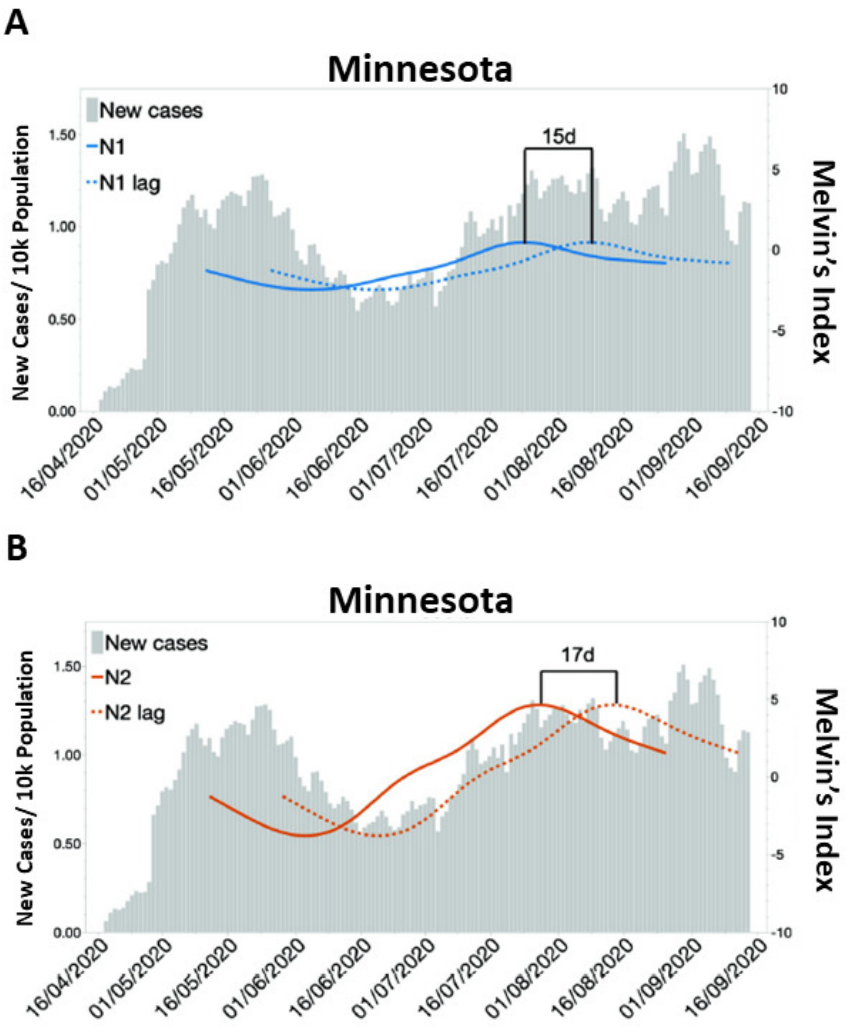
Key findings:

- In Minnesota, wastewater SARS-CoV-2 RNA levels, using RT-PCR to amplify 2 nucleocapsid gene targets (N1 and N2), predicted new clinical cases with a lag of 15 days for N1 ($r = 0.73$, $p < 0.001$) and 17 days for N2 ($r = 0.77$, $p < 0.001$) (Figure).

Methods: Compared Minnesota Department of Health COVID-19 case data with indexed SARS-CoV-2 RNA levels in municipal wastewater from 19 Minnesota cities in summer 2020. Developed a novel index (Melvin's Index) of wastewater SARS-CoV-2 viral load, standardized based on a plant virus that is abundant in human feces, to control for factors such as treatment facility capacity, flow rate, and population size. Successively lagged Melvin's Index values in 1-day increments to find the lag time (between observing an increase in SARS-CoV-2 RNA in wastewater and the appearance of confirmed new COVID-19 positive tests) that maximized correlation (r) between Melvin's Index and new confirmed cases. *Limitations*: Variations in clinical SARS-CoV-2 testing might affect correlation with population wastewater viral load.

Implications: Wastewater surveillance for SARS-CoV-2 might allow early detection of local outbreaks, especially where access to healthcare services is limited. A study in Barcelona found SARS-CoV-2 was detected in sewage collected 41 days before the first COVID-19 case.

Figure.



Note: Adapted from Melvin *et al*. Correlation and lag analysis of wastewater SARS-CoV-2 levels with new COVID-19 clinical cases in Minnesota. **A)** Indexed **N1 levels in real time** and **transposed (dotted line)** to show lag (15 days) to clinical case reports **B)** **N2 levels in real time** and **transposed (dotted line)** to show lag (17 days) to clinical case reports. Licensed under CC BY-ND 4.0.

Transmission

PEER-REVIEWED

Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence. Sabino *et al.* Lancet (January 27, 2021).

Key findings:

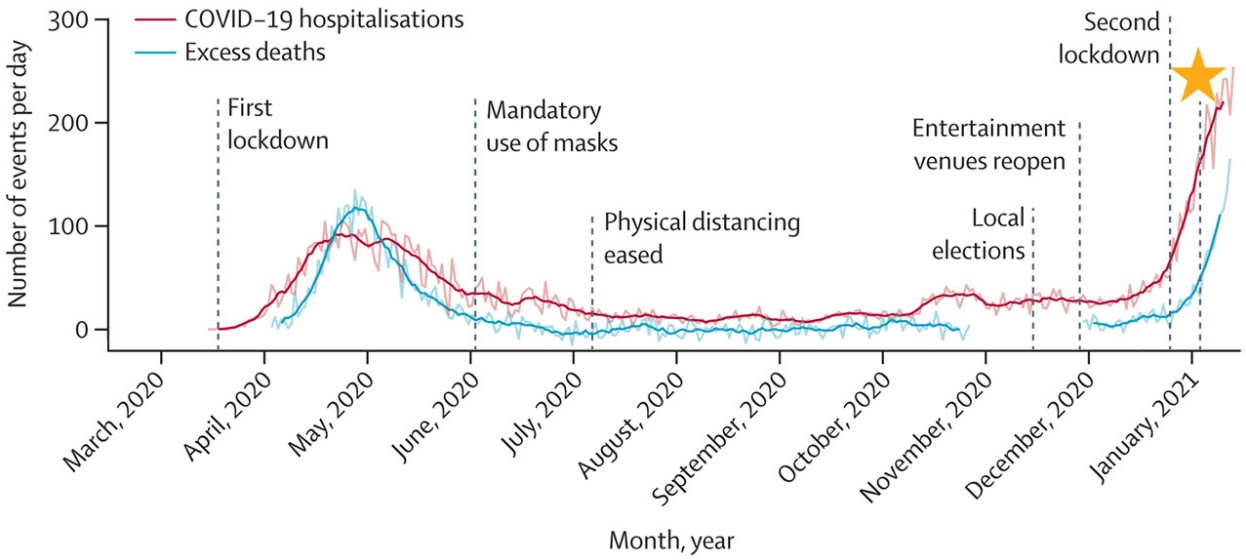
- Manaus, Brazil experienced a sharp rise in COVID-19 hospitalizations in January 2021 despite extensive transmission earlier in the pandemic and rates that had been stable and low for 7 months during relaxed COVID-19 mitigation (Figure).
- There are 4 possible explanations for the surge.
    - Greater mixing of susceptible and infected persons in December 2020.

- Waning immunity in the population.
- Circulating variants, specifically B.1.1.7 (501Y.V1) and P.1 with the E484K mutation, evading immunity.
- New variants being more transmissible.

Methods: COVID-19 hospitalizations, excess deaths, and real-time effective reproductive numbers were assessed from the literature and qualitatively compared monthly from March 2020 to January 2021 in Manaus, Brazil. *Limitations*: Associations were not directly estimated.

Implications: New variants of SARS-CoV-2 might demonstrate changes in transmissibility and/or virulence and could lead to a resurgence of COVID-19 despite high reported seroprevalence. In Rio Grande do Sul, another state in Brazil, da Silva Francisco *et al.* found wide circulation of the B.1.1.28 variant, with the E484K mutation, co-infection of variants, and new emerging variants. These findings stress the importance of tracking circulating viruses and of reaffirming COVID-19 mitigation measures.

Figure.



Note: Adapted from Sabino *et al.* Smoothed COVID-19 **hospitalizations** and **excess deaths** since March 2020 in Manaus, Brazil. Key mitigation events are marked with dotted lines. The gold star indicates the first detection of P.1 variant. Reprinted from The Lancet, Vol. 397 number 10273, Sabino *et al*, Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence., Pages 452– 455, Copyright (2021), with permission from Elsevier.

Natural History of SARS-CoV-2 Infection

PREPRINTS (NOT PEER-REVIEWED)

SARS-CoV-2 seropositivity and subsequent infection risk in healthy young adults: a prospective cohort study. Letizia *et al.* medRxiv (January 29, 2021).

Key findings:

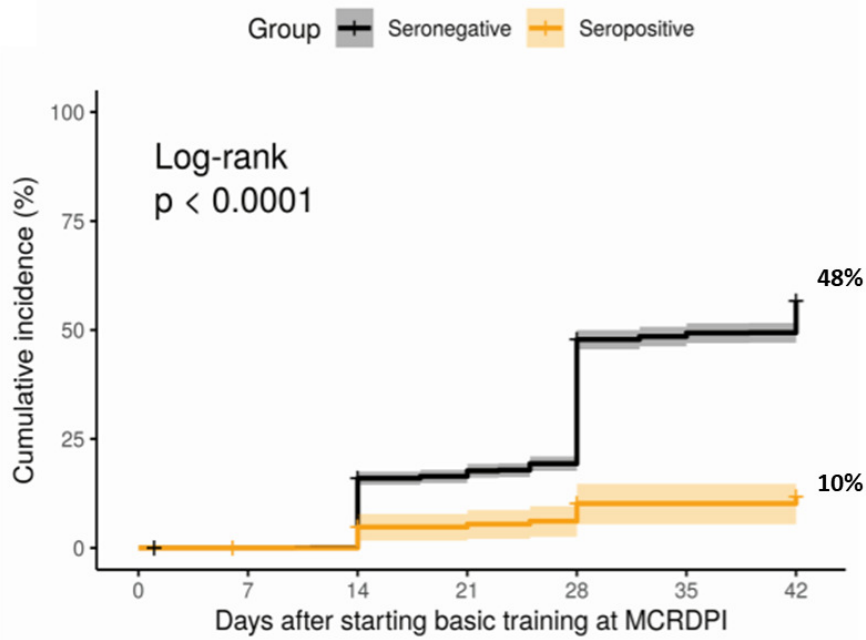
- Although seropositivity conferred an 82% reduced incidence rate, 10.1% of 189 seropositive participants had ≥1 positive RT-PCR test for SARS-CoV-2 (compared with 48.0% of 2,247 seronegative participants) (Figure).

    - Among those infected, seropositive participants had only a modest, approximately 10-fold decrease in nares virus load compared with seronegative participants.
- Among seropositive participants
    - New infection was associated with significantly lower baseline full-length spike protein IgG titers.
    - Baseline neutralizing titers were detected in 83.3% of the first 54 participants who never became PCR positive compared with 31.6% of the 19 infected participants.

Methods: Prospective 6-week observational study of 3,249 predominantly male, 18–20-year-old Marine recruits, who underwent baseline 2-week supervised quarantine and SARS-CoV-2 RT-PCR and IgG antibody testing. Serial RT-PCR testing was conducted and questionnaires on development of symptoms were completed during and after quarantine. *Limitations*: Overall high attack rate might not be generalizable to other populations and settings; unknown when seropositive participants were initially infected.

Implications: Although persons with SARS-CoV-2 antibodies are largely protected, subsequent infection is possible for some persons due to lack of sterilizing immunity. Some re-infected individuals could have a similar capacity to transmit virus as those infected for the first time.

Figure.



Note: Adapted from Letizia *et al*. SARS-CoV-2 PCR positive incidence curves during the six-week follow-up period among baseline **seropositive** and **seronegative** groups. Licensed under CC BY 4.0.

Kinetics and correlates of the neutralizing antibody response to SARS-CoV-2. Vanshylla *et al.* bioRxiv (January 26, 2021).

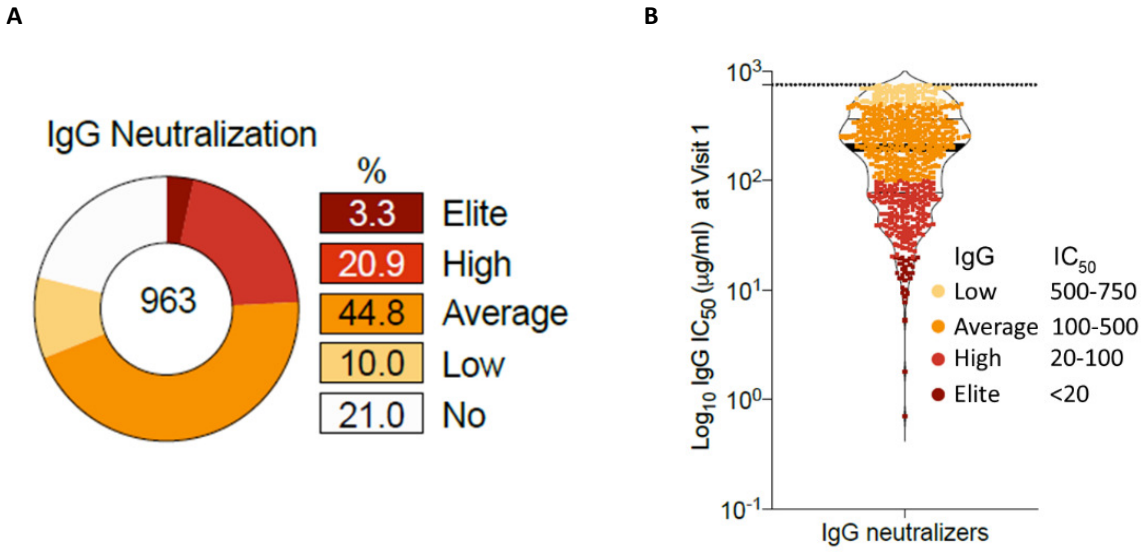
Key findings:

- 82% of individuals developed serum, and 79% IgG, neutralizing antibodies (NAb) to SARS-CoV-2.
- Neutralizing activity was highly variable, ranging from 3% who were initially 'elite' neutralizers, with a 50% Inhibitory Concentration [IC_{50}] of <20 µg/ml of IgG, to 21% who had no neutralizing activity (Figure).
- Higher anti-spike IgG levels, older age, time since disease onset, and fever during acute infection were predictors of SARS-CoV-2 neutralizing activity in mild courses of COVID-19.
- NAb had an initial half-life of 7 weeks in serum and 31 weeks in IgG titer samples.

Methods: NAb responses to SARS-CoV-2 were examined in 963 persons recently recovered from (mostly) mild COVID-19, during up to 4 follow-up visits between April 6 and December 17, 2020. Statistical modeling was used to infer antibody decay rates and to build a prediction model to evaluate how clinical features correlate with NAb titers. *Limitations:* Loss to follow up may bias results.

Implications: Although NAb can persist for up to 10 months after infection, persons who recover from mild COVID-19 illness have a broad spectrum of neutralizing activity which might affect protective immunity at a population level.

Figure.



Note: Adapted from Vanshylla *et al*. **(A)** Donut chart depicts the initial fraction of persons who developed NAb at study visit 1. **(B)** Violin plot depicts IgG IC_{50} values for the persons who developed neutralizing antibodies (n=760), categorized by IgG IC_{50}: **low** (IC_{50} >500-750 µg/ml), **average** (IC_{50} >100-500 µg/ml), **high** (IC_{50} 20-100 µg/ml), **and elite** (IC_{50} <20 µg/ml). Dotted line represents the limit of detection of the assay. Used by permission of authors.

Protection in Healthcare and Non-Healthcare Work Settings

PREPRINT (NOT PEER-REVIEWED)

Strategies to minimize SARS-CoV-2 transmission in classroom settings: combined impacts of ventilation and mask effective filtration efficiency. Rothamer *et al.* medRxiv. (January 4, 2021).

Key findings:

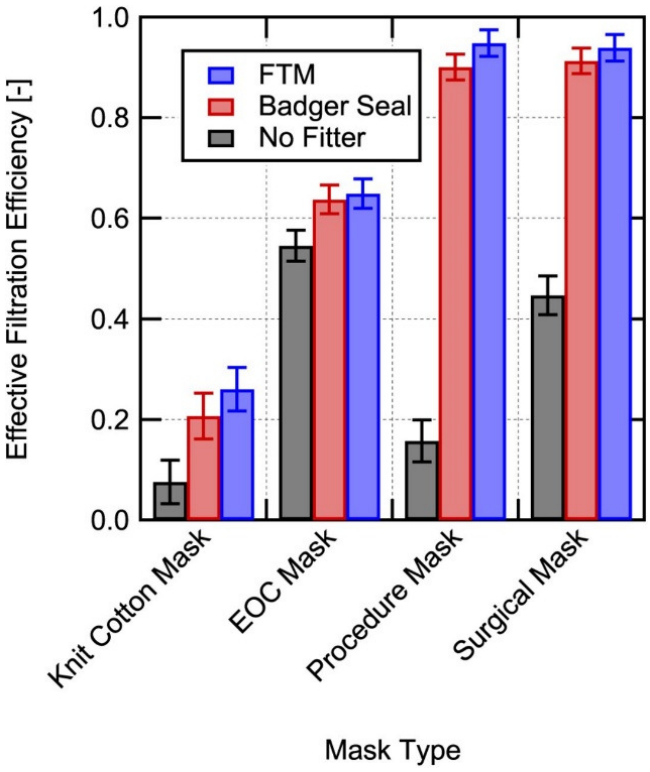
- Filtration efficiencies of four masks tested ranged from 7.5% to 54.5%.
- The addition of mask fitters, devices to improve the seal of a mask, increased filtration efficiency from 20.6% to 91.3% (Figure).
- Ventilation alone did not substantially reduce infection risk.

Methods: A simulation study to evaluate ventilation and mask filtration efficiency of non-medical grade masks, with and without mask fitters, on aerosol transmission in a classroom setting using CPR manikins fitted with aerosol-releasing tubing. Two mask fitters were tested, Badger Seal and Fit the Mask (FTM), using 4 masks: 1) a commercial 4-ply knit cotton mask, 2) a 3-ply polypropylene mask, 3) a 3-ply disposable procedure mask, and 4) a

surgical mask. *Limitations*: Potential overestimation of mask efficacy because manikins were fitted to minimize leakage; simulation might not represent real-world settings.

Implications: All non-medical grade masks are prone to leakage; however, the use of mask fitters can significantly reduce aerosol transmission of SARS-CoV-2 in a classroom setting. Gandhi *et al.* hypothesized that the use of multi-layered, well-fitting masks could achieve >90% efficiency at reducing aerosol transmission.

Figure.



Note: Adapted from Rothamer *et al*. Overall effective filtration efficiency for inhalation for 4 masks by fitter status (with **no mask fitter**, with the **Badger Seal mask fitter**, with the **Fit the Mask (FTM) mask brace**). Licensed under CC BY-ND 4.0.

Prevention, Mitigation and Intervention Strategies

PEER-REVIEWED

Model-informed COVID-19 vaccine prioritization strategies by age and serostatus. Bubar *et al.* Science (January 21, 2021).

Key findings:

- Prioritizing adults ≥60 years old shows the greatest reduction in mortality and years of life lost (YLL) after accounting for country-specific age structure, age-contact structure, infection fatality rates, seroprevalence, and age-varying efficacy of vaccine.
- Prioritizing adults aged 20–49 years old minimizes cumulative incidence but is only superior at minimizing deaths when R_0 = 1.15 and vaccine efficacy is ≥80% or vaccine rollout is ≤0.2%, or when vaccine efficacy is lower in older adults (≥60 years old) compared to individuals <60 years.
- Prioritizing seronegative individuals provides the greatest benefit where seroprevalence is high.

Methods: A mathematical model quantified the impact of five age-stratified COVID-19 vaccine prioritization strategies on cumulative incidence, mortality and YLL. *Limitations*: Model assumptions limit generalizability; disease severity is considered by age only.

Implications: Pairing vaccination with serological testing of individuals may be a useful strategy for prioritization of limited vaccine supplies and to reach vulnerable populations.

PREPRINTS (NOT PEER-REVIEWED)

mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. Wu *et al.* bioRxiv (January 25, 2021).

Key findings:

- Moderna mRNA-1273 vaccine was able to neutralize all known strains of SARS-CoV-2.
    - Full neutralization was still achieved despite diminished neutralizing responses against the B.1.351 (South Africa) variant, with the E484K mutation, because neutralizing titers remained relatively high (1:290).
    - No significant differences in neutralizing antibody titers against B.1.1.7 (UK), 20E, 20A.EU2, DG614-N439K, or mink cluster 5, variants were detected.

Methods: Neutralization assays using pseudovirus expressing SARS-CoV-2 spike protein mutations found in major current variants were used to determine the neutralizing capacity of sera from 8 human subjects and 12 non-human primates vaccinated with the Moderna mRNA-1273 vaccine. Neutralization was compared to the neutralization observed against D614G, the dominant strain of 2020. *Limitations*: Small sample size; P.1 variant was not included.

Implications: Moderna mRNA-1273 vaccine appears to be effective against both the UK and South African SARS CoV-2 variants. However, further studies are warranted to substantiate these findings.

The effectiveness of the first dose of BNT162b2 vaccine in reducing SARS-CoV-2 infection 13-24 days after immunization: real-world evidence. Chodick *et al.* medRxiv (January 29, 2021).

Key findings:

- The cumulative incidence of SARS-CoV-2 infection was 0.57% (n=2,484) during days 1-12 and 0.27% (n=614) during days 13-24 following the first dose of the BNT162b2 mRNA COVID-19 vaccine.
- There was a 51.4% reduction in the weighted average daily incidence of SARS-CoV-2 infection at days 13–24 after the first dose (21.8 per 100,000 population), compared to days 1–12 (43.41 per 100,000 population).

Methods: A retrospective cohort study of 503,875 individuals aged ≥16 years old in Israel estimated the effectiveness of the first dose of the BNT162b2 vaccine administered from December 19, 2020 to January 15, 2021. Daily and cumulative infection rates during days 13-14 were compared to days 1-12 after the first dose using generalized linear models. *Limitations*: Unreported vaccinations might bias results.

Implications: Based upon temporal incidence, the BNT162b2 vaccine (Pfizer-BioNTech) is approximately 51% effective at reducing the risk of SARS-CoV-2 infection at 13 to 24 days following the first dose.

In Brief

Detection, Burden, and Impact

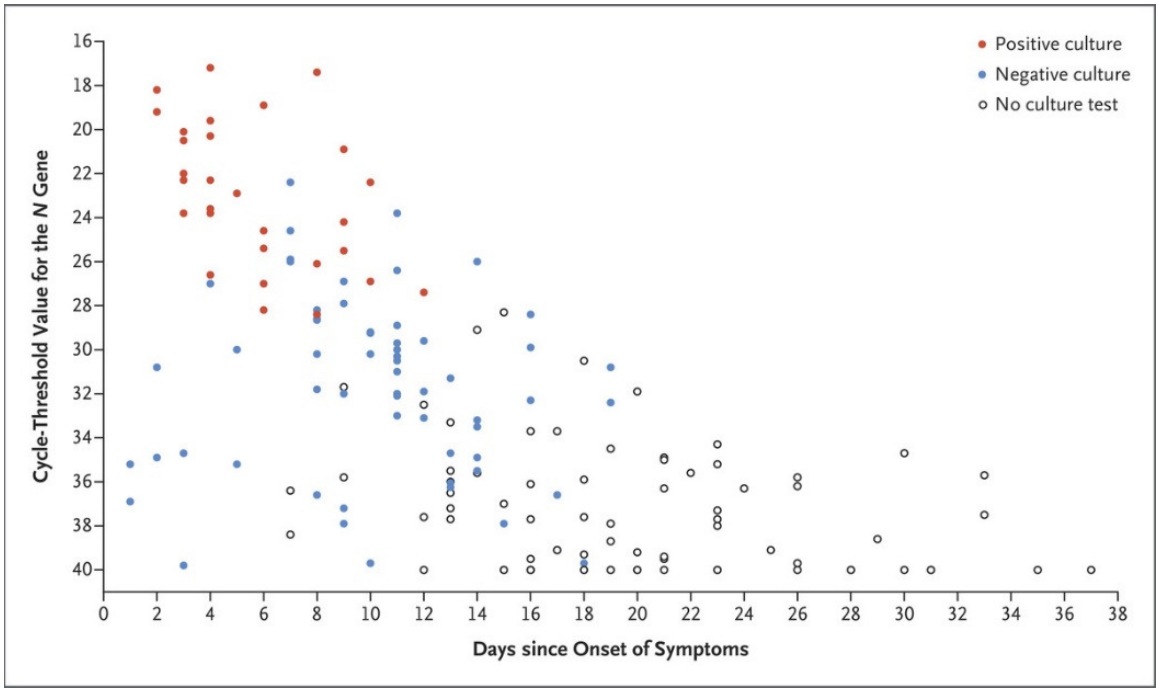
- Lowe *et al.* **Association of smoking and cumulative pack-year exposure with COVID-19 outcomes in the Cleveland Clinic COVID-19 registry.** JAMA Internal Medicine. (January 25, 2021). Of 7,102 adults with COVID-19 in the Cleveland Clinic COVID-19 registry between March 8 and August 25, 2020, 341 persons who smoked >30 pack-years had higher odds of hospitalization and death, although the odds were attenuated with inclusion of comorbidities; these data demonstrate an apparent dose-dependent relationship between smoking and adverse COVID-19 outcomes.

- Ehrenberg *et al.* **Launching a saliva-based SARS-CoV-2 surveillance testing program on a university campus.** medRxiv (Preprint, January 26, 2021). Describes a successful university-based surveillance system using saliva-based testing for SARS-CoV-2 among 3,653 persons to identify asymptomatic and pre-symptomatic cases and prevent outbreaks.

Natural History of SARS-CoV-2 Infection

- Kim *et al.* **Duration of culturable SARS-CoV-2 in hospitalized patients with COVID-19.** NEJM (January 27, 2021). Based on all 2-day RT-PCRs and viral cultures among 21 hospitalized patients with COVID-19, the median duration of shedding of viable virus was approximately 7 days (95% CI 5-10).

Figure.



Adapted from Kim *et al.* Timing of presence or absence of viable SARS-CoV-2 on viral culture and Ct values for 165 serial samples. Viral loads were determined with the Ct value for the *N* gene of SARS-CoV-2. Each circle represents a sample obtained on the specified day. Viral culture was either **positive** or **negative**. DOI: 10.1056/NEJMc2027040. Copyright © (2021) Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

- Al-Samkari et al. **Thrombosis, bleeding, and the observational effect of early therapeutic anticoagulation on survival in critically ill patients with COVID-19.** Annals of Internal Medicine (January 26, 2021). In a multi-center, observational cohort study of 3,239 critically ill patients admitted between March 4 and April 11, 2020, early therapeutic anticoagulation did not affect in-hospital survival.

- Starr *et al.* **Prospective mapping of viral mutations that escape antibodies used to treat COVID-19.** Science (January 25, 2021). Mapping of viral mutations to SARS-CoV-2 receptor binding domain showed that a single amino acid mutation (E406W) escapes the two monoclonal antibody REGN-CoV2 cocktail.

- Rappazzo *et al.* **Broad and potent activity against SARS-like viruses by an engineered human monoclonal antibody.** Science (January 25, 2021). An engineered human monoclonal antibody demonstrated neutralization potency similar to neutralizing antibodies currently in clinical use providing significant protection against COVID-19 in mouse models.

- Nemani *et al.* **Association of psychiatric disorders with mortality among patients with COVID-19.** JAMA (January 27, 2021). In a retrospective cohort study of 7,348 patients with confirmed COVID-19 at 4 acute care hospitals in New York City from March 3 to May 31, 2020, persons with schizophrenia had significantly increased odds of 45-day mortality.

- Alam *et al.* **An interactive COVID-19 virus mutation tracker (CovMT) with a particular focus on critical mutations in the receptor binding domain (RBD) region of the spike protein.** medRxiv (Preprint, January 25, 2021). As new SARS-CoV-2 variants emerge with increased transmissibility and potential immune escape, it is important to monitor sequencing efforts and evolution of mutations. These authors developed a global mutation tracker that is updated daily and includes clinical data.

Protection in Healthcare and Non-Healthcare Work Settings

- Moghadas *et al.* **Evaluation of COVID-19 vaccination strategies with a delayed second dose.** medRxiv (Preprint, January 29, 2021). Based on an assumed 80% efficacy after the first dose, modelling showed that delaying the second dose of the Moderna vaccine by 9-12 weeks could reduce infections, hospitalizations, and deaths. However, for the Pfizer-BioNTech COVID-19 vaccine, with an assumed 52% efficacy after the first dose, there was no clear advantage to delaying the second dose due to waning immunity.

Prevention, Mitigation, and Intervention Strategies

- Crane *et al.* **Change in reported adherence to nonpharmaceutical interventions during the COVID-19 pandemic, April-November 2020.** JAMA (January 22, 2021). National survey responses from 7,705 participants between April 1 and November 24, 2020, showed a decrease in adherence to nonpharmacological interventions indicating "pandemic fatigue; however, there was in increase in self-reported mask-wearing which may reflect improved public health messaging.

Social, Behavioral, and Communication Science

- Ayers *et al.* **Suicide-related internet searches during the early stages of the COVID-19 pandemic in the US.** JAMA Network Open (January 21, 2021). Google searches related to suicide between January 1 and July 5, 2020, showed a decline after a national emergency was declared in March 2020. This decline was likely due to increased social support, called the "pulling together" phenomenon, often associated with catastrophes.

Disclaimer: The purpose of the CDC COVID-19 Science Update is to share public health articles with public health agencies and departments for informational and educational purposes. Materials listed in this Science Update are selected to provide awareness of relevant public health literature. A material's inclusion and the material itself provided here in full or in part, does not necessarily represent the views of the U.S. Department of Health and Human Services or the CDC, nor does it necessarily imply endorsement of methods or findings. While much of the COVID-19 literature is open access or otherwise freely available, it is the responsibility of the third-party user to determine whether any intellectual property rights govern the use of materials in this Science Update prior to use or distribution. Findings are based on research available at the time of this publication and may be subject to change.

cdc.gov/coronavirus

ELC Enhancing Detection Expansion

Questions & Answers

As of February 2, 2021

All questions are hyperlinked to their respective answers below; click on a question to be brought to its answer. Click on 'ELC Enhancing Detection Expansion' at the bottom of each page to be brought back to the start of the document. Appendices available at the end which include allowable expense comparisons between ELC Enhancing Detection Expansion and Immunization VFC Supplemental Funding.

Budget and Allowable Costs

1. Is there a budget template?
2. What are examples of some costs not allowed in Enhancing Detection (ED) Expansion?
3. Can we use the funds to pay for activities done in months before the grant was awarded?
4. Can funding be used to support providers with Electronic Laboratory Reporting (ELR) or telemedicine technology to enhance testing?
5. Can funding be used to purchase vaccines?
6. When submitting a revised budget as an amendment, do you have to submit other forms?
7. Can resources be used for quarantine/isolation-related costs?
8. When setting up and operating pop-up testing sites, what types of expenses are allowable through ED Expansion?
9. If a recipient's partners and community providers meet the testing goal and need to provide additional supplies/resources for expanded testing, what costs are allowable through ELC Enhancing Detection Expansion?
10. Are funds intended to support activities for the duration of the 30-month period? For example, if a jurisdiction liquidates all their funds prior to the end of the 30 months, are they still required to continue activities in the guidance until the end of the 30 months?
11. If a jurisdiction liquidates most or all funds towards supporting a few activities in the workplan, are they still required to complete the remaining activities?
12. Can ELC ED Expansion funds be used to cover the costs of COVID-19 testing?
13. When reporting the monthly expenses in the REDCap Financial Reporting page, what are 'unliquidated obligations' and how do they differ from expenses?
14. Am I required to have prior approval (redirection/contract approval) before I can use the funds that were placed in the "Other" cost category of my ELC ED Expansion Notice of Award (NOA) for COVID-19 response activities?
15. The Notice of Award for ELC ED Expansion has a budget period from August 1, 2020, to July 31, 2023; does this mean that contracts and other acquisitions using ELC ED Expansion funds cannot go past July 31, 2021?
16. How does expanded authority work for the supplemental COVID-19 funds?
17. May social services be supported with ED Expansion funds?
18. Can ELC ED Expansion funding be used to purchase vehicles, including mobile testing vans?
19. Can ELC ED Expansion funding be used for renovations and minor construction costs?
20. Can recipients request more than the recommended "1 program manager, 1 budget staff" in the budget?
21. With this new funding opportunity, and the allowance of covering existing core staff's percent of work redirected to COVID-19 activities, what happens to our (base) core ELC funding?
22. Are recipients able to start spending funds, before revised budgets are approved?
23. Now that workplans are being combined into ED Expansion for ELC CARES and Enhancing Detection, will financial reporting be bundled as well?

Workforce Capacity:

24. If the health department has previously reached the personnel/hiring cap in their jurisdiction, should this be addressed or acknowledged in the budget?

ELC Enhancing Detection Expansion Testing & Testing Plan Template:

25. Can you confirm that the target coverage for our testing projections is 2% of population each month?

26. What level of continued federal support can recipients expect for laboratory testing (e.g., provision of specimen collection and testing kits) as the COVID-19 response evolves?
27. Is the laboratory test order and reporting activity required?

Advance Electronic Data Exchange at Public Health Labs:

28. Is the laboratory test order and reporting activity required?
29. I cannot find the ED Expansion performance measures, where are they located?
30. What elements are needed in the line level testing data reporting to CDC?
31. Will these expectations for lab test reporting affect current reporting feeds from labs to health departments? If the state feed changes, does the originating reporting feed at the lab have to change?
32. Our jurisdiction is having difficulty with ensuring all laboratories are reporting line-level test data (including negatives); how important is this element to our ELC activities?
33. Can CDC provide additional clarity on what specific activities under "Improve Surveillance and Reporting of Electronic Health Data" are considered to "enable comprehensive, automated, daily reporting to the CDC and others in a machine-readable format"?

Activities:

34. Could you elaborate on what activities are allowable under contact tracing?
35. Are we able to obligate subcontracts before our revised budgets are submitted?
36. If ED Expansion is a copy of ED in REDCap, do we still report milestones and progress updates for ED?

Coordinate and Engage with Partners:

37. If a jurisdiction is largely de-centralized, to what extent is the State Health Department expected to partner at the local level?
38. What are examples of partners to consider funding when addressing health equity needs?

Other projects:

39. We attended the webinar presented by the United States Digital Service (USDS) and are interested in participating. Can the ELC facilitate this?
40. For ELC COVID performance measures, where are measures E23, E24 and E25 located in the REDCap portal?

Appendices

A: Basic Comparison & Examples of Allowable
B: Costs Allowable Expenses At-A-Glance

ELC Enhancing Detection Expansion Answers

Budget & Expenses:

1. Is there a budget template?
   - Yes, the ELC budget workbook (Excel) was provided in a Grant Note in GrantSolutions (GMM). You can also contact your ELC Project Officer. Recipients must complete the budget revision using the Excel budget workbook and adhere to the CDC guidelines (https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.pdf). The revised budget must then be sent back to CDC through a budget revision amendment in GrantSolutions, along with a cover letter signed by the Authorized Organizational Representative (AOR) of record in GrantSolutions.
2. What are examples of some costs not allowed in Enhancing Detection (ED) Expansion?
   - Research, lobbying, and clinical care (except as may be allowed by law) cannot be supported with funds awarded under ELC Enhancing Detection (ED) Expansion. However, all questions should be submitted as a Grant Note in GMM for review by your Grants Management Specialist (GMS) at CDC's Office of Grant Services (OGS) and your ELC Project Officer.
3. Can we use the funds to pay for activities done in months before the grant was awarded?
   - Legislative language was not included in this appropriation to permit retroactive charges; therefore, only costs associated with activities from time of award issuance are allowable.
4. Can funding be used to support providers with Electronic Laboratory Reporting (ELR) or telemedicine technology to enhance testing?
   - Certain costs not associated with the delivery of clinical care may be allowable. Please email your ELC Project Officer for a more individualized consult to discuss the specifics of your situation.
5. Can funding be used to purchase vaccines?
   - Per OGS, the purchase of vaccines is not permissible using ED Expansion funds. However, certain vaccine related costs may be allowable using ED Expansion funds. This includes storage and administration costs (i.e., injection cost if not covered in question #12). Recipients are encouraged to coordinate with PHEP and Immunization partners within the jurisdiction to effectively plan necessary activities and optimize use of resources.
6. When submitting a revised budget as an amendment, do you have to submit other forms?
   - The following must be part of the submission:
     i. The workplan completed in REDCap (and exported as a PDF);
     ii. The revised ELC budget workbook, using the Excel workbook provided at the time of award issuance;
     iii. A cover letter which is on agency/recipient stationary and signed by the Authorizing Official of record in GrantSolutions;
     iv. The State Testing and Case Investigation & Contact Tracing Plan completed in REDCap (and exported as a PDF); and
     v. The ELC Governance Team support letter.
7. Can resources be used for quarantine/isolation-related costs?
   - Costs associated with quarantine and isolation may be allowable as they relate to one or more activities in the workplan. For example, resources necessary to support testing and monitoring of individuals traveling from high-risk areas (within or outside of the U.S.) may be allowable and within scope of this project (this includes wrap- around services). Resources necessary for quarantine under a legal order (hotel, wraparound services, etc.) may also be allowable; recipients should simply tie these requests to their ELC workplan. ELC Project Officers should be contacted to discuss the specifics of such a request.
8. When setting up and operating pop-up testing sites, what types of expenses are allowable through ED Expansion?
   - Most costs associated with setting up and operating alternate testing sites are allowable under ED Expansion if the workplan reflects these sites in one or more of the activities. Please see question #12 for additional details pertaining to insurance.

9. If a recipient's partners and community providers meet the testing goal and need to provide additional supplies/resources for expanded testing, what costs are allowable through ELC Enhancing Detection Expansion?
    - Most costs, in particular supplies and resources, are allowable so long as they relate to one or more of the activities in the workplan. However, testing costs, even for the uninsured would not be allowable when any/all of the associated costs are being reimbursed in any fashion. Please see question #12 for additional details pertaining to insurance.
10. Are funds intended to support activities for the duration of the 30-month period? For example, if a jurisdiction liquidates all their funds prior to the end of the 30 months, are they still required to continue activities in the guidance until the end of the 30 months?
    - The expected timeframe for completion of all required activities under ELC ED Expansion is 30 ½ months. It is possible that certain activities may be completed in a shorter period (e.g., 24 months); however, the overall project period is 30 ½ months to allow sufficient time to conduct the range of activities. As this award builds on the ELC ED award, it is important to gauge progress based on the achievement of the required expansion of activities, not the spending of funds. Expenditures that are not aligned with the commensurate level of completion of the approved activities will be scrutinized. Should it be found that resources were not utilized in the manner consistent with grant regulations, the award terms and conditions and/or approved work plans and budget submissions, the jurisdiction may be found to be noncompliant and could be required to reimburse the federal government. Additionally, as indicated in the Guidance associated with this award (https://www.cdc.gov/ncezid/dpei/elc/resources.html), if required tasks and activities in the Guidance are not addressed, funds may be restricted in the Payment Management System (PMS). It is highly recommended that recipients continue to engage their ELC Project Officer and the OGS GMS as funds are activities are undertaken and funds are expended to ensure appropriate progress during the ED Expansion project period.
11. If a jurisdiction liquidates most or all funds towards supporting a few activities in the workplan, are they still required to complete the remaining activities?
    - The ELC ED Expansion Guidance sets out the required activities in furtherance of the purpose and use of the funds and the award. Budgets should align to the workplans and are intended to support the breadth of all required activities.
12. Can ELC ED Expansion funds be used to cover the costs of COVID-19 testing?
    - Yes, COVID-19 testing can be covered using ELC Enhancing Detection Expansion funds in the following ways:
        i. Uninsured: ELC Enhancing Detection Expansion funds can cover costs associated with COVID-19 testing for the uninsured.
        ii. Unable to bill: ELC Enhancing Detection Expansion funds can cover costs associated with COVID-19 testing when billing is not feasible. While not an exhaustive list, some examples are the following: mobile testing sites; non-traditional testing sites; state/local laboratories not having the authority or ability to bill insurance; etc.
        iii. Billing serves as a real or perceived barrier to timely test delivery: ELC Enhancing Detection Expansion funds can cover costs associated with COVID-19 testing when establishing billing services (directly or through a contractual agreement) would delay testing and/or reduce the jurisdiction's ability to rapidly increase testing capacity to meet needs.
        iv. Payor of last resort when billing insurance: In situations where COVID-19 testing is billed to insurance and is either not covered or partially covered by a third-party payor (e.g., private insurance, CMS, etc.), after the claim is rejected or partial reimbursement occurs, the outstanding balance can be covered by ELC Enhancing Detection Expansion funds.
13. When reporting the monthly expenses in the REDCap Financial Reporting page, what are 'unliquidated obligations' and how do they differ from expenses?
    - The funds awarded fall into one of three categories:
        i. Unobligated: Funds in a budget or spend plan that are available for use, but not yet encumbered or committed.

ii. Unliquidated obligations (ULOs): Funds that have been encumbered/committed but have not yet been paid out. Examples include: (1) executing a $100K contract and having to pay 10% upfront would result in $10K in 'expenditures' and $90K in 'unliquidated obligations'; (2) using a purchase order to acquire a piece of equipment for $50K would result in $50K in 'unliquidated obligations' until the equipment is delivered, the agency is invoiced, and the invoiced is paid.
iii. Expenditures: Funds that have been drawn down from the account and paid out.

- Note: It is important to remember that once an unliquidated obligation is paid, the following monthly reporting should transfer the amount paid from 'unliquidated obligations' to 'expenditures' as the obligation has now been liquidated.

14. Am I required to have prior approval (redirection/contract approval) before I can use the funds that were placed in the "Other" cost category of my ELC ED Expansion Notice of Award (NOA) for COVID-19 response activities?
    - All awarded funds were placed in the 'Other' cost category as an initial means to obligate and award funding. This action allowed CDC to expedite your award and facilitate your emergency response. Based on the emergency, you have been authorized to use these funds consistent with the issued Guidance and terms of the award set out therein, including entering into contracts as required to address the needs of COVID-19. Please ensure that such funds are expended in accordance with your organization's policies and procedures and are reasonable, allocable, allowable, and necessary as per 2 CFR Part 200 and 45 CFR Part 75. All costs must also be reflected in the budget and workplan you are preparing for submission by March 18, 2021. You are not required to wait until your budget is submitted and approved to execute any needed contracts or other obligations. We do however require that this information is incorporated in the budget and that the contract(s) are in alignment with the issued CDC Guidance, applicable terms and conditions, and your internal procurement policies. This ability to use the funds prior to the budget submission and approval is an exception that applies solely to COVID-19 awards within ELC.
15. The Notice of Award for ELC ED Expansion has a budget period from August 1, 2020, to July 31, 2023; does this mean that contracts and other acquisitions using ELC ED Expansion funds cannot go past July 31, 2021?
    - The ELC ED Expansion awards were issued in ELC Budget Period 2. There was specific guidance in the Terms and Conditions of the Notice of Award that provided an extended fiscal period (i.e., extending past the end of the budget period in which funds were awarded) for these special COVID-19 funds. The 30 ½ -month fiscal period for the ELC Enhancing Detection Expansion awards means that contracts can extend past the July 31, 2021, end of Budget Period 2, by exercising option years. Additionally, other costs (e.g., purchasing equipment, supplies, etc.) can also occur after July 31, 2021, in accordance with the terms and conditions of this award.
16. How does expanded authority work for the supplemental COVID-19 funds?
    - Unlike funding in ELC (base) core awards, the supplemental ELC ED Expansion COVID-19 awards are issued with an expanded budget period; therefore, expanded authority is not needed to extend use of COVID supplemental funds from one ELC budget period to the next.
    - During the regular ELC budget period closeout (i.e., October 30), when submitting the annual FFRs, one FFR will need to be submitted for each document number that ELC awards were made on. The special COVID-19 document numbers will be reported on separate FFRs from the (base) core ELC award for Budget Periods 1 & 2. For base (core) funding only, whatever funds remain unobligated at time of submitting the annual FFR should be noted in Section #12 along with the intended use of Expanded Authority.
    - Given the ELC ED Expansion award has an extended fiscal period, the account will continue to be active in the Payment Management System (PMS) and can have funds drawn down to cover expenses through the end of the ED Expansion award budget period.
17. May social services be supported with ED Expansion funds?
    - Social services that are critical to facilitating the detection, prevention, and control of COVID-19 may be allowable. For example, those services that help facilitate compliance with isolation and quarantine and/or case investigation and contact tracing efforts may be allowable expenses and may be a part of recipient workplans (e.g., health educators, counselors, etc.). ELC Project Officers should be contacted to

discuss the specifics of such a request. Recipients are reminded that funds are to be expended in accordance with your organization's policies and procedures and are reasonable, allocable, allowable, and necessary as per 2 CFR Part 200 and 45 CFR Part 75.

18. Can ELC ED Expansion funding be used to purchase vehicles, including mobile testing vans?
    - Yes, but recipients must include three (3) quotes and/or a blanket purchasing agreement along with a justification for leasing/purchasing in the revised budgets that are due by March 18, 2021. For situations where the acquisition needs to occur before the revised NOA is issued, please submit the request and associated quotes in GrantSolutions via Grant Note. This information must also be included in the revised budget once submitted.
    - For redirecting funds to purchase vehicles, including mobile testing vans, that were not in the approved budgets, please work with your ELC Project Officer to submit a redirection request. The request will need to include a cost analysis between lease versus purchase options and quote. For mobile testing vans, due to the nature of having to customize the vehicle, it is understood that a lease versus purchase analysis might not be applicable.
19. Can ELC ED Expansion funding be used for renovations and minor construction costs?
    - Yes, but recipients must include the quotes and justification for renovations and/or minor construction in the revised budgets that are due by March 18, 2021. For situations where the alterations need to occur before the revised NOA is issued, please submit the request and associated quotes in GrantSolutions via Grant Note.
    - For redirecting funds to conduct renovations and/or minor construction that were not in the approved budgets, please work with your ELC Project Officer to submit a redirection request. The request will need to include:
        i. A description of the renovation or minor construction,
        ii. The justification of how the renovations or minor construction will relate to activities in the approved workplan, and
        iii. A quote or bid justifying the cost that is being requested in the redirection.
20. Can recipients request more than the recommended "1 program manager, 1 budget staff" in the budget?
    - Yes, this is a minimum recommendation for basic management of this project. Recipients may also need to increase overall administrative staff support to accommodate the demands of managing their portfolio.
21. With this new funding opportunity, and the allowance of covering existing core staff's percent of work redirected to COVID-19 activities, what happens to our (base) core ELC funding?
    - Recipients' (base) core dollars should be reserved for non-COVID programmatic activities. As numerous health department staff are working on COVID-19 currently, it is understandable if (base) core funding spending is lower than usual. These programmatic activities can be extended into Budget Period 3.
    - ELC staff who are typically supported through (base) core funding but are working all or a portion of their time on the COVID-19 response should have their associated personnel costs charged to the ELC CARES, ELC Enhancing Detection, and/or ELC ED Expansion COVID accounts as appropriate.
22. Are recipients able to start spending funds, before revised budgets are approved?
    - Yes, funds are available for use now. In the interim (before revised budgets are accepted), make sure your expenses align with activities described in the ELC Guidance (https://www.cdc.gov/ncezid/dpei/elc/resources.html). Also, please see response to #14 above. Also, recipients are reminded that funds are to be expended in accordance with your organization's policies and procedures and are reasonable, allocable, allowable, and necessary as per 2 CFR Part 200 and 45 CFR Part 75.
23. Now that workplans are being combined into ED Expansion for ELC CARES and Enhancing Detection, will financial reporting be bundled as well?
    - No, each COVID-19 supplemental award requires its own, monthly financial report due to the nature of being awarded on separate accounts in the Payment Management System (PMS) and the need to track and account for spending by each separate supplemental appropriation.

Workforce Capacity:

24. If the health department has previously reached the personnel/hiring cap in their jurisdiction, should this be addressed or acknowledged in the budget?
    - Increased staffing (e.g., contractual, temporary, term staff, etc.) may be essential to achieve the targets and requirements of this award, but we understand expanding human resources in your jurisdictions may not be in your control. If you anticipate insurmountable challenges with hiring or starting new contracts, please let your ELC Project Officer know immediately. Direct assistance and technical assistance can be discussed on a case-by-case basis, and major challenges will also be proactively communicated to the Department of Health and Human Services (HHS).

ELC Enhancing Detection Expansion Testing & Testing Plan Template:

25. Can you confirm that the target coverage for our testing projections is 2% of population each month?
    - Yes, and 2% is the minimum threshold as recommended by HHS/Office of the Assistant Secretary for Health (OASH).
26. What level of continued federal support can recipients expect for laboratory testing (e.g., provision of specimen collection and testing kits) as the COVID-19 response evolves?
    - The ELC can only speak to the funding that CDC administers. Questions regarding the monthly allocations of Viral Transport Medium (VTM) and swabs should be directed to your regional HHS/OASH representative. Of note: the published Jurisdictional Testing Plans may be found at: https://www.hhs.gov/coronavirus/testing-plans/index.html. Any questions should be directed to your HHS/OASH representative.

Advance Electronic Data Exchange at Public Health Labs:

27. Can recipients accelerate previously on-going activities to improve laboratory informatics, for example, more rapid interfacing diagnostic equipment to improve the automation of reporting?
    - Yes, ELC expects all funded jurisdictions will make measurable progress in improving the efficiency of laboratory management and operations, as well as improving the analytic capacity within the laboratory settings. This may include improving automation of reporting with increased test volumes to efficiently manage throughput and staffing, or new analytic capacity to better inform the jurisdictional response efforts.
28. Is the laboratory test order and reporting activity required?
    - Yes, all activities included in the Guidance document (https://www.cdc.gov/ncezid/dpei/elc/resources.html) should be considered required with the ELC ED Expansion award.
29. I cannot find the ED Expansion performance measures, where are they located?
    - At the time the Guidance was published, the performance measures were not yet finalized. Recipients should anticipate their performance under the ED Expansion award will continue to be measured by and monitored as was done with the ELC Enhancing Detection award. Once changes are finalized for the ELC ED Expansion award, information will be shared via the ELC mailbox and a webinar will be held.
30. What elements are needed in the line level testing data reporting to CDC?
    - This includes all RT-PCR, antigen, and antibody tests and results (positives, negatives, and indeterminants), patient demographics, as well as reporting, performing and ordering facilities. For more detailed guidance please refer to standard CSV file, which ELC will share.
    - Critical data elements should be the primary focus for lab data reporting to CDC for COVID-19:
        i. Test ordered – use harmonized LOINC codes provided by CDC
        ii. Device Identifier – use if LOINC codes do not indicate device/test kit
        iii. Test result
        iv. Test Result date
        v. Accession #/Specimen ID
        vi. Age (or DOB)
        vii. Patient race

viii. Patient ethnicity
ix. Patient gender
x. Patient residence zip code
xi. Patient residence county
xii. Ordering provider name and NPI or CLIA (as applicable)
xiii. Ordering provider zip
xiv. Performing Lab name and CLIA number, if known
xv. Performing Lab zip code
xvi. Specimen Source - use appropriate LOINC, SNOMED-CT, SPM4 codes, or equivalently detailed alternative codes
xvii. Date test ordered (date format)
xviii. Date specimen collected (date format)

- "Ask On Order" questions that are highly desired are shown below. These are secondary in importance to the critical data elements above:
  i. First test (Y/N/U)
  ii. Employed in healthcare? (Y/N/U)
  iii. Symptomatic? Y/N/U and then Date of Symptom Onset (mm/dd/yy)
  iv. Hospitalized? (Y/N/U)
  v. ICU? (Y/N/U)
  vi. Resident in a long-term care facility (including skilled nursing facilities, nursing homes, long-term care for the developmentally disabled, and assisted living homes): (Y/N/U)
  vii. Pregnant? (Y/N/U)

31. Will these expectations for lab test reporting affect current reporting feeds from labs to health departments? If the state feed changes, does the originating reporting feed at the lab have to change?
    - It is possible reporting fields or feeds will be expanded to accommodate for this reporting, but please defer to your local and state health department guidance. It should result in laboratories collecting and sending more complete data, though laboratories should continue to report the most complete data they have to their jurisdictional health departments. States should include the more complete data they receive to CDC. Any changes with reporting to CDC will be handled and managed through the epidemiology and informatics sections of your health departments.
32. Our jurisdiction is having difficulty with ensuring all laboratories are reporting line-level test data (including negatives); how important is this element to our ELC activities?
    - The public health response to COVID-19 depends on having comprehensive laboratory testing data - at scale, in near real-time, and including critical geographic and demographic information, to the fullest extent as feasible and with sufficient granularity. These data will contribute to understanding disease incidence and testing coverage and may contribute to the identification of testing issues and/or supply shortages. Additionally, the ELC has several performance measures that rely on the reporting of these data. The ELC has elected to reduce the burden placed on recipients by utilizing data sources and elements where states/jurisdictions are already reporting. Without the successful line-level test data reported (see: https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html), the ELC would need to institute a separate reporting process for laboratory data.
33. Can CDC provide additional clarity on what specific activities under "Improve Surveillance and Reporting of Electronic Health Data" are considered to "enable comprehensive, automated, daily reporting to the CDC and others in a machine-readable format"?
    - This suite of activities is intended to improve the health department's access to and interoperability of many relevant data sources for visibility on the spread of disease and to increase the usefulness of all data sources. Health departments should be able to receive all data message types and have the systems, processing ability, and staffing to consume and analyze new feeds alongside existing data, such as: increased testing volumes from new sites, death registry reports, and ADT data feeds from emergency departments and urgent care clinics. Linked data should be accessible to local public health

(and the public, where possible), in a format that can be easily uploaded into commonly used analysis and visualization tools, such as ESRI, Tableau, and PowerBI.

Activities:

34. Could you elaborate on what activities are allowable under contact tracing?
    - Activities allowable under contact tracing may include:
        i. Temporary staff used for incremental tracing
        ii. Public education/awareness campaign
        iii. Contracted vendor for contact tracers and monitors
        iv. Management and supervision of trainers, as well as the conducting of training
        v. Data and software platforms needed to support the training programs
35. Are we able to obligate subcontracts before our revised budgets are submitted?
    - Yes, you are able to grant subawards at this time, so long as the activity is undertaken consistent with the Guidance and the terms of the award. Please see response to #14 above.
36. If ED Expansion is a copy of ED in REDCap, do we still report milestones and progress updates for ED?
    - We are in the midst of Quarter 2 workplan milestone progress reporting for ED. Once that ends, we will close the ED workplan monitoring portal. Starting with Quarter 3 reporting, the Community-based Surveillance, ELC CARES, and ELC Enhancing Detection workplan milestone progress reporting will cease. Recipients will only be required to report the workplan milestone progress for ELC ED Expansion as these activities cover the other prior COVID awards.

Coordinate and Engage with Partners:

37. If a jurisdiction is largely de-centralized, to what extent is the State Health Department expected to partner at the local level?
    - CDC encourages State Health Departments to continue working collaboratively with city, county, and local health departments, and other partners (e.g., academic, regional organizations) to improve capacity for addressing gaps in addressing COVID-19 within their communities (e.g., testing, outbreak investigation, infection prevention and control (IPC) practices, etc.). Providing financial resources to local health departments is strongly encouraged, where possible, to build local public health capacity.
38. What are examples of partners to consider funding when addressing health equity needs?
    - Examples of partners may include but are not limited to:
        i. Tribal affiliates and community-based organizations colleges and universities
        ii. Occupational health settings for large employers
        iii. Churches or religious or faith-based institutions
        iv. Federally Qualified Health Centers (FQHCs), including Community Health Centers (CHCs)
        v. Pharmacies
        vi. Long-term care facilities (LTCFs), including independent living facilities, assisted living centers, and nursing homes
        vii. Organizations and businesses that employ critical workforce
        viii. First responder organizations
        ix. Non-traditional providers and locations that serve high-risk populations
        x. Other partners that serve underserved populations

Other Projects:

39. We attended the webinar presented by the United States Digital Service (USDS) and are interested in participating. Can the ELC facilitate this?
    - The USDS webinar provided an overview of the three projects which will be piloted in interested jurisdictions to help with better, faster data to public health departments. The ELC is not directly involved with the projects or the decision-making process for pilot selection. It is ELC's understanding that any products developed through the pilots will be open source and available for all jurisdictions to

adopt. While you may utilize ELC resources to support a project, you will need to tie the project back to your workplan and ensure successful completion of all the required ELC Enhancing Detection Expansion activities. If you have any questions about USDS-CDC collaboration or any specific projects, please email USDS@cdc.gov.

40. For ELC COVID performance measures, where are measures E23, E24 and E25 located in the REDCap portal?
    - Measures E23, E24 and E25 are collected by the HAI/AR program via their performance measure REDCap site "HAI/AR Performance Measures 2019 - 2020 (BP1)". Recipients will be notified directly by the HAI/AR program when these measures are available on REDCap.

Appendices

A: Basic Comparison & Examples of Allowable
B: Costs Allowable Expenses At-A-Glance

ELC Enhancing Detection Expansion & Immunization CoAg COVID-19 Funding Supplementals

A: Basic Comparison & Examples of Allowable Costs

Please ensure that such funds are expended in accordance with your organization's policies and procedures and are reasonable, allocable, allowable, and necessary as per 2 CFR Part 200 and 45 CFR Part 75.

All costs must alignment to the workplan and the impact to the overall ability to complete required activities.

	ELC Enhancing Detection (ED) Expansion	Immunization & VFC Cooperative Agreement
Purpose	Provide critical resources to state, local, & territorial health departments in support of a broad range of COVID- 19/SARS-CoV-2 testing & epidemiologic surveillance related activities. Activities intended to complement activities covered through other ELC COVID resources and explicitly expand upon those strategies and activities in ELC Enhancing Detection Expansion.	Provide resources to support and strengthen critical COVID-19 immunization planning and implementation requirements and activities to ensure effective and efficient vaccination in phases 1 (a, b, and c), 2, and 3 for state, local, and territorial awardees.
Funding appropriation	Coronavirus Response and Relief Act, 2020 (P.L. 116-260)	Coronavirus Response and Relief Supplemental Appropriations Act of 2021 (P.L. 116-260)
Key Activities	All Activities are required: 1. Enhance Laboratory, Surveillance, Informatics, and other Workforce Capacity (5 Activities) 2. Strengthen Laboratory Testing (3 Activities) 3. Advance Electronic Data Exchange at Public Health Labs (1 Activity) 4. Improve Surveillance and Reporting of Electronic Health Data (6 Activities) 5. Use Laboratory Data to Enhance Investigation, Response, and Prevention (3 Activities) 6. Coordinate and Engage with Partners (2 Activities)	1. Increase COVID-19 vaccination capacity across the jurisdiction, including among high-risk and underserved populations 2. Ensure high-quality and safe administration of COVID-19 vaccines 3. Ensure equitable distribution and administration of COVID-19 vaccines 4. Increase vaccine confidence through education, outreach, and partnerships 5. Develop and implement community engagement strategies to promote COVID-19 vaccination efforts 6. Support high vaccination uptake in tribal nations 7. Use immunization information systems to support efficient COVID-19 vaccination
Amount	$19.11 billion	$3 billion
Previous COVID funding	Over $11 billion and 15 projects represented. Of this, $10.25 billion was for ELC Enhancing Detection—the guidance upon which ED Expansion builds	This is the 3rd IP19-1901 COVID supplement during budget year 2 (July 2020 - June 2021) and the 4th total IP19-1901 COVID supplement. In total between all the supplements, approximately $3.48 billion in COVID funding has been awarded to the 64 immunization jurisdictions.
Funding period	1/15/2021 - 7/31/2023	7/1/2020 - 6/30/2024
Number of recipients	64	64
Funding strategy	PHEP formula (per legislation)	PHEP formula (per legislation)
Project director	Project Directors largely from Epi and Lab	Immunization and VFC CoAg Principal Investigator which is largely the immunization program manager

	ELC Enhancing Detection (ED) Expansion	Immunization & VFC Cooperative Agreement
Engagement with local health departments	While no formula exists for the advisable level of funding to local health departments (LHD), LHD needs should be reflected within budgets. Workplans should indicate how LHD engagement will take place to successfully complete the activities. Recipients should also be able to estimate the resources provided to LHDs for quarterly reporting and highlight any barriers to relaying this support.	Allowable and encouraged. LHD needs should be reflected within budgets. Workplans should indicate how LHD engagement will take place to successfully complete the activities. Recipients should also be able to estimate the resources provided to LHDs for quarterly reporting and highlight any barriers to relaying this support.
Mandate to support local health departments at a specified level	No, however, budgets and workplans should reflect how LHD needs will be addressed through these resources. Recipients should also be able to estimate the resources provided to LHDs for quarterly reporting and highlight any barriers to relaying this support.	No, however, LHD and partners work plans must include activities and deliverables to meet vaccination needs of their community.
Financial reporting	Monthly reporting via REDCap & GrantSolutions	Monthly reporting via REDCap & GrantSolutions
Progress on activities reporting	Quarterly reporting via REDCap. Includes updates to Jurisdictional Testing and Contact Tracing/Case Investigation plans	Quarterly through REDCap
Performance measure reporting	Quarterly, through REDCap, but reporting frequency may be adjusted	Quarterly, through REDCap, but reporting frequency may be adjusted
Reimbursement of allowable costs	Officially allowable but activities supported would largely fall upon award/post-award. Prior incurred costs would need to be associated with activities in the workplan. Charges not related to the workplan activities may result in the health department having to pay the money back.	Allowable
Restrictions	Research as defined by CDC, clinical care (except as may be allowed by law), purchasing vaccines, and major construction (e.g., new building, modification of more than 50% of structure, etc.) are not allowed. Renovations and minor construction (e.g., modification of less than 50% of structure, concrete slabs for modular labs/generators, etc.) are allowable.	Research as defined by CDC, clinical care (except as may be allowed by law), purchasing vaccines, and major construction (e.g., new building, modification of more than 50% of structure, etc.) are not allowed. Renovations and minor construction (e.g., modification of less than 50% of structure, concrete slabs for modular labs/generators, etc.) are allowable.
Of note: Allowable, allocable, reasonable; and consistent with the appropriation, grant regulations, grant terms and conditions	Resources to complement, but not duplicate, other CDC vaccine delivery efforts (e.g., those activities covered under IP19-1901). Costs can include infrastructure needs (e.g. staff, contractors, call centers, storage, space, etc.) that support testing as well as vaccination operations.	Resources to complement, but not duplicate, other CDC vaccine delivery efforts (e.g., those activities covered under IP19-1901). Costs can include infrastructure needs (e.g., staff, contractors, call centers, storage, space, etc.) that support testing as well as vaccination operations.

ELC Enhancing Detection Expansion & Immunization CoAg COVID-19 Funding Supplementals

B: Allowable Expenses At-A-Glance

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
Personnel (term, temporary, students, overtime, contract staff, etc.)	**Laboratorians**	Yes	No
	Informaticians	Yes	Yes
	Epidemiologists	Yes	Yes
	Data Entry Clerks, managers/analysists	Yes	Yes
	Data Visualization Specialists	Yes	Yes
	Vaccine registry data manager	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
	Health Communicators (including those specializing in risk comms.)	Yes	Yes
	Health Educators	Yes	Yes
	Management, budget, & administrative support	Yes	Yes
	Infection Prevention & control staff	Yes	Yes, may be allowable if the position is responsible for vaccine-related work
	Community Health Workers & organizations working with populations at higher risk for COVID-19	Yes	Yes
	Security staff (for personnel and clinic settings)	Yes	Yes
	Nurses or other staff used to administer vaccine	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
Equipment	**Laboratory equipment & necessary maintenance contracts at PHL (includes state PHLs that are affiliated with clinical or academic institutions)**	Yes	May be allowable if support is not available through the ELC CoAg.

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
Equipment	**Laboratory equipment & necessary maintenance contracts at local or regional PHLs**	Yes, to the extent that equipment is necessary to successfully complete the Activities listed in the guidance, resources (e.g. equipment) may be purchased. Disposition of these items, including any reporting on their location/condition, is the responsibility of the prime recipient of funds & must be in accordance with grant regulations and OGS policies.	Yes, to the extent that equipment is necessary to successfully complete the Activities listed in the guidance, resources (e.g. equipment) may be purchased. Disposition of these items, including any reporting on their location/condition, is the responsibility of the prime recipient of funds and must be in accordance with grant regulations and OGS policies. Equipment may include items such as vaccine storage units.
	General equipment (generators, freezers, computers)	Yes	Yes, may be allowable as they support COVID- 19 vaccine administration & reporting
	Vaccine storage equipment & necessary maintenance contracts	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
	Hardware/software necessary for robust implementation of electronic laboratory & surveillance data exchange between recipient & other entities (e.g. healthcare entities, jurisdictional public health, & CDC)	Yes	Yes
	Hardware/software that may be used to assist with case investigation & contact tracing	Yes	No
	Equipment necessary to ensure safety of laboratory workers (e.g. BSCs, HVAC, etc.)	Yes	No
Supplies	**Collection supplies, test kits, reagents, consumables & other necessary supplies for existing testing or onboarding new platforms**	Yes	May be allowable if support is not available through the ELC CoAg.
	Collection supplies, test kits, reagents, consumables & other testing or onboarding new platforms at regional or local health departments	Yes	May be allowable if support is not available through the ELC CoAg.
	Ancillary supplies & consumables necessary to perform testing for SARS-CoV-2 within or outside of traditional PHL setting	Yes	May be allowable if support is not available through the ELC CoAg.
	PPE for laboratorians or other staff conducting sample collection or	Yes	May be allowable if support is not available through the ELC CoAg.

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
Supplies	**processing. Also includes PPE for general staff as needed & deemed necessary by the work conditions**		
	PPE for use during vaccine	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
Software	**Software or systems to assist with laboratory resource management (e.g. software for inventory management, temperature notifications, etc.), quality management, biosafety, or training needs**	Yes	Yes, as it applies to vaccine management and Immunization Information Systems
	Software/hardware necessary for robust implementation of electronic laboratory and surveillance data exchange between recipients and other entities, jurisdictional public health & CDC	Yes	Yes, as it applies to vaccine management and Immunization Information Systems
	Tools that assist in the rapid identification, electronic reporting, monitoring, analysis, & evaluation of control measures to reduce the spread of disease (e.g. GIS software, visualization dashboards, cloud services, etc.)	Yes	Yes, as it applies to vaccine management and Immunization Information Systems
	Software or applications that allow for more efficient case investigation & contact tracing	Yes	No
	Software associated with vaccine registries or tracking of vaccine	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
	Vaccine Registry enhancements	Enhancements to registries already initiated with ELC resources may be completed if it does not interfere with the successful completion of all required activities; however, these should be considered one-time system improvements. The ELC will not be able to maintain the costs of these systems or upgrades.	Yes
Construction & Renovation	**Renovations & minor construction (e.g. alteration of less than 50% total square footage of an existing structure, installation of a concrete**	Yes, may be considered for unique cases where conditions do not currently allow for safe or effective testing and/or delivery of effective public health services.	Yes, on a case by case basis and as it relates to vaccines or vaccination activities.

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
	slab for modular laboratory units, etc.)		
Vehicles	**Leasing/purchasing vehicles (e.g. mobile testing, providing public health services in underserved areas, etc.)**	Yes, recipients will need to submit quotes with their revised budgets that are due within 60 days of award issuance and receive prior approval from OGS. After the revised NOA is issued, any further request for leasing/purchasing must be made through GrantSolutions and include the necessary quotes. Vehicles already purchased or leased for the purpose of testing may also be utilized for vaccine delivery	Leasing and rentals allowable, however, purchase is not
Quarantine & Isolation	**Quarantine & isolation support necessary for preventing the spread of COVID-19 (including wraparound services such as hoteling, food, laundry, mental health services, etc.)**	Yes, and may include wraparound services but not medical costs associated with treatment.	No
	Medication & patient treatment	No	No
Outreach & Education	**Expenses associated with outreach & assistance (e.g. support provided through community-based organizations) for those at higher risk of COVID-19**	Yes, these may include but are not limited to organizations that work with tribes, individuals experiencing homelessness, and racial and ethnic minority populations.	Yes, these may include but are not limited to organizations that work with tribes, individuals experiencing homelessness, and racial and ethnic minority populations.
	Health communications materials & health education services to inform & protect communities	Yes, health communications materials & health education services to inform & protect communities are allowable, if they do not duplicate activities covered by other CDC funding mechanisms (e.g., IP21-2106, IP21-2107). Recipients are reminded to be cognizant of the statutory & policy requirements for acknowledging the HHS/CDC funding when issuing statements, press releases, publications, requests for proposal, bid solicitations & other documents. In accordance with CDC General Terms & Conditions for Non-research Awards - Acknowledgement of Federal Funding, in your base award.	Yes, health communications materials & health education services to inform & protect communities are allowable, if they do not duplicate activities covered by other CDC funding mechanisms (e.g., IP21-2106, IP21-2107). Recipients are reminded to be cognizant of the statutory & policy requirements for acknowledging the HHS/CDC funding when issuing statements, press releases, publications, requests for proposal, bid solicitations & other documents. In accordance with CDC General Terms & Conditions for Non-research Awards - Acknowledgement of Federal Funding, in your base award.
	Support for social services & health education efforts that will facilitate compliance with isolation & quarantine and/or case investigation & contact tracing efforts	Yes	Yes, as it relates to vaccination activities
	Mass vaccination campaigns	Aspects of this activity may be supported if not already covered by another source.	Yes

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
Stipends & Incentives	**Incentives to encourage participation by individuals (e.g., have testing done) or by a facility (e.g., onboard ELR for timely reporting of results)**	Stipends/incentives may be considered to encourage participation in testing and/or vaccination coverage for those put at higher risk for COVID-19 (individual level) or for facilities/agencies to enroll and/or report data to the health department (institutional level). Recipients interested in exploring this option (individual and/or institutional) must submit a plan that covers all of the following elements: (a) justification, (b) cost savings [e.g., how it will defray costs or have a positive return on investment], (c) defined amount, (d) qualifications for issuance, & (e) method of tracking. When submitting the revised budget within 60 days of award issuance, stipend/incentive plans must be included in the 'budget justification' section of the ELC budget workbook and receive CDC approval before implementation. After the revised NOA is issued, any subsequent requests for using funds to support stipends/incentives must be made in GrantSolutions, including the stipend/incentive plan, and receive CDC approval before implementation.	No, but please also speak with your POB Project Officer.
Contracts	**Contracts with academic institutions, private laboratories, other non-commercial healthcare entities, and/or commercial entities**	Yes	Yes, as it relates to vaccines or vaccination activities
	Contracts (or mini grants) with local or regional health departments	Yes	Yes
	Courier service (new or expansion of existing agreements)	Yes	Yes
	Contracts to support testing at non-traditional testing sites or POC tests	Yes	No
	Contracts to support testing at clinical, private, or academic institutions	Yes	No
Social Services	**Support for social services and health education efforts that will facilitate compliance with isolation & quarantine and/or case investigation & contact tracing efforts**	Support for social services & health education efforts that will facilitate compliance with isolation & quarantine and/or case investigation & contact tracing efforts.	Support for social services & education efforts that support vaccination activities.

12 Things States Need to Know about the Vaccine Adverse Event Reporting System (VAERS)

The federal government takes all reports of vaccine adverse events seriously, and CDC and the U.S. Food and Drug Administration (FDA) are actively engaged in safety monitoring of COVID-19 vaccines. CDC uses numerous vaccine safety monitoring systems, including VAERS, to watch for adverse events (possible side effects) after vaccination.

Q. What is the Vaccine Adverse Event Reporting System?

After a vaccine has been authorized or approved by the FDA, post-approval monitoring using VAERS begins. VAERS is a national system used by FDA and CDC to collect reports of adverse events that happen after vaccination. VAERS can provide vaccine safety experts with valuable information to assess possible safety concerns. VAERS is especially useful for quickly detecting unusual or unexpected patterns of adverse event reporting that might signal a possible safety problem with a vaccine.

Q. Who can report post-vaccination adverse events to VAERS?

Anyone can submit a report to VAERS. Healthcare professionals, health departments, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine are encouraged to submit a VAERS form if they experience any adverse events after getting any vaccine.

Q. What do CDC and FDA do when a VAERS report is submitted?

Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. All serious reports are reviewed daily by vaccine safety experts. Scientists at CDC and FDA use statistical models to help understand whether there are any safety signals for a vaccine product and compare them with safety signals for other vaccines to determine if further investigation is needed.

Helpful Hints for States:

- Work with your communications team when considering developing statements about reporting adverse events after COVID-19 vaccination.
- Each state has a vaccine safety coordinator who can serve as a liaison with local health departments, providers, and partners on vaccine safety issues.
- CDC staff is available to provide state and local health departments with technical support and communications around adverse events after COVID-19 vaccination.
- Contact COVID19VaxSafety@cdc.gov to reach CDC for non-urgent matters. For urgent matters, call **(770) 488-7100** to reach the CDC Emergency Operations Center.

Q. When does CDC follow up on reports submitted to VAERS?

VAERS staff obtains follow-up medical records for reports classified as serious. A serious report describes an event that resulted in permanent disability, hospitalization, life-threatening illness, or death. VAERS staff may also obtain follow-up medical records for adverse events of interest, like anaphylaxis. Reviewing these records can help CDC and FDA medical staff better understand cases.

www.cdc.gov/coronavirus/vaccines

MS-DOH-21-1816-A-000507

CS322534-A 02/03/21

Q. Will CDC follow up with people who submit VAERS reports?

The person who submits a VAERS report will receive a confirmation that VAERS has received the report or a reminder if important information was left out of the initial report. If additional information is needed, CDC may reach out to healthcare providers relevant to the case.

Q. What happens when a death is reported to VAERS?

When a death is reported to VAERS, CDC obtains medical records about the person's death, including an autopsy report, if available. If no autopsy was performed, CDC will obtain a death certificate and other relevant medical records. VAERS scientists will **not** reach out to the person who submitted the report, unless the name of the hospital or vaccination provider is **not** included.

Q: Do CDC and FDA provide VAERS reporters with an assessment following reports of serious adverse events, including death?

No. One of the limitations of VAERS is that VAERS generally cannot assess causality. However, as a hypothesis-generating system, VAERS is valuable for identifying potential vaccine safety concerns that can be studied further.

Q. Who are vaccine safety coordinators?

Vaccine safety coordinators are public health officials at jurisdiction health departments that serve as CDC's "eyes and ears" on vaccine safety issues and coordinate with CDC on incident response. They also serve as primary educators for vaccine safety reporting at the state and local level and coordinate local efforts to report vaccine adverse events to VAERS.

Q. What information from VAERS does CDC make available to vaccine safety coordinators each week?

Each week, CDC makes available via Epi-X a summary of VAERS reports received within the jurisdiction in the last week and a summary of VAERS data from other jurisdictions. CDC also sends a daily email notification whenever VAERS receives death reports from the jurisdiction. These reports are available via Epi-X.

Q. Do we need to follow up on VAERS reports filed in our jurisdiction?

Public health jurisdiction staff does **not** need to follow up on VAERS reports. VAERS staff will routinely follow up to obtain medical records for all reports of serious adverse events or death.

Q. When should we consider contacting CDC about COVID-19 vaccine adverse event reports?

Vaccine safety coordinators, immunization program managers, and other health department staff are welcome to contact CDC about vaccine safety issues at any time. Consider contacting CDC about:

- Unusual or unexpected vaccine adverse event reports
- Clusters of adverse events
- Vaccine administration errors
- Events that may impact public confidence in vaccination programs
- CDC laboratory and/or pathology support
- Requests for investigation by high-ranking state or local health officials
- Adverse event reports that may generate an increased level of media attention

Q. How can we contact CDC if there is an emergency relating to COVID-19 vaccine safety?

For public health emergencies, jurisdictions and providers may call the CDC Emergency Operations Center at **(770) 488-7100**.
For non-urgent concerns, jurisdictions and providers may email covid19vaxsafety@cdc.gov. For medical emergencies call **911**.

MS-DOH-21-1816-A-000508

From:	Byers, Paul
To:	Dobbs, Thomas E; Central Office Epi COVID Team; Craig, Jim; Broom, Sarah; Pearson, Meg; Smith, Elisabeth
Subject:	FW: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)
Date:	Tuesday, January 11, 2022 4:27:00 PM
Attachments:	image001.png image002.png N95 effectiveness as source control .pdf PARTNER ALERT CDC Expands Booster Shot Eligibility.msg COVID-19 Partner Updates January 10 2022.msg HHS Therapeutics Projected Allocations_7 Jan 2022.pdf HHS Update COVID-19 allocation projections for January .pdf Lindsley-2021-A comparison of performance metr.pdf Lindsley-2021-Efficacy of face masks, neck gai.pdf

Please see updates.

Paul Byers, MD
State Epidemiologist

From: CSTE Emergency Response <Preparedness@cste.org>
Sent: Tuesday, January 11, 2022 4:17 PM
To: CSTE Emergency Response <Preparedness@cste.org>
Cc: CSTE Novel Coronavirus 2019 <CSTEncov2019@cste.org>
Subject: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Partner Alert: N95 Effectiveness as Source Control [Attachments]
    - Today, **Tuesday, January 11**, CDC issued a partner update (attached) in response to numerous questions about N95 mask effectiveness as source control. The update shared two peer reviewed publications from National Institute for Occupational Safety and Health (NIOSH) researchers (both attached) on N95 mask effectiveness, including findings that a N95 respirator was 99% effective at blocking cough aerosols.

HHS Update: COVID-19 Allocation Projections for January [Attachments]

- On **Friday, January 7**, the U.S. Department of Health and Human Services (HHS) issued an update with a projected calendar of allocation amounts and cadence of COVID-19 therapeutics for the remainder of January (attached). Questions may be directed to us COVID19Therapetuics@hhs.gov.

- Partner Alert: CDC Expands Booster Shot Eligibility [Attachment, Link]
  - On **Saturday, January 6**, CDC issued a partner alert (attached) adjusting its recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months. CDC has extended this recommendation to recipients of a Moderna primary series. This means that people 12 years of age and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.
- CDC COCA Call: What Clinicians Need to Know About the New Oral Antiviral Medications for COVID-19 [Links]
  - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **tomorrow, Wednesday, January 12 at 2:00 pm EST** to discuss the recent emergency use authorizations (EUAs) for new oral antiviral medications intended to decrease hospitalizations, as well as prevent severe COVID-19 and death Call information is below:
    - Weblink: https://www.zoomgov.com/j/1612974214?pwd=VitYMEorako1YWhCaXpnaWdsc2Ixdz09
      Telephone: (660) 254-5252 or (646) 828-7666 or (669) 216-1590 or (551) 285-1373
      Webinar ID: 161 297 4214
      Passcode: 180866
      Post-Event Recording:
      https://emergency.cdc.gov/coca/calls/2021/callinfo_011222.asp
- Reminder: CDC Preventive Medicine Grand Rounds: "The Public Health System of the Future – Moving Ahead in Partnership with Health Care & Other Sectors" [Link]
  - CDC will host its monthly Preventive Medicine Grand Rounds **tomorrow, Wednesday, January 12** at **1:30 pm EST**. The session will focus on the public health system of the future and the speaker is John Auerbach, Director of Intergovernmental and Strategic Affairs for CDC. Continuing education (CE) is available at no cost. Registration information is available here.

Standing Updates

- CDC Partner Update – January 10 [Attachment]
  - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – January 10 [Link]
  - Please click here for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.

- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
  - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am ET**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
  - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
  - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Monday, January 10, 2022 4:53 PM EST
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>
Subject: COVID-19 Partner Updates: January 10, 2022

Good afternoon Partners,
Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC at eocevent424@cdc.gov. Thank you for your partnership.

January 10, 2022

Morbidity and Mortality Weekly Report (MMWRs)

- Effectiveness of BNT162b2 (Pfizer-BioNTech) mRNA Vaccination Against Multisystem Inflammatory Syndrome in Children Among Persons Aged 12–18 Years — United States, July–December 2021. Link here.
- Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 years — United States, March 1, 2020–June 28, 2021. Link here.
- Risk Factors for Severe COVID-19 Outcomes Among Persons Aged ≥18 Years Who Completed a Primary COVID-19 Vaccination Series — 465 Health Care Facilities, United States, December 2020–October 2021. Link here.
- Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021. Link here.

CDC Resources

New & Updated

- CDC Recommends Moderna Booster at 5 Months: On January 4th, CDC made this recommendation for recipients of a Pfizer-BioNTech primary series. After FDA action on January 7th, we're extending this recommendation to recipients of a Moderna primary series. This means that people who initially received an mRNA vaccine series——two doses of Moderna or Pfizer-BioNTech —can now receive an mRNA booster shot 5 months after completing their initial series.
- Guidance for COVID-19 Prevention in K-12 Schools was recently updated to reflect new recommendations for isolation for people with COVID-19 and recommendations for people who have come into close contact with a person with COVID-19.
- CDC Expands Booster Shot Eligibility and Strengthens Recommendations for 12-17 Year Olds: CDC now recommends that adolescents age 12 to 17 years old should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccination series.
- CDC Recommends Pfizer Booster at 5 Months, Additional Primary Dose for Certain Immunocompromised Children: On January 4th, CDC updated its recommendation for when many people can receive a booster shot, shortening the interval from 6 months to 5 months for people who received the Pfizer-BioNTech COVID-19 Vaccine.
- Stay Up to Date with Your Vaccines: To align with standard language CDC uses about other vaccinations, CDC is now using the phrase "up to date" when talking about COVID-19 vaccination. CDC recommends that individuals stay "up to date" by receiving any additional doses they are eligible for, according to CDC's recommendations, to ensure they have optimal protection against COVID-19. The technical definition of "fully vaccinated"—two doses of an mRNA vaccine or one dose of the J&J vaccine—has not changed.
- What We Know About Quarantine and Isolation provides information on why CDC shortened quarantine and isolation guidance for the general population.

School and Work

- Guidance for COVID-19 Prevention in K-12 Schools
- Overview of COVID-19 Isolation for K-12 Schools
- Overview of COVID-19 Quarantine for K-12 Schools
- What you Should Know About COVID-19 Testing in Schools
- Responding to COVID-19 Cases in K-12 Schools: Resources for School Administrators
- Schools, Child Care, and Colleges
- Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2
- Strategies to Mitigate Healthcare Personnel Staffing Shortages
- School Learning Modalities (HHS Protect Public Data Hub)

Community

- Communication Resources for Travelers
- CDC COVID-19 Travel
- 12 COVID-19 Vaccination Strategies for Your Community
- Find a COVID-19 vaccine near you: Vaccines.gov
  - Individuals in the U.S. can utilize a text messaging service to locate vaccine locations, available in both English and Spanish. Individuals can text their ZIP code to 438829 (GETVAX) and 822862 (VACUNA) to find three locations nearby that have vaccines available.

Science and Data

COVID-19 Variants

- Science Brief: Omicron (B.1.1.529) Variant provides an overview of the current scientific information regarding the Omicron (B.1.1.529) variant. New data continue to emerge, and recommendations will be updated periodically, as needed.
- Omicron Variant: What You Need to Know provides information on what is currently known about the Omicron (B.1.1.529) variant.
- What You Need to Know About Variants

COVID-19 Testing Guidance

- Testing Strategies for SARS-CoV-2 describes and compares different types of testing strategies for SARS-CoV-2.
- Self-Testing provides information on when, why, and how to use a self-test for COVID-19.

Influenza (flu) Guidance

- Increasing Seasonal Influenza A (H3N2) Activity, Especially Among Young Adults and in College and University Settings, During SARS-CoV-2 Co-Circulation
- FAQ: CDC Distribution of COVID-19 Assays
- CDC Digital Media Toolkit: 2021-22 Flu Season

COVID-19 Vaccines

- CDC Endorses ACIP's Updated COVID-19 Vaccine Recommendations
- CDC Expands COVID-19 Booster Recommendations to 16-and-17-year-olds
- COVID-19 Vaccine Booster Shots
- COVID-19 Vaccines for Children and Teens
- COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19: CDC strongly recommends COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.
- Science Brief: Evidence Used to Update the List of Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19
- Quick Conversation Guide on COVID-19 Vaccines for Children
- Resources to Promote the COVID-19 Vaccine for Children & Teens
- Using the COVID-Vac Tool to Assess Your COVID-19 Vaccination Clinic Staffing and Operations Needs

References to non-CDC sites are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites. URL addresses listed were current as of the date of publication.

Kind regards,

Shyonna Johnson, MPH (She/Her)
STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
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CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

DRAFT – PRE-DECISIONAL & DELIBERATIVE

Therapeutic Allocation

	Drug Class	Allocation Cadence	Sweep Schedule	Allocation Jan 3	Planned Allocation Jan 10	Planned Allocation Jan 17	Planned Allocation Jan 24	Planned Allocation Jan 31
Paxlovid *Pfizer*	Oral antiviral	Bi-Weekly	N/A	0	100,000	0	100,000	0
Molnupirivir *Merck*	Oral antiviral	Bi-Weekly	N/A	0	400,000	0	400,000	0
Evusheld *AstraZeneca*	Monoclonal for prevention	Weekly	N/A	50,000	75,000	75,000	75,000	75,000
Sotrovimab *GSK/Vir*	Monoclonal for treatment	Weekly	N/A	50,000	52,250	52,250	52,250	52,250
Bamlanivimab/ Etesevimab *Lilly*	Monoclonal; omicron resistance	Weekly	Weekly; Saturday	45,000	**45,000*	**45,000*	**45,000*	**45,000*
REGEN-COV *Regeneron*	Monoclonal, omicron resistance	Weekly	Weekly; Saturday	55,000	**55,000*	**55,000*	**55,000*	**55,000*
Remdesivir *Gilead*	IV antiviral	N/A; Commercial Market	N/A	N/A	N/A	N/A	N/A	N/A

** With the rise of the omicron variant, clinically appropriate use should be considered for bam/ete and REGEN-COV. Allocations of these products are subject to change based on omicron prevalence data.*

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From: ASPR Stake Holder (OS/ASPR) <ASPRStakeholder@hhs.gov>
Sent: Friday, January 7, 2022 5:41:02 PM
Subject: HHS Update: COVID-19 allocation projections for January

Dear State and Territorial Health Officials,

Thank you for your continued partnership in this all-of-America approach to fighting the COVID-19 pandemic. It remains our goal to facilitate a fair and equitable process in the allocation of COVID-19 therapeutics, and we certainly couldn't do this without you. We know that providing a longer look ahead for expected allocation amounts will help further support your jurisdictional planning. As such, attached is a projected calendar of allocation amounts and cadence for the remainder of January. Of course, the COVID-19 environment is very dynamic; so, these projections could change based on daily analysis of related data.

Additionally, we wanted to provide you with an update regarding Gilead's product - VEKLURY(tm) (remdesivir), which is not allocated by the federal government but is available commercially. Following the recent statement from the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel regarding therapies for the COVID-19 Omicron variant, CMS created HCPCS code J0248 for the VEKLURY(tm) (remdesivir) antiviral medication when administered in an outpatient setting. This code is available for use by all payers and is effective for dates of service on or after December 23, 2021:

* Long descriptor: Injection, remdesivir, 1 mg
* Short descriptor: Inj, remdesivir, 1 mg

Medicare Administrative Contractors (MACs) determine Medicare coverage when there is no national coverage determination, including in cases when providers use FDA-approved drugs for indications other than what is on the approved label. The MACs consider the major drug compendia, authoritative medical literature and accepted standards of medical practice to determine medical necessity when considering coverage. Therefore, the MACs will determine Medicare coverage for HCPCS code J0248 for VEKLURY(tm) (remdesivir) administered in an outpatient setting.

Thank you, again, and please contact us at COVID19Therapetuics@hhs.gov with any questions.

Regards,
HHS - Coordination Operations and Response Element (H-CORE)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Aerosol Science and Technology

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/uast20

A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols

William G. Lindsley, Francoise M. Blachere, Donald H. Beezhold, Brandon F. Law, Raymond C. Derk, Justin M. Hettick, Karen Woodfork, William T. Goldsmith, James R. Harris, Matthew G. Duling, Brenda Boutin, Timothy Nurkiewicz, Theresa Boots, Jayme Coyle & John D. Noti

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AEROSOL SCIENCE AND TECHNOLOGY
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A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols

William G. Lindsley[a], Francoise M. Blachere[a], Donald H. Beezhold[a], Brandon F. Law[a], Raymond C. Derk[a], Justin M. Hettick[a], Karen Woodfork[b,c], William T. Goldsmith[b,c], James R. Harris[d], Matthew G. Duling[d], Brenda Boutin[d], Timothy Nurkiewicz[a,b,c], Theresa Boots[a], Jayme Coyle[a], and John D. Noti[a]

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ABSTRACT

Universal mask wearing is recommended to help control the spread of COVID-19. Masks reduce the expulsion of aerosols of respiratory fluids into the environment (called source control) and offer some protection to the wearer. Masks are often characterized using filtration efficiency, airflow resistance, and manikin or human fit factors, which are standard metrics used for personal protective devices. However, none of these metrics are direct measurements of how effectively a mask blocks coughed and exhaled aerosols. We studied the source control performance of 15 cloth masks (face masks, neck gaiters, and bandanas), two medical masks, and two N95 filtering facepiece respirators by measuring their ability to block aerosols $\leq$7 µm expelled during simulated coughing and exhalation (called source control collection efficiency). These measurements were compared with filtration efficiencies, airflow resistances, and fit factors measured on manikin headforms and humans. Collection efficiencies for the cloth masks ranged from 17% to 71% for coughing and 35% to 66% for exhalation. Filtration efficiencies for the cloth masks ranged from 1.4% to 98%, while the fit factors were 1.3 to 7.4 on headforms and 1.0 to 4.0 on human subjects. The Spearman's rank correlation coefficients between the source control collection efficiencies and the standard metrics ranged from 0.03 to 0.68 and were significant in all but two cases. However, none of the standard metrics were strongly correlated with source control performance. A better understanding of the relationships between source control collection efficiency, filtration efficiency, airflow resistance, and fit factor is needed.

ARTICLE HISTORY
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EDITOR
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Introduction

Humans infected with SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), can produce droplets and aerosols of respiratory fluids containing the virus when they cough, breathe, talk, sing and sneeze (Anderson et al. 2020; CDC 2020b; Hamner et al. 2020; Ma et al. 2020; Morawska and Milton 2020). To reduce the transmission of SARS-CoV-2, public health agencies have recommended that the general public wear cloth masks (CDC 2020c, 2020d, 2021; Edelstein and Ramakrishnan 2020; WHO 2020). The primary purpose of masks (which in this article includes face masks, neck gaiters, bandanas and other face coverings) is to block the expulsion of infectious droplets and aerosols from the wearer into the environment (called source control) and thereby reduce the exposure of other people to the virus (CDC 2020a). Laboratory studies using manikins and human subjects have shown that cloth face masks can partially block respiratory aerosols produced during coughing, breathing and talking (Asadi et al. 2020; Davies et al. 2013; Lindsley et al. 2021; Pan et al.

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2021). Wearing medical face masks (i.e., "surgical masks" as defined by the U.S. Food and Drug Administration [FDA 2004]) reduces the dispersion of potentially infectious aerosols from patients with respiratory infections (Leung et al. 2020; Milton et al. 2013). Masks may also provide some personal protection to the wearer by reducing their exposure to infectious droplets and aerosols produced by others, although they are not as effective as a respiratory protective device such as a NIOSH-approved N95 filtering facepiece respirator (N95 respirator) (CDC 2020a; Lawrence et al. 2006; Oberg and Brosseau 2008; Pan et al. 2021). Several community level studies have shown that universal masking helps reduce the spread of COVID-19 (CDC 2020a). For example, a comparison of counties in the US state of Kansas found that mask mandates were associated with lower incidence rates of COVID-19 (Van Dyke et al. 2020). A study of 10 US states found that statewide mask mandates were associated with a decline in weekly COVID-19–associated hospitalization growth compared to states without such mandates (Joo et al. 2021).

In response to the need for source control devices for the general public, manufacturers worldwide have produced a broad array of masks. Unfortunately, because of the many different designs and construction materials, it is not possible to predict how well a particular mask will perform as a source control device without testing, which is rarely done for non-medical masks not intended for occupational use. Although general guidelines have been developed (CDC 2020d), it is very difficult for public health organizations, governments, medical facilities, and the general public to know which of the available devices are most effective.

Test methods and performance standards do exist for regulated medical face masks and respiratory protective devices (Rengasamy et al. 2017). In the United States, respiratory protective devices, which are devices such as N95 filtering facepiece respirators that are intended to protect the wearer from airborne particles, must be approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 Code of Federal Regulations (CFR) Part 84 (NIOSH 1995). The approval process includes testing the filtration efficiency for the most-penetrating aerosol particle size and measuring the airflow resistance of the device (NIOSH 2019). Medical face masks that are not intended to be used as respiratory protective devices are cleared by the Food and Drug Administration (FDA), which reviews manufacturer-supplied information on filtration efficiency, airflow resistance, resistance to fluid penetration and flammability (FDA 2004). The FDA recommends that manufacturers use the ASTM standards F2299 for measuring particle filtration efficiency through the mask material using latex microspheres (ASTM 2003), and the F2101 Standard test method of evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of *Staphylococcus aureus* (ASTM 2019). Bacterial filtration efficiency can also be measured with the modified Greene and Vesley method using human test subjects (Greene and Vesley 1962; Quesnel 1975).

In addition to filtration performance, how well a respiratory protective device protects the wearer depends upon how well the device fits the face and whether the seal between the face and the device has gaps or leaks (Lawrence et al. 2006). ASTM Standard F3407-20 outlines procedures for testing respirators using a bivariate panel of human test subjects with different facial dimensions (ASTM 2020). The NIOSH approval test for respirators measures the filtration properties but does not include tests of how well the device fits faces of different shapes, although this has been proposed. Consequently, in the United States, when a worker is required to wear a respirator, the Occupational Safety and Health Administration (OSHA) requires that a respirator fit test be performed annually for each worker to determine how well the respirator protects the worker (OSHA 2020). Quantitative fit tests measure the aerosol particle concentration inside and outside the respirator during a series of exercises, and this information is used to calculate the fit factor (outside concentration/inside concentration) (Janssen and McKay 2017). The minimum acceptable fit factor for a respirator depends upon the exposure level and potential health consequences of the hazards to which the worker may be exposed (OSHA 2020).

The existing test methods for respirators and medical face masks provide a possible basis for developing standards for non-medical masks used as source control devices. The American Association of Textile Chemists and Colorists (AATCC) published guidelines for cloth face coverings that include the use of ASTM F2299 and other national and international performance standards (AATCC 2020). Leith, L'Orange, and Volckens (2021) proposed an estimated mask protection factor that is calculated based on tests of filtration efficiency and fit and on estimates of the average time spent speaking, inhaling, and exhaling. ASTM International has released a standard for testing barrier face coverings that includes tests of filtration efficiency and airflow resistance, and an assessment of leakage, which are standard metrics that are commonly used to test personal protective devices (ASTM 2021). The use of these standard performance metrics has many advantages, most notably that the equipment and procedures needed to conduct the tests are widely available. However, none of these metrics are

Table 1. Performance metrics used in this study. Outward mask airflow is in the direction of exhalation. Inward airflow is in the direction of inhalation.

Performance metric	**Parameter measured**	Mask airflow direction	Measurement instrument	**Measurement method**	Particle size	**Instrument airflow rate (liters/minute)**
Cough aerosol collection efficiency	Aerosol mass escaping beyond mask into collection chamber	Outward	Andersen impactor	Fluorescence of aerosol on impactor stages	0.1 to 7 μm	28.3
Exhaled aerosol collection efficiency	Aerosol mass escaping beyond mask into collection chamber	Cyclical	Andersen impactor	Fluorescence of aerosol on impactor stages	0.1 to 7 μm	28.3
Filtration efficiency	Aerosol mass concentration upstream & downstream of mask	Inward	TSI 8130 A	Photometer	75 nm count median diameter (GSD 1.86)	85
Airflow resistance	Pressure required for 85 lpm flow	Inward	TSI 8130 A	Manometer	n/a	85
Manikin fit factor	Aerosol particle count inside & outside mask	Cyclical	TSI PortaCount	Size classifier & condensation particle counter	55 nm (N95 mode)	0.35
Human fit factor	Aerosol particle count inside & outside mask	Cyclical	TSI PortaCount	Size classifier & condensation particle counter	55 nm (N95 mode) 0.02–1.0 μm (Class 100 mode)	0.35

direct measurements of the ability of a mask to block aerosols expelled during coughing and exhalation. To assist in the further development of these types of standards and guidelines, the relationship between the efficacy of masks as source control devices and their performance using standard metrics needs to be better understood. For example, it is possible to measure the filtration efficiency of the mask material, but it is not clear how that filtration efficiency translates to source control efficacy or what minimum performance level should be required.

The purpose of this study was to compare the performance of a variety of N95 respirators, medical masks, and cloth masks as source control devices with their filtration efficiencies, airflow resistances, fit factors measured using manikin headforms, and fit factors measured on humans. The results of these experiments will assist in the development of appropriate test methods and standardized performance metrics to evaluate the efficacy of cloth masks as source control devices for respiratory aerosols.

Materials and methods

Experimental design

A source control measurement system was used to assess the efficacy of N95 respirators, medical masks, and cloth masks as source control devices. The source control performance was determined by measuring the source control collection efficiency of the mask, which is the fraction of the mass of the coughed or exhaled test aerosol particles that were blocked by the mask from reaching the collection chamber. The filtration efficiencies and airflow resistance of the construction materials were measured using a modified version of the test method used for respirator approvals. Fit tests were performed both on a manikin headform with pliable skin and with human test subjects. The source control collection efficiencies were then compared with the fit factors, filtration efficiencies and airflow resistances measured on the same devices. A summary of the performance metrics used in the study is shown in Table 1.

Respiratory aerosol source control measurement system

The efficacy of respirators, medical masks, and cloth masks as source control devices for aerosols produced during coughing and exhalation was determined using a respiratory aerosol source control measurement system described previously (Lindsley et al. 2021). The system includes a coughing and breathing aerosol simulator, a manikin headform, an 136 L aerosol collection chamber, and a cascade impactor (Figure 1). The manikin headform used in the study has pliable skin that mimics the elastic properties of human skin in order to create a realistic simulation of how each source control device would fit a human face (Bergman et al. 2014).

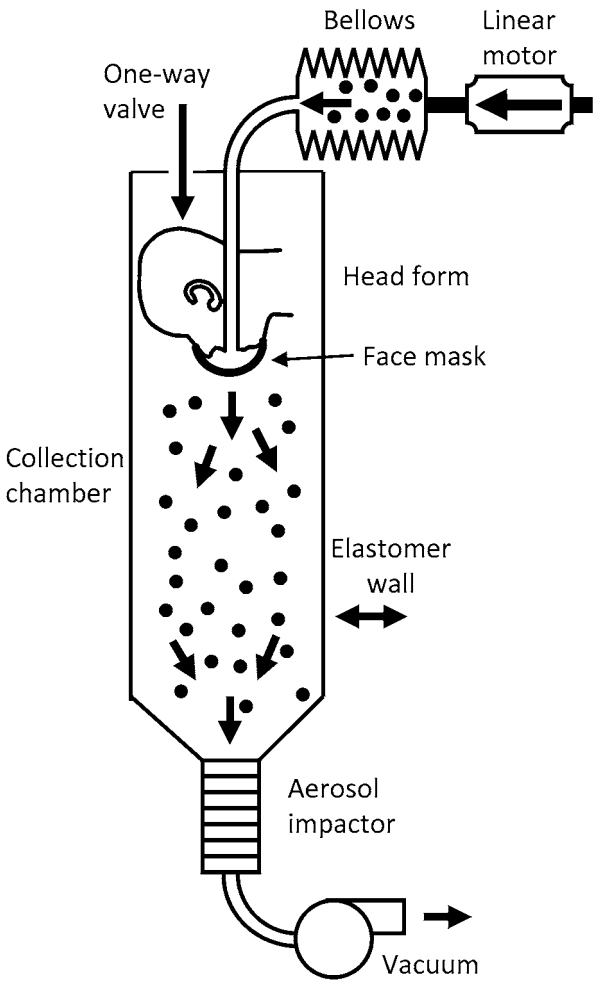

Figure 1. Source control measurement system. The system consists of an aerosol generation system, a bellows and linear motor to produce the simulated coughing and breathing, a pliable skin headform on which the source control device is placed, a 136 liter collection chamber into which the aerosol is coughed or exhaled, and a cascade impactor to separate the aerosol particles by size and collect them. The system is oriented vertically as shown to minimize the loss of aerosol particles due to settling before collection. The system is described in more detail in Lindsley et al. (2021).

The test aerosol was produced using a solution of 14% potassium chloride (KCl) and 0.4% sodium fluorescein in a single-jet Collison nebulizer (BGI, Butler, NJ, USA) at 103 kPa (15 lbs./in^2). The aerosol passed through a diffusion drier (Model 3062, TSI, Shoreview, MN, USA), mixed with dry filtered air flowing at 10 L/min for the cough tests and 15 L/min for the breathing tests, and neutralized using a bipolar ionizer (Model HPX-1, Electrostatics). An elastomeric bellows driven by a computer-controlled linear motor produced the coughing or breathing airflow.

For cough tests, the test aerosol was loaded into the elastomeric bellows and then coughed out using a single cough with a volume of 4.2 L and a peak flow rate of 11 L/s (Lindsley et al. 2013). An Andersen cascade impactor (Model TE-10-830, Tisch Environmental) collected all aerosol particles that traveled through or around the device for 20 min after each cough. For breathing tests, the system used a ventilation rate of 15 L/min with a breathing rate of 12 breathes/min and a tidal volume of 1.25 liters, which corresponds to the ISO standard for a female performing light work (ISO 2015). The test aerosol was only generated for the first 30 s of breathing to avoid overloading the impactor. The breathing continued for 20 min total. The impactor collected the aerosol particles in the chamber during the 20-minute breathing period followed by an additional five minutes of collection after the breathing had stopped.

The impactor operated at a flow rate of 28.3 liters/minute and had six collection stages and a filter that separated the aerosol particles into seven size fractions based on the aerodynamic diameter of the particles: <0.6 µm; 0.6–1.1 µm; 1.1–2.1 µm; 2.1–3.3 µm; 3.3–4.7 µm; 4.7–7.0 µm; and >7 µm. The impactor collection plates were coated with a solution of glycerol and Brij 35 to prevent particles from bouncing off the plates during collection (Mitchell 2003). Because the amount of aerosol in the largest size fraction was small (<0.7% of total aerosol mass) and because of possible losses due to settling of the large aerosol particles, data for the largest size fraction were not included in the analysis. After aerosol collection was completed, the aerosol particles were eluted from the impactor plates using a 0.1 M Tris solution and the fluorescence of the solution was read using a spectrofluorometer (SpectraMax M4, Molecular Devices).

To control for variations in the amount of aerosol in each experiment, a sample of each test aerosol was collected from the bellows prior to coughing or breathing using a 47 mm 5 µm PVC filter. The aerosol was eluted from the filter using 0.1 M Tris. An adjustment factor for the experiment (A) was calculated as:

$$A = \frac{Mass\ of\ aerosol\ on\ filter}{Mean\ (mass\ of\ aerosol\ on\ filter\ for\ all\ control\ experiments)} \quad (1)$$

The adjusted mass of aerosol on each impactor stage for the experiment was then calculated as:

$$M_{stage,\ adjusted} = \frac{M_{stage,\ unadjusted}}{A} \quad (2)$$

The adjusted masses were used for all subsequent calculations. The adjusted aerosol masses collected by the cascade impactor during the experiments are

Table 2. Source control devices used in experiments.

Type	Manufacturer	Product	Fastener	Material
Medical masks & respirators	3M	Model 1860 N95 respirator and surgical mask (TC-84A-0006)	Two elastic straps around head	Polypropylene and polyethylene composition
	BYD	N95 filtering facepiece respirator (TC-84A-9221)	Two elastic straps around head	IL and OL: Polypropylene spun-bound nonwoven fabric. ML: Polypropylene melt-blown nonwoven + hot air cotton
	3M	Model 1818 surgical mask	Two ties behind head	Poly(ethylene terephthalate) and polypropylene
	Excellent Artisan	Procedure mask	Ear loops	3-ply, Nonwoven. Fabric composition unknown
Reusable cloth face masks	Hanes	Defender 3-ply mask	Ear loops	100% cotton
	EnerPlex	3-ply mask	Ear loops	IL and ML: 65% polyester, 35% cotton. OL: 100% polyester
	Craft & Soul	2-ply mask	Ear loops	65% polyester, 35% cotton
	Lefty	2-ply face mask	Ear loops	92% polyester, 8% spandex
	Badger	4-ply mask	Ear loops	IL : 100% cotton. MLs: melt blown filters. OL: air mesh polyester
	Debrief Me	3-ply mask with PM 2.5 filter	Ear loops	IL 100% cotton, ML and OL: polyester blend
	Fabrique Innovations	Mask	Ear loops	100% cotton
	Besungo	Mask with PM 2.5 filter & exhalation valves	Ear loops and Velcro neck strap	Nylon
	Inspire	2-ply mask with PM 2.5 filter	Ear loops	Polyester/cotton blend
Neck gaiters	FKGIONG	Neck gaiter	Encircles head	95% polyester, 5% spandex
	AXBXCX	Neck gaiter	Encircles head	Polyester
	Retro Brand	Neck gaiter	Encircles head	100% polyester
	Givon	Neck gaiter	Encircles head	100% polyester fleece
Bandanas	L & M	Bandana	Ties behind head	100% cotton
	Underwear	Bandana/gaiter	Ear loops	Polyester blend

In this article, the reusable cloth face masks, neck gaiters and bandanas are referred to collectively as "cloth masks". IL is inner layer, ML is middle layer, and OL is outer layer. Photographs are shown in Figures S3–S5 (SI).

shown in Tables S1 and S2 in the supplemental information (SI).

The source control performance, or source control collection efficiency, of a face covering is defined as the fraction of the mass of the respiratory aerosol that is blocked from entering the environment around the wearer. For example, if 80% of the mass of the aerosol from a cough is blocked by a face mask and 20% of the aerosol mass is able to flow through or around the mask into the air around the wearer, then the mask is said to have a collection efficiency of 80%. The performance of each source control device was evaluated by calculating the collection efficiency as:

$$Collection\ efficiency = 1 - \frac{M_{mask}}{M_{control}} \qquad (3)$$

where:

M_{mask} = adjusted total mass of the aerosol particles that passed through or around the source control device and was collected by the impactor.

$M_{control}$ = adjusted total mass of the aerosol particles collected by the impactor while not wearing a source control device.

Note that the collection efficiency is based on the mass of the aerosol rather than a measure such as particle counts. Also, the aerosol is flowing from the inside of the mask toward the outside; that is, in our test system the aerosol flows in the same direction as it would flow during a cough or exhalation by a person wearing the mask.

Respirators, medical masks, and cloth masks

In our study, the term "cloth mask" refers to a cloth face mask, neck gaiter or bandana constructed from textiles or fabrics (both natural and synthetic) that is not a surgical mask or N95 respirator and is not intended for use as personal protective equipment. The term "medical masks" in this article refers to non-woven disposable masks that are held on the face with elastic ear loops. These masks are loose-fitting and are not expected to provide the wearer with as reliable a level of protection against airborne or aerosolized particles as N95 respirators regulated by NIOSH. Commercial manufacturers often refer to

masks held on by ear loops as procedure masks and masks that tie behind the head as surgical masks. However, the U.S. Food and Drug Administration uses the term "surgical mask" to describe commercially produced masks regulated by the under 21 CFR 878.4040 for performing medical procedures (FDA 2004). The FDA definition applies to all masks that cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials, and includes masks that are labeled as surgical, laser, isolation, dental or medical procedure masks with or without a face shield.

Nineteen commercially available N95 respirators, medical masks, and cloth masks were selected to provide a broad cross-section of the different types of source control devices that are available (Table 2). For the source control tests, each device was placed on the headform as it would normally be worn by a person. Three of the neck gaiters were tested both as a single layer of fabric and folded over to provide two layers of fabric. Before the source control test, the manikin fit factor (Janssen and McKay 2017) was measured by performing a respirator fit test (Bergman et al. 2015) for each device using a PortaCount® Pro + respirator fit tester (Model 8038, TSI, Shoreview, MN) in N95 mode with the system breathing at 36 L/min but not producing an aerosol. Each device was used for two consecutive tests. Photographs of the source control devices on the headform are shown in the SI (SI; Figures S1–S3).

Filtration efficiency and airflow resistance measurements

The filtration efficiency of the face covering is the fraction of the test aerosol that is collected as the aerosol passes through the mask material. For example, if 70% of the test aerosol is collected by the mask material and 30% of the aerosol passes through it, then the filtration efficiency is 70%. Note that the filtration efficiency tests are performed by fastening the mask to a holder so that all the aerosol flows through the mask material, and none can escape through face seal leaks. Thus, the filtration efficiency is a property of the mask material.

The filtration efficiency and airflow resistance of the construction materials were measured using automated filter testers (Models 8130 and 8130 A, TSI). Material samples were secured to a test plate using beeswax as shown in Figure S4 in the SI. Measurements were made using a modified version of the NIOSH standard testing procedure (STP) (NIOSH 2019). Under the modified STP, samples were tested at ambient temperature and humidity but were not subjected to conditioning at 38°C and 85% relative humidity for 25 h, and sample testing was limited to 10 min. The device to be tested was oriented in the filter tester so that the air and aerosol flowed from the exterior of the device toward the interior (that is, as if the wearer were inhaling, which is the same direction as when testing a respirator as a personal protective device). The challenge aerosol was generated using a 2% sodium chloride (NaCl) solution in distilled water, conditioned to 25 °C and 30% relative humidity and neutralized to the Boltzmann equilibrium state. The challenge aerosol had a count median diameter of 75 nm ± 20 nm, a mass mean diameter of 260 nm and a geometric standard deviation (GSD) $\leq$ 1.86 (TSI 8130 A specifications). The automated filter tester compares particle mass concentration readings from upstream and downstream light-scattering laser photometers to calculate the material filtration efficiency. An electronic pressure transducer measures the pressure difference across the material sample to indicate airflow resistance. Tests were performed with an airflow of 85 L/minute.

Fit tests on human subjects

A convenience sample of eleven subjects (six males and five females) participated in fit testing. Subjects complied with CDC/NIOSH guidelines for facial hair styles intended for workers who wear tight-fitting respirators (CDC 2017). Fit testing was performed with a PortaCount® fit tester (model 8038, TSI) using OSHA's modified ambient aerosol condensation nuclei counter (CNC) protocol for filtering facepiece respirators (OSHA 2019). Because only fit factors were measured and no identifiable private information was collected, the West Virginia University Office of Human Research Protections determined that Institutional Review Board approval was not required. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy (see e.g., 45 C.F.R. part 46; 21 C.F.R. part 56; 42 U.S.C. §241(d), 5 U.S.C. §552a, 44 U.S.C. §3501 et seq.). All measurements were performed in a room with volume of 43.4 m^3 (1531 ft^3) at 19 °C (67 °F).

An NaCl aerosol generator (Model 8026, TI) was used to supplement the naturally occurring particles in the air. The particle generator was placed 10 feet away from all sampling apparatus and fit testing equipment. The generator was turned on ten minutes prior to testing to seed aerosols and turned off while

a triplicate series of fit tests were performed (around 7 min). As the aerosol concentration in the room had started to slightly decline at this point, the generator was turned on between tests (around 7 min) and then turned off during subsequent tests. This process was repeated until testing for the day was completed.

To verify that suitable aerosol concentrations were present during testing, particle concentrations were measured with a condensation particle counter (CPC Model 3775, TSI) for 25 min beginning at 2 min prior to the nebulizer being initially turned on. Particle size distributions were measured for 20 min with a scanning mobility particle sizer (SMPS Model 3938, TSI) and an electrical low-pressure impactor (ELPI+, Dakati). Information on the aerosol particle size distribution and concentration are shown in the SI (Figures S5 and S6).

Each source control device was tested by three subjects; for each subject three replicate measurements were made using each of the two protocols described below. One individual administered all fit tests. Subjects were instructed in the proper donning of medical masks and respirators, and they were asked to don cloth masks in the manner that they ordinarily don similar coverings for public use. If a cloth mask was too large, it was modified using materials that would be accessible to most lay individuals: tape was used to shorten mask ear loops or head straps, and a binder clip was used to decrease the circumference of neck gaiters. These adjustments were made so that the covering was held flush to the face, but the materials were not under tension.

Two particle measurement protocols were performed on all source control devices: the PortaCount® N95 Companion protocol (referred to here as N95 mode), which counts negatively charged particles 40–70 nm (mean 55 nm) in diameter; and the PortaCount® standard protocol (referred to here as Class 100 mode), which counts all particles from 0.02–1.0 µm (TSI 2010). The "Class 100 mode" is also called "N99 mode". For both modes, the fit factor (FF) was calculated by the PortaCount® software as (Janssen and McKay 2017; TSI 2015):

$$FF = \frac{C_B + C_A}{2C_R} \quad (4)$$

where:

C_B = ambient particle concentration measured before the particle concentration is measured inside the respirator.

C_A = ambient particle concentration measured after the particle concentration is measured inside the respirator.

C_R = particle concentration measured inside the respirator.

Note that the TSI PortaCount instrument used in our experiments measures the aerosol concentration based on the number of aerosol particles rather than the particle mass.

Data analysis

The source control results were compared with the filtration efficiencies, airflow resistances, and fit factor measurements by calculating the Spearman's rank correlation coefficients (ρ) between the metrics. Fit factors were transformed into fit efficiencies (= 1-1/fit factor) to allow for a direct comparison with the other parameters. For example, a fit factor of 5 corresponds to a fit efficiency of 80%, indicating that the mask blocked 80% of the ambient aerosol from being inhaled by the wearer. Because the replicate numbers were different for the different performance metrics, the correlations were calculated based on the mean results for each device. When analyzing the human fit factor results, we did not attempt to account for differences among test subjects. The p-value was calculated based on ρ and the number of types of devices that were tested (22 for all source control devices and 18 for the cloth masks alone, with the 1-layer and 2-layer gaiter tests counted separately). Correlations were considered significant if $p \leq 0.05$.

Results

Efficacy of N95 respirators, medical masks, and cloth masks as source control devices for respiratory aerosols

Twenty-six cough experiments were performed without a source control device to measure the cough aerosol output from the source control measurement system. The cough aerosol had a geometric mean aerodynamic diameter of 1.3 µm with a GSD of 2.3 and a mean mass of 525 µg (standard deviation [SD] 65; Figure 2 and SI Figure S7). Thirty-five breathing aerosol experiments were performed without a source control device to measure the exhaled aerosol output. The exhaled aerosol had a geometric mean aerodynamic diameter of 1.3 µm with a GSD of 2.3 and a mean mass of 495 µg (SD 68; Figure 2 and SI Figure S8). The experiments without source control devices were used as control experiments when evaluating performance of the devices.

The collection efficiencies of the 19 source control devices are shown in Figure 3 and Table 3. The mean

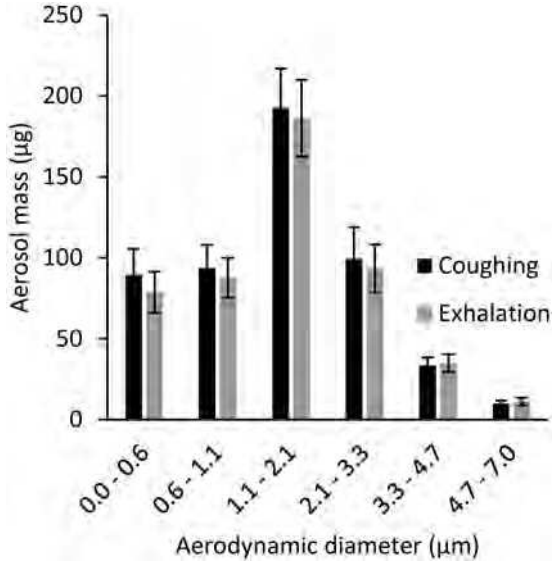

Figure 2. Mass of aerosol expelled by the source control measurement system during coughs and exhalations. The size bins correspond to the stages of the Andersen impactor. The size distribution is shown in units of µg/µm in Figures S7 and S8 in the SI.

collection efficiencies of the N95 respirators and the surgical mask ranged from 83% to 99% for aerosol particles during coughing and exhalation. For the procedure and cloth masks, the mean collection efficiencies ranged from 35% to 71% for coughing (except for the bandana at 17%) and 35% to 66% for exhalation. The collection efficiencies for the coughing and breathing source control experiments were correlated, with a Spearman's correlation coefficient (ρ) of 0.76 ($p < 0.001$; Table 4) when considering all the devices and 0.67 ($p = 0.003$; Table 4) when considering only the cloth face masks, gaiters and bandanas. The amounts of aerosol collected on each stage of the impactor are shown in Tables S1 and S2 in the SI.

Filtration efficiencies and inhalation airflow resistance

The mean material filtration efficiencies were >99% for the respirators, 80% to 93% for the medical masks, and 1.4% to 36% for the cloth face masks, neck gaiters, and bandanas, except for the Besungo sports mask at 98% (Figure 4 and Table 3). The inhalation

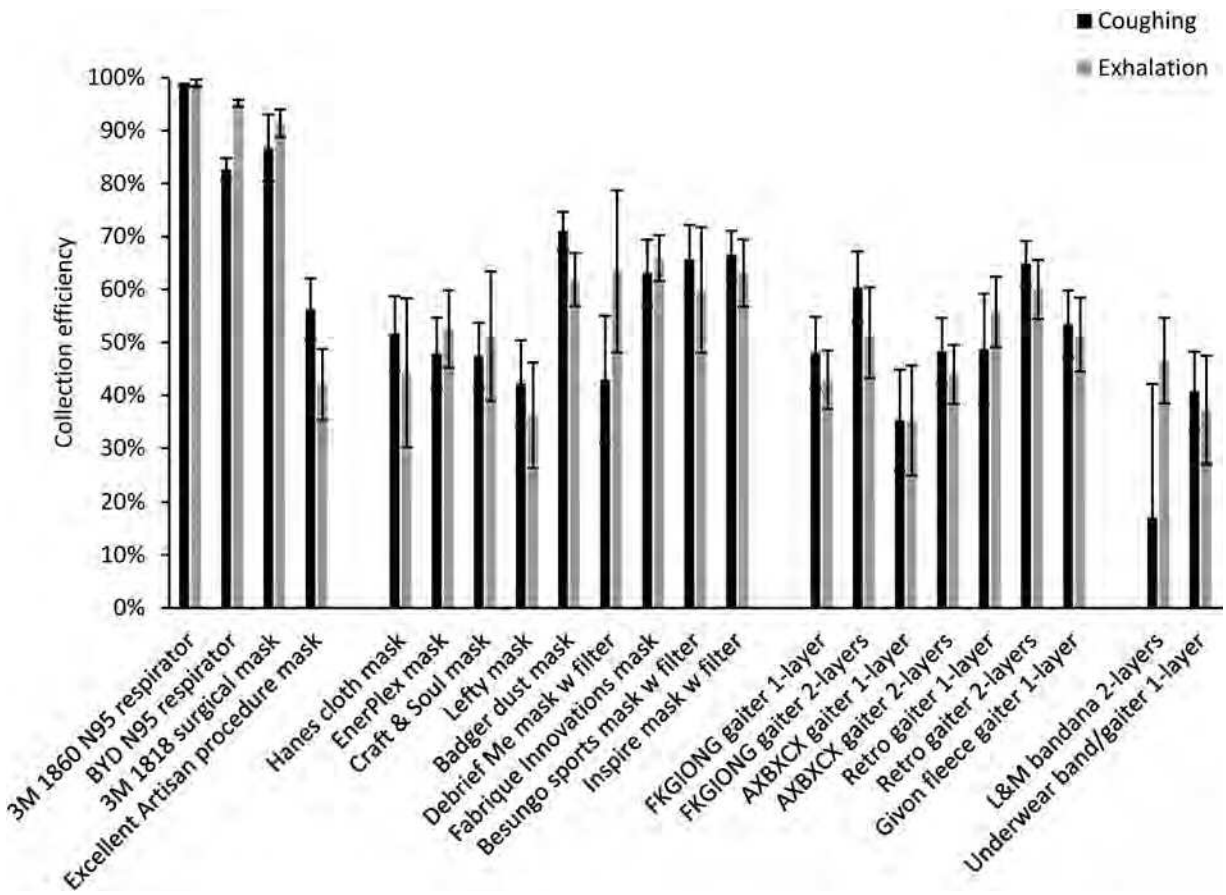

Figure 3. Source control collection efficiencies of N95 respirators, medical masks, cloth face masks, neck gaiters and bandanas during coughing and exhalation aerosol tests with the respiratory aerosol source control measurement system. Each bar is the mean of 4 or 6 experiments. Error bars show the standard deviation.

Table 3. Results for all performance metrics for source control devices.

Face covering	COUGHING				EXHALATION				Filtration Efficiency (%)		Inhalation airflow resistance (Pa)		Human fit factor			
	Collection efficiency (%)		Manikin fit factor		Collection efficiency (%)		Manikin fit factor						N95 mode		Class 100 mode	
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
3M 1860 N95 respirator	98.6%	0.3%	198.0	3.5	99.0%	0.7%	132.5	78.5	99.1%	0.1%	72.2	8.1	163.8	56.2	45.3	10.9
BYD N95 respirator	82.7%	2.1%	25.0	11.3	95.2%	0.6%	113.5	122.3	99.1%	0.1%	150.8	14.5	147.9	33.5	54.9	7.8
3M 1818 surgical mask	86.8%	6.3%	26.1	26.7	91.4%	2.6%	27.5	12.0	92.7%	0.6%	48.0	7.8	78.6	92.0	9.6	5.8
Excellent Artisan procedure mask	56.3%	5.8%	7.4	3.4	42.0%	6.7%	6.1	5.5	79.7%	3.6%	108.0	34.3	3.3	0.7	1.7	0.5
Hanes cloth mask	51.7%	7.1%	1.3	0.1	44.3%	14.0%	2.3	1.1	18.8%	2.7%	64.1	9.5	1.7	0.5	1.0	0
EnerPlex mask	48.0%	6.7%	5.1	1.3	52.6%	7.3%	2.5	0.4	19.9%	3.9%	23.8	10.7	2.1	1.2	1.8	0.7
Craft & Soul mask	47.4%	6.2%	2.5	1.2	51.2%	12.2%	2.3	1.0	9.7%	3.9%	11.4	8.2	2.0	0.5	1.3	0.5
Lefty mask	42.3%	8.1%	2.4	0.7	36.3%	9.9%	1.9	n/a	20.2%	0.8%	96.3	5.9	1.8	0.7	1.6	0.5
Badger dust mask	71.1%	3.5%	5.0	0.1	61.8%	5.0%	3.2	0.6	36.0%	9.9%	92.1	1.0	2.8	1.6	1.7	0.5
Debrief Me mask w filter	43.0%	12.0%	4.6	1.8	63.4%	15.3%	3.0	1.5	30.8%	1.5%	154.1	34.9	2.9	0.9	2.1	0.8
Fabrique Innovations mask	63.2%	6.2%	2.1	n/a	65.9%	4.4%	2.2	0.4	14.8%	n/a	61.7	n/a	1.4	0.7	1.1	0.3
Besungo sports mask w filter	65.7%	6.5%	4.8	n/a	59.9%	11.9%	3.2	0.3	97.8%	0.3%	142.7	22.9	2.7	1.7	1.9	1.4
Inspire mask w filter	66.5%	4.5%	4.3	3.0	63.1%	6.4%	2.7	0.5	27.1%	5.1%	149.8	85.4	4.0	1.4	2.4	0.5
FKGIONG gaiter 1-layer	48.1%	6.7%	1.7	0.5	42.9%	5.5%	1.5	0.2	3.3%	4.3%	13.1	8.0	1.1	0.3	1.0	0
FKGIONG gaiter 2-layers	60.5%	6.7%	1.9	0.4	51.8%	8.6%	1.7	n/a	7.9%	0.5%	23.8	8.4	1.0	0	1.4	0.5
AXBXCX gaiter 1-layer	35.4%	9.5%	1.7	0.1	35.3%	10.3%	1.4	0.1	2.7%	1.1%	14.4	5.7	1.3	0.7	1.0	0
AXBXCX gaiter 2-layers	48.3%	6.3%	1.8	0.1	43.9%	5.6%	1.9	0.5	3.6%	0.3%	29.4	4.5	1.3	0.5	1.3	0.5
Retro gaiter 1-layer	48.7%	10.5%	2.6	n/a	55.8%	6.6%	2.5	0.6	2.2%	n/a	40.2	n/a	1.6	0.7	1.3	0.5
Retro gaiter 2-layers	64.9%	4.2%	2.3	0.4	60.0%	5.5%	2.1	0.4	8.6%	n/a	69.5	n/a	1.7	1.0	1.7	0.5
Givon fleece gaiter 1-layer	53.5%	6.3%	2.1	0.5	51.4%	7.0%	2.3	0.8	8.4%	0.8%	19.3	7.4	1.0	0	1.3	0.5
L&M Bandana 2-layers	17.1%	25.0%	1.3	0.2	46.5%	8.1%	1.6	0.1	1.4%	0.4%	5.2	8.2	1.1	0.3	1.0	0
Underwear Bandana/gaiter 1-layer	40.8%	7.5%	6.9	7.3	37.3%	10.2%	1.4	0.1	3.5%	1.1%	19.3	8.2	1.1	0.7	1.0	0

Manikin fit factors were measured with the fit tester in N95 mode only (as described in the Discussion). Human fit factors were measured using both the N95 mode and Class 100 mode.

Table 4. Correlations between different performance metrics for all source control devices.

		All source control devices		Cloth face masks, gaiters, and bandanas only	
Correlation parameter #1	Correlation parameter #2	ρ	*p*-value	ρ	*p*-value
Cough aerosol collection efficiency	Exhaled aerosol collection efficiency	0.76	<0.001	0.67	0.003
	Filtration efficiency of material	0.69	0.001	0.51	0.032
	Airflow resistance of material	0.55	0.009	0.54	0.020
	Human subject fit (N95 mode)	0.57	0.005	0.30	0.208
	Human subject fit (Class 100 mode)	0.68	<0.001	0.48	0.035
	Manikin fit before coughing	0.39	0.076	0.03	0.890
Exhaled aerosol collection efficiency	Filtration efficiency of material	0.60	0.004	0.54	0.023
	Airflow resistance of material	0.51	0.016	0.58	0.012
	Human subject fit (N95 mode)	0.60	0.003	0.51	0.024
	Human subject fit (Class 100 mode)	0.71	<0.001	0.63	0.003
	Manikin fit before breathing	0.72	<0.001	0.68	0.002
Manikin fit before coughing	Manikin fit before breathing	0.61	0.003	0.38	0.112
Filtration efficiency of material	Airflow resistance of material	0.78	<0.001	0.78	<0.001

Each Spearman's rank coefficient (ρ) was calculated based on data from 22 experiments for all source control devices and 18 experiments for cloth masks (cloth face masks, gaiters, and bandanas). A correlogram of the ρ values in shown in Figure S9 in the SI.

airflow resistances were from 5.2 to 154 Pa (Table 3). When comparing the data for all devices, the filtration efficiencies were correlated with cough aerosol collection efficiency ($\rho = 0.69$, $p = 0.001$) and exhaled aerosol collection efficiency ($\rho = 0.60$, $p = 0.004$; Table 4). For the group of cloth masks, the correlations were not as strong; the cough aerosol collection efficiency and filtration efficiency had an ρ of 0.51 ($p = 0.032$) while the exhaled aerosol collection efficiency and filtration efficiency had an ρ of 0.54 ($p = 0.023$; Table 4). The airflow resistance did not correlate as well as the filtration efficiency when all devices were considered ($\rho = 0.55$ and $p = 0.009$ for coughing; $\rho = 0.51$ and $p = 0.016$ for exhalation). However, when examining the cloth masks alone, the airflow resistance was slightly better correlated than filtration efficiency ($\rho = 0.54$ and $p = 0.020$ for coughing; $\rho = 0.58$ and $p = 0.012$ for exhalation).

Human fit tests

The fit factors measured on the human test subjects are shown in Table 3 and Figure 5. The mean fit factors for the two N95 respirators were 148 and 164

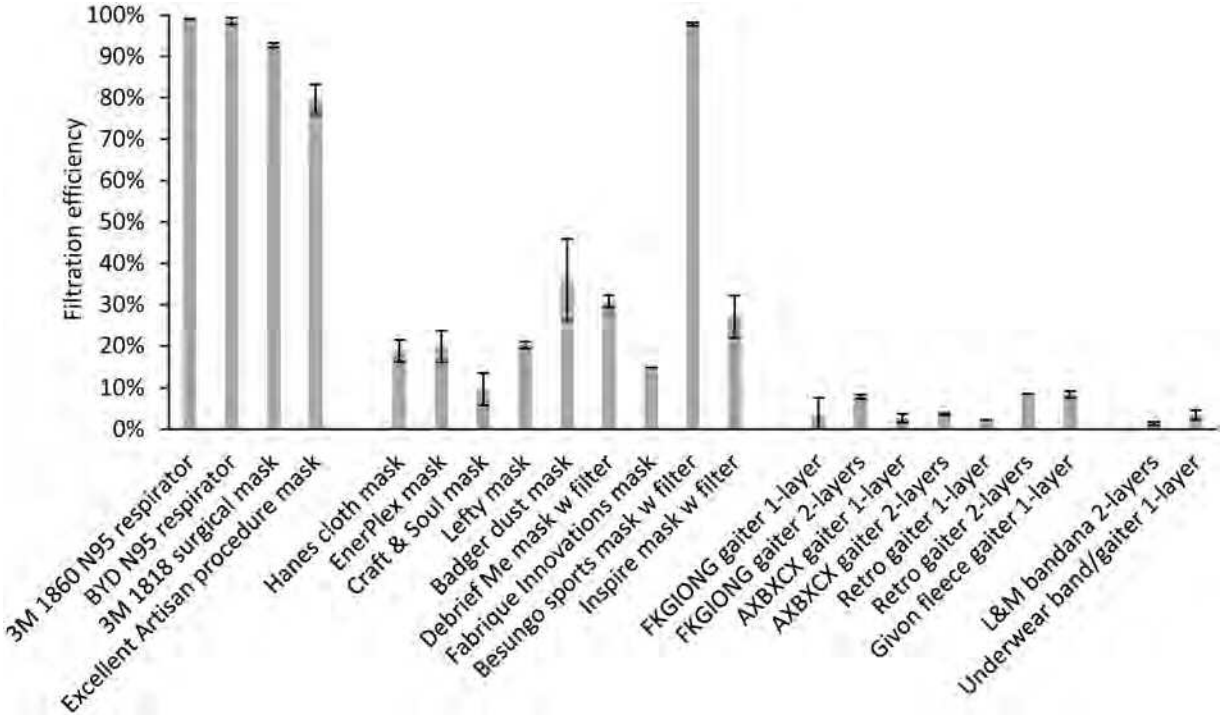

Figure 4. Filtration efficiencies for the source control devices used in the study. Three samples of each device were tested, except for the 3 M 1860 N95 respirator and Hanes cloth mask (10 samples each) and the Fabrique Innovations mask, Retro gaiter 1-layer, and Retro gaiter 2-layers (one sample each). Error bars show the standard deviation.

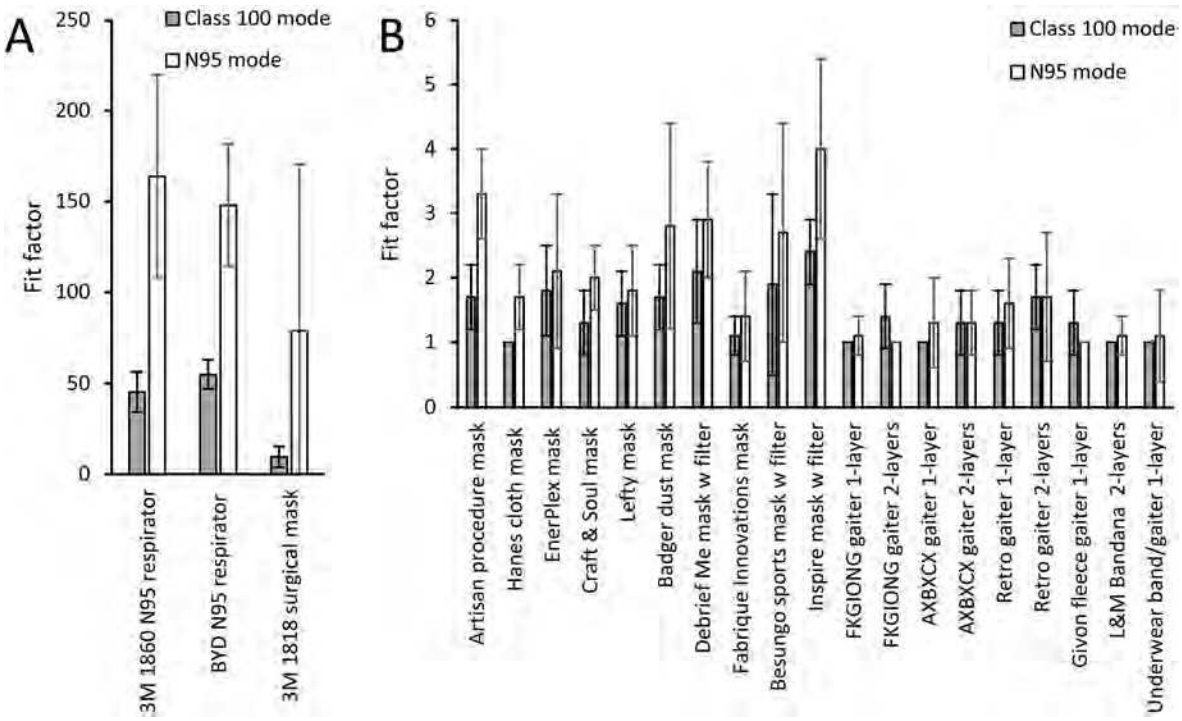

Figure 5. Fit factors measured with human subjects for (a) N95 respirators and surgical mask and (b) procedure mask, cloth face masks, gaiters and bandanas. The plot shows the means and standard deviations. Results for all human fit tests are given in Table S3 in the SI.

when using the N95 mode on the fit tester and 55 and 45 with the Class 100 mode. The surgical mask provided a mean N95 mode fit factor of 79 and a much lower mean fit factor of 9.6 in Class 100 mode. The mean N95 mode fit factor of the reusable cloth face masks ranged from 1.4 to 4.0, and the all sizes

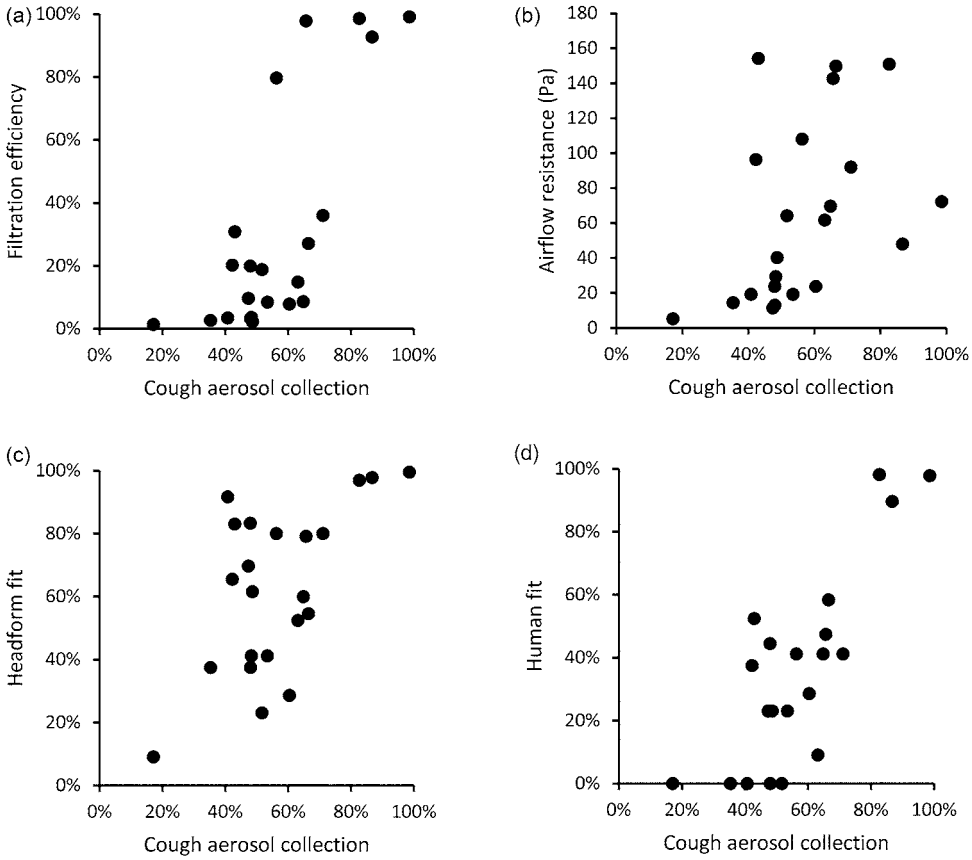

Figure 6. Comparison of collection efficiencies for aerosols from coughs to (a) filtration efficiency of construction material; (b) airflow resistance; (c) fit on manikin headform (using N95 mode); and (d) fit on human test subjects (using Class 100 mode). Each dot corresponds to the mean result for one type of source control device.

mode mean fit factors ranged from 1.0 to 2.4. Neck gaiters and bandanas demonstrated N95 mode fit factors ranging from 1.0 to 1.7 and all particle size mode mean fit factors from 1.0 to 1.7. The performance of cloth masks sometimes varied considerably when worn by different subjects. The fit test results for individual subjects are shown in Table S3 in the SI.

The cough and exhalation aerosol collection efficiencies for all devices were well correlated with the fit factors when measured using the Class 100 mode ($\rho = 0.68$ and $p < 0.001$ for coughing, $\rho = 0.71$ and $p < 0.001$ for exhalation, Table 4). When looking at the results for the cloth masks, gaiters, and bandanas in the all sizes mode, the correlations were not as strong, with $\rho = 0.48$ for coughing ($p = 0.035$), and $\rho = 0.63$ for exhalation ($p = 0.003$; Table 4). In all cases, the correlation coefficients were higher when the fit tester was in the Class 100 mode than when the tester was in N95 mode.

Manikin fit tests

The manikin fit factor measurements found using the source control measurement system before the cough tests were 25 to 198 for the N95 respirators and the surgical mask and 1.3 to 7.4 for the procedure mask and cloth masks (Table 3). Before the breathing tests, the manikin fit factors were 28 to 133 for the N95 respirators and the surgical mask and 1.4 to 6.1 for the procedure mask and cloth masks. The cough aerosol collection efficiencies and the pre-cough manikin fit factors were not significantly correlated, with a ρ of 0.39 ($p = 0.076$) for all devices (Table 4 and Figure 6) and a ρ of only 0.03 ($p = 0.890$) for the cloth masks (Table 4). The correlation was better between the exhaled aerosol collection efficiency and pre-breathing manikin fit factors, with a ρ of 0.72 ($p < 0.001$) for all devices (Table 4 and Figure 7) and 0.68 ($p = 0.002$) for the cloth masks (Table 4).

Discussion

The COVID-19 pandemic has resulted in considerable interest in the performance characteristics of masks and respirators as a means of reducing the person-to-person transmission of SARS-CoV-2. Some studies have looked at the emission of particles from human volunteers wearing different face coverings, which has

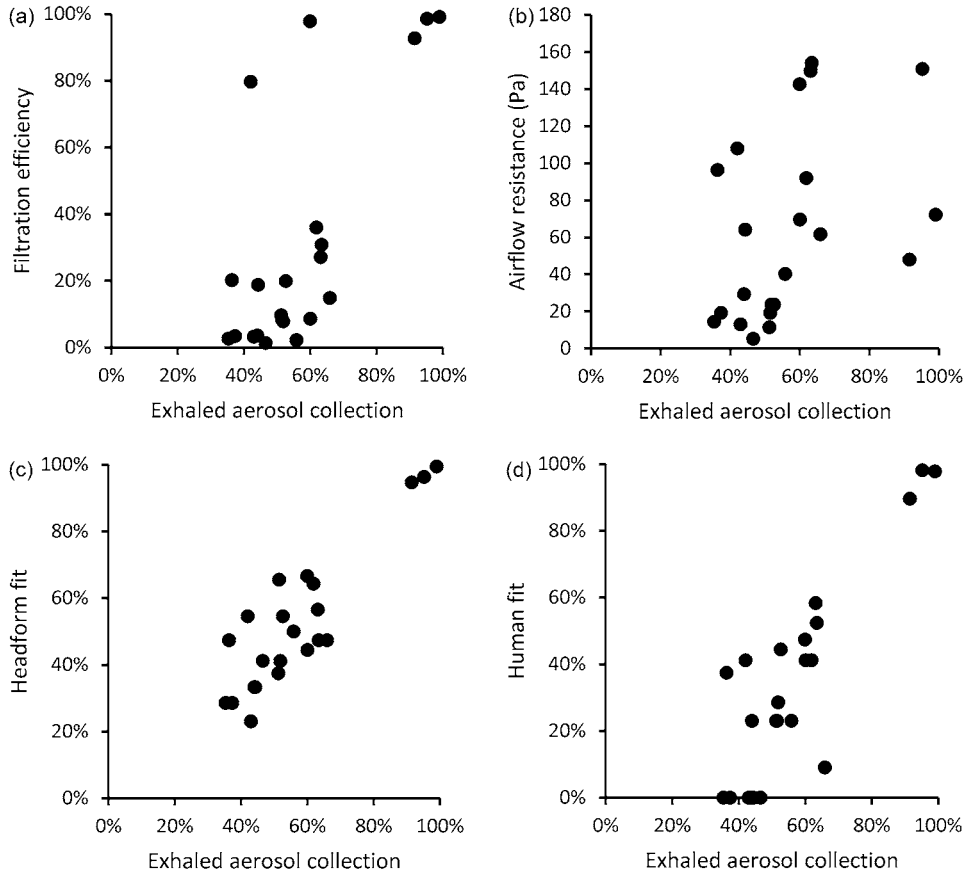

Figure 7. Comparison of collection efficiencies for exhaled aerosols from simulated breathing to (a) filtration efficiency of construction material; (b) airflow resistance; (c) fit on manikin headform (using N95 mode); and (d) fit on human test subjects (using Class 100 mode). Each dot shows the mean result for one type of source control device.

the advantage of directly examining the expulsion of aerosols into the environment by people (Asadi et al. 2020; Davies et al. 2013; Leung et al. 2020; Li, Niu, and Zhu 2021). However, the collection and measurement of human-generated respiratory aerosols is challenging and can be hazardous when the subject has a contagious respiratory infection. In addition, the amount and size distribution of aerosol particles produced by people during coughing, breathing and other respiratory activities varies tremendously from person to person and even for a particular person over time, which makes it difficult to compare results (Asadi et al. 2019; Fennelly 2020; Gralton et al. 2011; Lindsley et al. 2012). Consequently, lab-based surrogate techniques are more frequently used to study source control devices. The most commonly reported methods have been tests of filtration efficiencies and fit factors (Clapp et al. 2021; Guha et al. 2021; Konda et al. 2020; Wang et al. 2020; Zhao et al. 2020). Other studies have used manikins in a chamber or room to assess the efficacy of medical masks and cloth masks both as source control devices and as personal protective equipment (Pan et al. 2021; Patel et al. 2016; Rothamer et al. 2021). Experimental data have also been used to develop computational fluid dynamics models of medical and cloth masks performance (Dbouk and Drikakis 2020; Mittal, Ni, and Seo 2020). These studies have provided valuable information about the properties of masks and respirators. However, it is unclear how the various metrics used in these studies are related to source control performance.

The source control measurement system used in this study allows for a direct quantitative comparison of the ability of different types of source control devices to block the expulsion of simulated cough and exhaled breath aerosol particles into the environment (Lindsley et al. 2021). However, the system is complex and requires expertise to operate, and it is neither commercially sold nor easily constructed. In contrast, filtration measurement systems and respirator fit testers are widely available. If a methodology could be developed to gauge source control performance using existing commercially available equipment, it could be rapidly expanded and adopted by manufacturers and public health entities.

The filtration efficiency of a mask or respirator is a measurement of the ability of the mask material to remove aerosol particles from an airstream traveling through the fabric. Filtration efficiency tests typically use aerosol particles at or near the most-penetrating aerosol particle size, which is around 300 nm for an uncharged filter at low air velocities but shifts to smaller sizes at higher velocities and when the filter and particles are electrostatically charged (Martin and Moyer 2000; Rengasamy, BerryAnn, and Szalajda 2013; Rengasamy et al. 2017). The mechanisms by which filters collect aerosol particles are strongly dependent upon the size of the particles; for example, large particles are more likely to be collected by impaction or interception while small particles are more likely to be collected by diffusion (Lindsley 2016). Although the SARS-CoV-2 virus is about 100 nm in diameter, contagious humans do not shed bare viral particles. Instead, they expel aerosols and droplets of respiratory fluids that contain respiratory virus, and the size of these virus-laden aerosols and droplets can range from hundreds of nanometers to visible droplets of 1 mm or more (Fennelly 2020; Gralton et al. 2011). Thus, the collection efficiencies for 100-300 nm particles may not predict the performance for larger particles (Drewnick et al. 2021). In our experiments, the coughing and exhalation source control collection efficiencies increased as the particle size increased (Tables S1 and S2 in the SI) and in most cases were higher than the filtration efficiencies, likely because our coughing and exhalation test aerosols were much larger than the 75 nm aerosol used for filtration tests.

The fit factor is normally used to determine how well a respiratory protective device fits the wearer by measuring the degree to which aerosol particles can enter through gaps between the wearer's face and the respirator (face seal leaks). It is determined by placing the device on a person or on a manikin headform and measuring the ratio of the aerosol concentration outside the respirator to the aerosol concentration inside the respirator (Janssen and McKay 2017). For example, a fit factor of 10 means that the ambient aerosol concentration is 10 times higher than the concentration inside the respirator. Fit factor measurements are not intended to test the filtration efficiency of the device itself. In fact, the calculation of the fit factor for a respirator assumes that any ambient aerosol particles passing through respirator material are filtered out and that any particles detected inside the respirator are due to face seal leaks, not penetration of particles through the filter material (Halvorsen 1998). For example, a fit factor of 10 is interpreted as indicating that 90% of the air inside the respirator has passed through the respirator filtration media (with aerosol particles being completely removed) and that 10% of the air bypassed the media and entered through face seal leaks.

For high efficiency filters such as P100 respirator filters, which filter out 99.97% of airborne particles, a respirator fit test is performed by measuring the concentrations of aerosol particles of all sizes inside and outside the respirator (referred to here as Class 100 mode). However, N95 respirators can allow up to 5% of aerosol particles of the most penetrating size to pass through the filtration media. These particles would reduce the apparent fit factor if they were included in the calculation. Thus, when fit testing N95 respirators, the respirator fit tester used in our experiments has a size classifier to count only negatively charged aerosol particles near 55 nm in size (referred to here as N95 mode). For an N95 respirator, these charged 55 nm particles are almost entirely filtered out by the filtration media, and thus any particles detected inside the respirator can then be assumed to have entered through face seal leaks and not through the respirator (Halvorsen 1998; Han and Prell 2010).

It is important to note, however, that this assumption is not correct when using the fit tester with cloth masks. As can be seen in Table 3, the filtration efficiencies of most cloth masks are much lower than those of respirators, and ambient particles therefore can penetrate more easily through the cloth material. Thus, the fit factor for a cloth mask is not a true measurement of face seal leakage alone; instead, it represents a combination of face seal leakage and particle penetration through the mask material.

Our findings suggest that the results from filtration efficiency, airflow resistance and fit factor tests are correlated with measurements made using our source control measurement system. For the cloth masks, all but two of the standard performance metrics were significantly correlated with the cough and exhaled aerosol collection efficiencies, which suggests that these other measures could be useful as part of a method for testing the performance of cloth masks. However, none of the standard metrics were strong predictors of source control performance, and no metric was clearly superior to the others.

The limited correlations between the different test methods in our study likely have several explanations. First, filtration efficiency and airflow resistance measurements do not account for how well the devices fit the wearer or for face seal leaks around the edges of

the device. Thus, for example, the Artisan procedure mask had an 80% filtration efficiency but a 56% collection efficiency for cough aerosols and a 42% collection efficiency for exhaled aerosols. The most likely explanation is that this mask's material is an efficient filter but that aerosol particles were able to travel around the mask through face seal leaks because the Artisan mask fits loosely on the headform. On the other hand, the Hanes Defender cloth mask had only a 19% filtration efficiency but had similar aerosol collection efficiencies of 52% for coughs and 44% for exhalations. In this case, the cloth mask was not an effective filter for the 75 nm aerosol used in filtration testing, but the Hanes mask fit the manikin headform more tightly. Thus, much of the aerosol then flowed through the mask rather than around it during coughing and breathing tests and the larger aerosol particles that were used in the coughing and breathing tests were filtered out more effectively than the 75 nm particles used in filtration testing. The results presented here are consistent with a previous study by our group in which knotting the Artisan procedure mask to improve the fit increased the cough aerosol collection efficiency to 77%, while wearing a Hanes Defender cloth mask on top of an Artisan procedure mask increased the cough collection efficiency to 85% (Brooks et al. 2021). Together, these results also support the recommendation by Gandhi and Marr that members of the public wear a high-quality mask that fits tightly or wear a tight-fitting cloth mask over a surgical mask in order to reduce face seal leaks and improve the source control performance and protection offered by the masks (Gandhi and Marr 2021).

Fit tests are designed to measure the effects of face seal leaks but have their own limitations when applied to cloth masks. As noted above, fit factor measurements for cloth masks reflect some combination of particle penetration through the media and face seal leakage which will likely vary from mask to mask. Thus, it is neither clear how to interpret fit factor measurements for cloth masks nor is it clear how this relates to the effectiveness of the mask as a source control device. In addition, fit test results can vary greatly from person to person and even somewhat for the same person during repeated tests (Lawrence et al. 2006). Similarly, a comparison of fit tests between humans and a pliable skin manikin headform found significant differences (Bergman et al. 2015). Much of this discrepancy is likely due to facial variations and differences in how the mask is placed on the person or manikin headform. It is possible to shift, stretch, tighten, loosen, or adjust the masks in many ways,

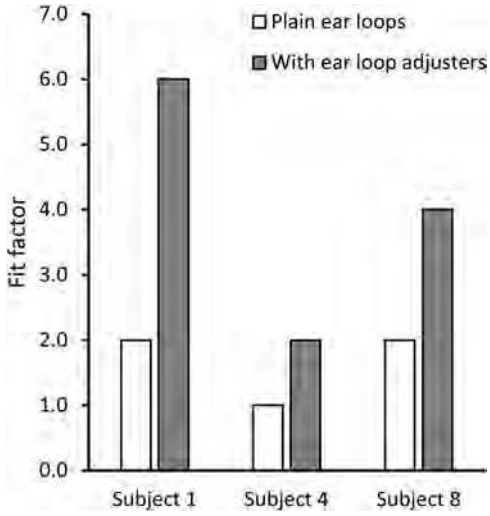

Figure 8. Effect on mask fit factor of adding ear loop adjusters to tighten the mask fit. Subjects were wearing the Excellent Artisan procedure mask. Tests were conducted with the fit tester in Class 100 mode. Each bar is the mean of three trials. All standard deviations were zero.

and small differences in how the mask is worn may have substantial effects on the fit test results. For example, in tests with three subjects using the Artisan procedure mask, we found that tightening the mask against the face by using silicone ear loop adjusters increased the mean fit factor from 1.7 to 4.0 (Figure 8). In experiments with cloth masks, the ρ value for the manikin headform fit tests done before coughing experiments compared with tests done before exhalation experiments was only 0.38, suggesting that differences were occurring even when the same model of mask was being placed on the same headform.

Finally, our study has several limitations. The source control measurement system produced a test aerosol with particles $\leq$7 µm in diameter, which is the size range of aerosol particles most likely to remain airborne and most difficult to block with source control devices. However, humans expel aerosol particles in a much broader range of sizes, particularly when coughing. We used a single cough flowrate profile and a single breathing ventilation rate for our studies; these parameters can vary greatly from person to person under different physiological conditions. Some internal losses of the test aerosol particles likely occurred due to settling or impaction on the surfaces of the collection chamber, which may affect the estimates of the collection efficiencies. We used representative examples of different types of source control devices, but many such devices are available with a wide range of shapes and compositions, which would be expected to affect their individual performance. As shown in Table 1, the instrumentation used for the

different performance metrics are based on different operating principles and thus caution should be used when comparing results; for example, the collection efficiency results from the impactors are based on aerosol mass, while the fit factor results from the PortaCount are based on particle counts. Lastly, because of the need to rapidly produce results in response to the COVID-19 pandemic, we only tested 2-3 samples of each source control device (each sample was used in two consecutive tests). By comparison, for example, the NIOSH procedure for evaluating N95 respirators calls for 20 samples to be tested (NIOSH 2019).

Current evidence indicates that masks like those tested in our experiments can substantially decrease the amount of respiratory aerosols released by the wearer, and also help reduce what the wearer breathes in (CDC 2020a). Both effects vary depending upon the material and construction of the mask, as well as how it is worn. In addition to consistent and correct mask use when in the company of others, other measures such as physical separation are important, particularly during brief exposures. In a room where someone sneezes, being six feet or further away is better than being closer. However, with prolonged exposure in the same space for more than a few minutes, the benefit of distance fades as exhaled respiratory aerosols drift, mix, and accumulate in the enclosed air space. Optimizing ventilation, air filtration, and the introduction of fresh air can help counter this effect, but at every distance, correct mask use reduces the risk for everyone.

Conclusions

The ongoing COVID-19 pandemic has created an urgent need for simple methods to evaluate cloth masks as respiratory aerosol source control devices and to produce meaningful performance metrics that can be used to determine the effectiveness of different materials and designs. Our results suggest that test methods such as filtration efficiency testing, airflow resistance testing, and fit factor measurements on manikin headforms or human subjects have potential as ways to estimate the performance of masks as source control devices for respiratory aerosols. However, more research and improvements in the test methodologies are needed before such methods can be reliably implemented. Until the factors controlling the performance of source control devices are better understood and better testing methodologies are developed, results from test methods such as filtration efficiency testing, airflow resistance testing, and fit factor measurements should be interpreted cautiously when used to evaluate source control devices for respiratory aerosols.

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Declaration of interests statement

The authors declare no competing interests.

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Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols

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ABSTRACT

Face masks are recommended to reduce community transmission of SARS-CoV-2. One of the primary benefits of face masks and other coverings is as source control devices to reduce the expulsion of respiratory aerosols during coughing, breathing, and speaking. Face shields and neck gaiters have been proposed as an alternative to face masks, but information about face shields and neck gaiters as source control devices is limited. We used a cough aerosol simulator with a pliable skin headform to propel small aerosol particles (0 to 7 μm) into different face coverings. An N95 respirator blocked 99% (standard deviation (SD) 0.3%) of the cough aerosol, a medical grade procedure mask blocked 59% (SD 6.9%), a 3-ply cotton cloth face mask blocked 51% (SD 7.7%), and a polyester neck gaiter blocked 47% (SD 7.5%) as a single layer and 60% (SD 7.2%) when folded into a double layer. In contrast, the face shield blocked 2% (SD 15.3%) of the cough aerosol. Our results suggest that face masks and neck gaiters are preferable to face shields as source control devices for cough aerosols.

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Introduction

SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), can be transmitted from person-to-person by large respiratory aerosols (airborne liquid droplets and dried particles greater than about 10 μm in diameter) produced by people who are infectious while they are talking, singing, coughing, breathing or sneezing (CDC 2020a; Hamner et al. 2020). Smaller aerosols also are emitted by people during these activities, suggesting that short-range airborne transmission of SARS-CoV-2 might be possible under some circumstances (Anderson et al. 2020; CDC 2020a; Fennelly 2020; Ma et al. 2020; Morawska and Milton 2020).

To interrupt this potential transmission route, the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and other public health organizations recommend the wearing of face masks or other face coverings by the general public during the ongoing COVID-19 pandemic (CDC 2020b, 2020c; Edelstein and Ramakrishnan 2020; WHO 2020). One of the primary benefits of face coverings is to act as source control devices to reduce the expulsion of aerosols containing the virus from people who are infectious during coughing, breathing, and speaking. Source control devices are intended to protect other people from infectious aerosols emitted by the wearer, as compared with personal protective equipment such as N95 respirators which are primarily intended to protect the wearer. A face covering can provide source control in two ways (Diaz and Smaldone 2010). First, and most importantly, the covering may collect aerosol particles by filtration, impaction, or other mechanisms, and thus prevent infectious aerosols from entering the environment. Second, the face covering may change the direction of travel and the velocity of the aerosol stream and thus possibly divert the aerosol away from a potential recipient. However, deflection is more uncertain as a source control mechanism. For example, if large aerosols are deflected downward, they may settle to the floor or otherwise be unable to reach the breathing zones of other people. However, since exhaled breath is often warmer than the surrounding air, this

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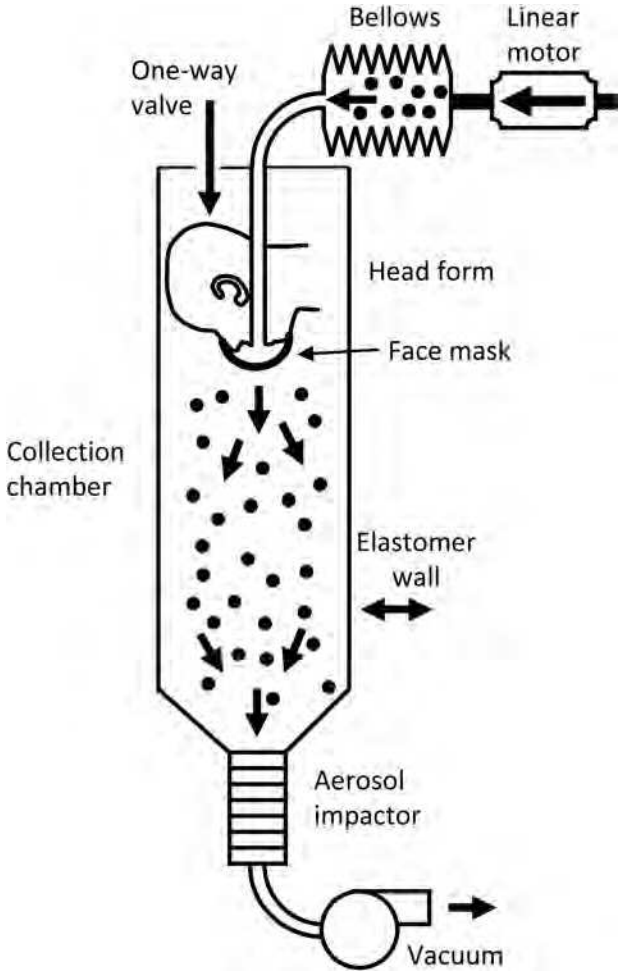

Figure 1. Cough aerosol simulator system for source control measurements. The system consists of an aerosol generation system, a bellows and linear motor to produce the simulated cough, a pliable skin head form on which the face mask, neck gaiter or face shield is placed, a 105 liter collection chamber into which the aerosol is coughed, and an Andersen impactor to separate the aerosol particles by size and collect them. More information about the cough aerosol simulator is provided in the SI.

downward deflection may be counteracted by the buoyancy of the breath for smaller aerosols. In addition, if the respiratory aerosols are deflected sideways, they may be diverted away from a person directly in front of the wearer but toward someone to the side or behind the wearer.

Studies using manikins (Lai, Poon, and Cheung 2012; Patel et al. 2016) and patients with respiratory infections (Leung et al. 2020; Milton et al. 2013) have shown that wearing medical face masks can reduce the dispersion of potentially infectious aerosols from patients. Two studies in which face masks were required for visitors and healthcare workers interacting with patients in bone marrow transplant centers found a reduction in respiratory viral infections among patients (Sokol et al. 2016; Sung et al. 2016). Studies of cloth face masks have suggested that they also can be effective at reducing the release of respiratory aerosols into the environment (Asadi et al. 2020; Davies et al. 2013; Konda et al. 2020). Several computational fluid dynamics studies have examined the generation and expulsion of respiratory aerosols and have provided important insights into the ability of face coverings to reduce the dispersion of large and small aerosols from the wearer (Dbouk and Drikakis 2020; Mittal, Ni, and Seo 2020).

Unfortunately, the use of face masks and other face coverings by the general public can present challenges. People often dislike wearing masks, and compliance can be low and inconsistent (Longtin et al. 2009). Mask wearers may repeatedly don, doff and adjust face masks, which can contaminate the hands and potentially lead to disease transmission, especially when the masks are reused (Brady et al. 2017; Casanova et al. 2008). For cloth masks, the filtration efficiency and air flow resistance of different textiles varies widely (Konda et al. 2020; Teesing et al. 2020; Wilson et al. 2020). Alternative face coverings such as neck gaiters (an elastic fabric tube that fits snugly around the head and neck) are commonly used, but information about their performance as source control devices is limited. Factors such as how well the mask fits the face and the coverage provided by a mask can have a substantial impact on the effectiveness of face masks (Davies et al. 2013; Lawrence et al. 2006). Comparisons of face coverings have found substantial differences in the ability of different types of these devices to reduce the release of respiratory aerosols (Asadi et al. 2020; Davies et al. 2013).

An opinion article in JAMA proposed that face shields would be more effective than face masks at reducing community disease transmission, in large part because the authors felt that face shields were more comfortable and thus that they were more likely to be widely adopted by the public (Perencevich, Diekema, and Edmond 2020). A previous study by our group of face shields used as personal protective devices showed that face shields protect the wearer from large cough aerosols directed at the face but are much less effective against smaller aerosols which were able to flow around the edges of the shield and be inhaled (Lindsley et al. 2014). However, very little work has been done examining face shields as source control devices. Two qualitative flow visualization studies of face shields and masks found that, although face shields deflected the air flow from the mouth, they did not stop aerosol particles from traveling around the face shield and entering the environment

(Verma, Dhanak, and Frankenfield 2020; Viola et al. 2020). Beyond these studies, quantitative data on the efficacy of face shields for source control are lacking.

The objective of our study was to conduct a quantitative comparison of the efficacy of an N95 respirator, a medical procedure mask, a commercial 3-ply cloth face mask, a single and double layer fabric neck gaiter, and a commercial disposable face shield as source control devices to reduce the expulsion of small cough-generated aerosol particles into the environment. Our results provide more information about the effectiveness of different types of source control devices and will help the public health community make recommendations about the best ways to use these devices to help reduce the spread of COVID-19.

Materials and methods

Experimental design

In our experiments, a cough aerosol simulator propelled a test aerosol through a headform into a collection chamber (Figure 1), and the amount of aerosol in the collection chamber was measured in each of six size fractions. The collection efficiency of each face mask, neck gaiter, or face shield was determined by comparing the amount of aerosol that was collected from the chamber with and without the device. Our test method was similar to the modified Greene and Vesley method used to test medical masks (Quesnel 1975), with the human test subject replaced by the cough aerosol simulator.

Cough aerosol simulator

The cough aerosol simulator is a modified version of the NIOSH cough aerosol simulator described previously (Lindsley et al. 2019; Lindsley et al. 2014; Lindsley et al. 2013). The experimental cough aerosol was generated by nebulizing a solution of 14% KCl and 0.4% sodium fluorescein using a single-jet Collison nebulizer (BGI, Butler, NJ, USA) at 103 kPa (15 lbs./in^2), passing the aerosol through a diffusion drier (Model 3062, TSI, Shoreview, MN, USA), and mixing it with 10 L/min of dry filtered air. The test aerosol was loaded into an elastomeric bellows, and the cough airflow was produced by a computer-controlled linear motor that compresses the bellows. The cough aerosol was expelled through the mouth of a headform into a collection chamber. The headform used in the study has pliable skin that mimics the elastic properties of human skin in order to create a realistic simulation of how each face covering or shield would fit a human face (Bergman et al. 2014).

Source control devices

The source control devices tested were an N95 medical respirator (3 M model 1860), a medical grade (ASTM Level 3) procedure mask with ear loops (Kimberly Clark model 47107), a cloth face mask with 3 layers of cotton fabric and ear loops (Hanes Defender), a fabric neck gaiter (FKGIONG Sun UV Protection Neck Gaiter, 95% polyester, 5% Spandex) and a disposable face shield (Fisher Scientific # 19-181-600 A). The neck gaiter was tested both as a single layer of fabric and doubled over to provide two layers of fabric. The masks and respirator were not equipped with exhalation valves. The face shield was 25 cm tall and extended from the forehead of the headform to 3 cm below the chin and around the side to 3 cm before the front of the ear. Photographs of the source control devices on the headform are shown in the online supplementary information (SI).

Mask fit test

For the experiments, either no device, a face mask, a neck gaiter, or a face shield were placed on the head form. Each device was used for two consecutive tests. For face masks and gaiters, a respirator fit test was performed using a PortaCount (TSI). The fit factor is a measure of the protection against airborne particles that is provided by a respiratory protective device. It is defined as the ratio of the aerosol concentration outside the respiratory protective device to the aerosol concentration inside the device (i.e., the aerosol concentration that is inhaled by the wearer). For example, a fit factor of 10 means that the ambient aerosol concentration is 10 times higher than the concentration inside the mask, and that the mask is therefore filtering out 90% of the ambient aerosol.

Aerosol collection and analysis

After placing the device on the headform and performing the fit test, the system was sealed. The test aerosol was then generated and propelled with a simulated cough through the headform and into the collection chamber. The Andersen impactor at the bottom of the collection chamber collected the aerosol particles that traveled through or around the device for 20 min after each cough. The Andersen impactor operates at a flow rate of 28.3 liters/minute and has six collection stages and a filter that separate the aerosol particles into seven size fractions based on the aerodynamic diameter of the particles: <0.6 µm; 0.6–1.1 µm; 1.1–2.1 µm; 2.1–3.3 µm; 3.3–4.7 µm;

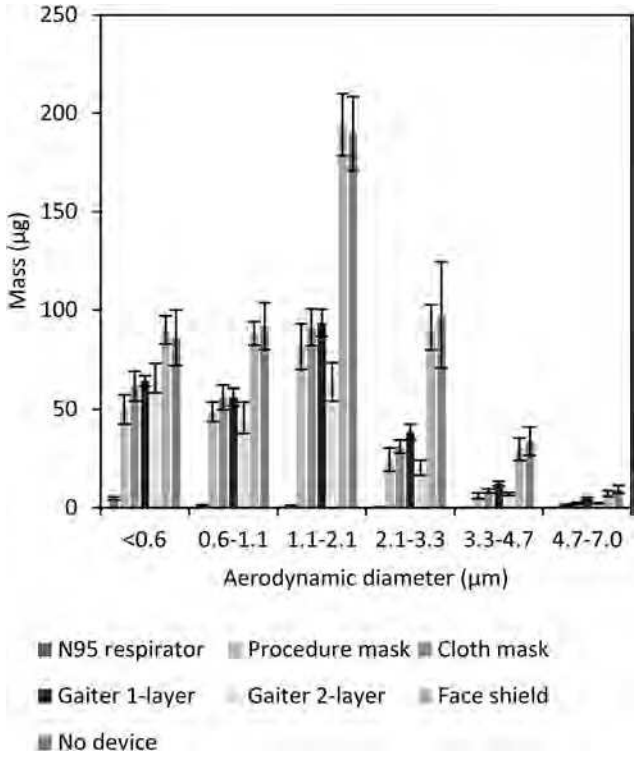

Figure 2. Mass of aerosol collected in each size fraction. The graph shows the amount of simulated respiratory aerosol that was collected from the collection chamber in each aerosol particle size fraction after a single simulated cough. The bars show the mean and standard deviation. A larger color version of this figure is shown in the SI.

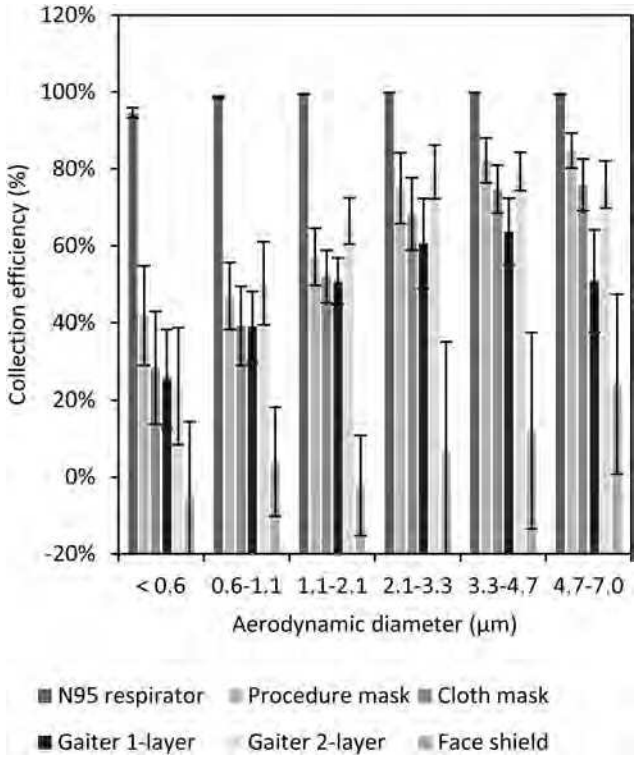

Figure 3. Collection efficiency of face masks, neck gaiter and face shield. The collection efficiency is the percentage of aerosol particles that were blocked by the face mask, neck gaiter or face shield compared with experiments without a device. The plot shows the means and standard deviations of the collection efficiency in each size fraction. A larger version of this figure is shown in color in the SI.

4.7–7.0 µm; and >7 µm. Because the amount of aerosol in the largest size fraction was small and because of possible losses due to settling of the large aerosol particles, data for the largest size fraction was not included in the analysis. The impactor collection plates were coated with a solution of glycerol and Brij 35 to prevent particles from bouncing off the plates during collection (Mitchell 2003). After aerosol collection was completed, the impactor plates were rinsed with 0.1 M Tris solution and the fluorescence of the solution was measured using a fluorometer (SpectraMax M4, Molecular Devices). The complete experimental protocol is given in the SI.

Statistical analysis

The performance of each device was evaluated by comparing the total mass of the aerosol particles from a single cough that passed through or around the device and was collected by the Andersen impactor. The results were evaluated using a one-way ANOVA and multiple comparisons among the different devices and the control experiments without a device were conducted using a Tukey-Kramer test. To control for variations in the amount of aerosol in each cough, a sample of each cough aerosol was collected from the bellows prior to coughing and used to normalize the aerosol mass collection results for each experiment.

Results

The cough aerosol simulator provides a cough with a controlled cough airflow rate containing a test aerosol with a consistent aerosol size distribution. The simulator allows for a direct quantitative comparison of the ability of different types of source control devices to block the expulsion of simulated cough aerosol particles of different sizes into the environment. The flow rate of the simulated cough used in our experiments was based on cough flow profiles recorded from influenza patients and had a volume of 4.2 L with a peak flow rate of 11 L/s (Lindsley et al. 2013). The cough aerosol collected from the control experiments without a face covering had a mass median aerodynamic diameter of 1.3 µm, a geometric standard deviation of 2.3 and a total aerosol mass of 505 µg (standard deviation 69).

For our study, we tested the collection efficiencies (that is, the fraction of the cough aerosol that was

Table 1. Total mass of aerosol expelled into collection chamber and device collection efficiencies.

Device tested	Number of experiments	Fit factor	Aerosol mass (μg)	Collection efficiency
No device	12	n/a	512 (64)	n/a
Procedure mask	6	2.9 (0.5)	212 (23)	58.5% (6.9%)
Cloth mask	6	1.3 (0.1)	251 (23)	50.9% (7.7%)
Neck gaiter (single layer)	6	1.7 (0.5)	270 (18)	47.2% (7.5%)
Neck gaiter (double layer)	6	1.9 (0.4)	206 (26)	59.8% (7.2%)
Face shield	6	n/a	502 (46)	1.8% (15.3%)
N95 respirator	6	198 (3.5)	7.2 (1.2)	98.6% (0.3%)

Note: The fit factor, aerosol mass, and collection efficiency are given as mean (standard deviation).

blocked) of a medical grade procedure mask, a cotton cloth face mask, a polyester neck gaiter, an N95 medical respirator and a disposable face shield. These source control devices were chosen to provide representative samples of the different types of face coverings and face shields that are in common use during the pandemic. Neck gaiters are typically worn either as a single layer of fabric over the mouth and nose or doubled over to provide two layers of fabric; for our experiments, we tested both configurations. The quantity of aerosol particles in six size fractions that were able to travel through or around each source control device are shown in Figure 2. The collection efficiencies of the devices are shown as a function of aerosol size in Figure 3. All the devices showed increased collection efficiencies as the aerosol size increased.

On average, the N95 respirator blocked 99% of the total mass of test aerosol from being released into the environment, while the medical procedure mask blocked 59%, the cloth face mask blocked 51%, the single-layer gaiter blocked 47%, the double-layer gaiter blocked 60%, and the face shield blocked 2% of the total aerosol (Table 1). The N95 respirator, procedure mask, cloth mask, and the single-layer and double-layer gaiters all significantly reduced the aerosol emitted into the environment compared with no device ($P < 0.0001$ for each), but the face shield did not ($P = 0.9993$). The collection efficiencies of the procedure mask, cloth mask, and the single and double-layer gaiters did not differ significantly from each other, but all blocked cough aerosols significantly better than did the face shield ($P < 0.0001$). The N95 respirator outperformed all the other devices ($P < 0.0001$) (Table 2).

Discussion

Humans continuously emit aerosols of respiratory fluids as they breathe, talk, cough, sneeze, sing, or carry out other respiratory activities. These respiratory aerosols can have a very broad size range, from tens of nanometers in diameter to visible droplets of a millimeter or more (Bourouiba, Dehandschoewercker, and Bush 2014; Fennelly 2020; Gralton et al. 2011; Morawska et al. 2009). Airborne particles larger than 100 μm are ballistic; that is, they are affected primarily by gravity and fall quickly to the ground. Respiratory aerosol particles in this size range tend to deposit within a few meters of the source (Prather et al. 2020). As the aerosol particle diameter decreases from 100 μm, a gradual transition occurs where the settling velocity rapidly decreases and the particles remain airborne for longer times. For example, a 100 μm aerosol particle takes 4 s to fall 1 m in still air, while a 10 μm aerosol particle takes 5.4 min and a 1 μm aerosol particle takes 8 h to settle the same distance (Hinds 1999). Air currents such as plumes of warm air rising from the body can lift these particles and extend the time for which they stay in the air. Thus, small aerosol particles can remain airborne for minutes to hours and can accumulate over time in environments with poor ventilation (Bahl et al. 2020). Small aerosol particles also are easier to inhale and can travel more deeply into the lungs (Vincent 2005).

The amount and sizes of aerosol particles containing SARS-CoV-2 that are expelled by people who are infected are not yet known. Two studies of aerosol samples collected in patient rooms found infectious (replication-competent) SARS-CoV-2 in aerosol particles <4 μm in diameter (Santarpia et al. 2020a) and <10 μm in diameter (Lednicky et al. 2020). Other studies have reported SARS-CoV-2 RNA in exhaled breath from infected patients (Ma et al. 2020), aerosol samples from biocontainment and quarantine units housing SARS-CoV-2 infected persons (Santarpia et al. 2020b), and in aerosol samples at multiple locations throughout two hospitals in Wuhan, China during a COVID-19 outbreak (Liu et al. 2020). The presence of small aerosol particles containing

Table 2. Comparison of aerosol mass expelled into the collection chamber while wearing face masks, neck gaiters and face shields.

		95% confidence intervals for mean differences (μg)			
PPE types compared		Lower limit	Mean difference	Upper limit	P-value
N95 respirator	No device	−567	−504	−442	<0.0001
Procedure mask	No device	−361	−299	−237	<0.0001
Cloth mask	No device	−322	−260	−198	<0.0001
Gaiter (single layer)	No device	−304	−241	−179	<0.0001
Gaiter (double layer)	No device	−368	−306	−243	<0.0001
Face shield	No device	−71	−9	53	0.9993
N95 respirator	Face shield	−567	−495	−423	<0.0001
Procedure mask	Face shield	−362	−290	−218	<0.0001
Cloth mask	Face shield	−323	−251	−179	<0.0001
Gaiter (single layer)	Face shield	−304	−232	−160	<0.0001
Gaiter (double layer)	Face shield	−369	−297	−225	<0.0001
N95 respirator	Gaiter (double layer)	−271	−199	−127	<0.0001
Procedure mask	Gaiter (double layer)	−65	7	79	0.9999
Cloth mask	Gaiter (double layer)	−26	46	118	0.4505
Gaiter (single layer)	Gaiter (double layer)	−7	64	136	0.1051
N95 respirator	Gaiter (single layer)	−335	−263	−191	<0.0001
Procedure mask	Gaiter (single layer)	−130	−58	14	0.1900
Cloth mask	Gaiter (single layer)	−91	−19	53	0.9825
N95 respirator	Cloth mask	−316	−244	−172	<0.0001
Procedure mask	Cloth mask	−111	−39	33	0.6336
N95 respirator	Procedure mask	−277	−205	−133	<0.0001

infectious SARS-CoV-2 detected in these studies suggests that in addition to large aerosols, these small aerosols might play a role in SARS-CoV-2 transmission (Anderson et al. 2020; Bahl et al. 2020; Ma et al. 2020; Morawska and Milton 2020).

Source control devices like face coverings and face shields collect respiratory particles larger than 0.3 μm primarily by impaction and interception of the aerosol particles against the fibers or solid surfaces of the device. As noted earlier, source control devices may also deflect aerosols, but this mechanism can be problematic as a means of source control because the infectious aerosol is not prevented from entering the surrounding environment; it is merely sent in a different direction which may or may not be protective depending upon local airflows and the locations of other people. Our experimental system measures particle collection only; any particles that are deflected but not collected by the face covering are still collected by the Andersen impactor. Thus, we are able to measure the particle collection efficiency of the face coverings without the potentially confounding variable of particle deflection. On the other hand, this does means that any potential benefits from, for example, deflecting large aerosol particles toward the ground were not measured by our system.

Small aerosols require much higher air velocities to deposit by impaction than do larger aerosols, and thus are more difficult to block with source control devices (Hinds 1999; Lindsley 2016). Consequently, small aerosols present the most challenging scenario for testing source control devices since devices that block small aerosol particles would be expected to block larger ones as well. Our results show that face masks and neck gaiters can significantly reduce the expulsion of small respiratory aerosol particles during coughing. This suggests that various types of face coverings can make an important contribution to reducing the quantity of aerosol particles containing SARS-CoV-2 released into the environment by people who are infected. N95 respirators, which are worn for personal protection by healthcare workers and others at highest risk of exposure, are also very effective source control devices. In contrast, the face shield blocked very little of the cough aerosol, indicating that face shields are not effective as source control devices for small respiratory aerosols.

The collection efficiencies of all the devices tested increased as the aerosol particle size increased, and this trend would be expected to continue for larger aerosol particles than were tested here. For example, the collection efficiency of the cloth face mask was 28% for the <0.6 μm particles and increased to 76% for the 4.7 to 7 μm particles. Similarly, the double-layer gaiter blocked 24% of the <0.6 μm particles and 76% of the 4.7 to 7 μm particles. These results suggest that cloth face coverings would be effective as source control devices against the large respiratory aerosols that are thought to play an important role in SARS-CoV-2 transmission.

Our study has several limitations. We used a single cough volume, air flow profile, and aerosol size distribution for our studies; these parameters can vary greatly from person to person. We examined the

performance of these devices during simulated coughing but not breathing or speaking, which have different air flow rates and aerosol size distributions. Some internal losses of the test aerosol particles likely occurred due to settling or impaction on the surfaces of the collection chamber, which may affect the estimates of the collection efficiencies. We only used a single representative example of each type of device. The shape and composition of face coverings vary widely, and this would be expected to affect the performance of individual devices. Some face masks have exhalation valves or vents which could reduce their efficacy as source control devices. The fit of a particular mask to an individual wearer and compliance in wearing the mask correctly (i.e., over the nose and mouth) also are important factors in how well the mask performs as a source control device. Because we used a < 0.6 to 7 µm test aerosol, our results do not indicate if face shields would be more effective as source control devices for large droplets. The face shield that we tested has a widely used design, but alternative designs are being marketed that provide greater facial coverage and, in some cases, include fabric skirts between the shield and the face. These alternative face shield designs might perform better as source control devices.

Previous studies have shown that face shields provide eye and facial protection to the wearer from droplets and splashes (Lindsley et al. 2014; Roberge 2016). When a face shield is worn in addition to a face mask, the face shield can also help reduce surface contamination of the mask by large aerosols and reduce the likelihood of hand contamination when the mask is removed or inadvertently touched (Lindsley et al. 2014). Our previous study showed that face shields provide some benefits as personal protective equipment when face masks cannot be worn (Lindsley et al. 2014), but as with all personal protection and source control devices, their limitations must be respected. Our results suggest that face masks and neck gaiters are more effective than face shields as source control devices to reduce the expulsion of respiratory aerosols into the environment as a public health measure to reduce the community transmission of SARS-CoV-2.

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Declaration of interests statement

The authors declare no competing interests.

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From: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>
Sent: Tuesday, January 11, 2022 2:05 PM
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
Cc: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>; McCalla, Haley (CDC/OD/OCS) <LNO3@cdc.gov>; Brunson, Juanita (CDC/DDNID/NCBDDD/DBDID) (CTR) <qrl8@cdc.gov>
Subject: N95 effectiveness as source control

Dear Partners,

We have had a number of questions from you and others about N95 effectiveness as source control and wanted to share some information back with you.

National Institute for Occupational Safety and Health (NIOSH) researchers have evaluated N95s as source control in two different peer reviewed publications. In the first paper (Lindsley et al. 2021a- attached), NIOSH researchers found that a N95 respirator (3M model 1860) was 99% effective at blocking cough aerosols. In a second paper (Lindsley et al. 2021b- attached), NIOSH researchers found that one N95 respirator (3M 1860 N95) was 99% effective at blocking coughed and exhaled aerosols, and a second N95 Respirator (BYD) was 83% effective at blocking cough aerosols and 95% effective at blocking exhaled aerosols.

References (attached)
Lindsley WG, et al. (2021a). Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols. AEROSOL SCIENCE AND TECHNOLOGY, VOL. 55, NO. 4, 449–457
https://doi.org/10.1080/02786826.2020.1862409

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Many thanks,
Aliki

Aliki Pappas Weakland, MPH MSW (she/her/hers)
Lead, Policy & Public Health Partnerships
State, Tribal, Local and Territorial Support Task Force
Coronavirus Disease-2019 (COVID-19) Response
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Coronavirus Disease 2019 (COVID-19) | CDC

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Saturday, January 08, 2022 1:55 PM EST
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
Subject: PARTNER ALERT: CDC Expands Booster Shot Eligibility

Dear Partners –

Yesterday, CDC adjusted our recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months.

Earlier this week CDC made this recommendation for recipients of a Pfizer-BioNTech primary seriesand, after FDA action this morning, we're extending this recommendation to recipients of a Moderna primary series. This means that people 12 and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.

Recently CDC strengthened our COVID-19 vaccination recommendations for children, now recommending that:

- Moderately to severely immunocompromised children ages 5–11 years receive an additional primary dose of Pfizer-BioNTech to ensure optimal protection from the vaccine.
- Children and teens ages 12–17 years should receive a booster shot.

Thank you,

Vaccine Task Force
COVID-19 Response

From:	Craig, Jim
To:	Adcox-Green, Ashley; Boxx, Robert; Byers, Paul; Craft, Christy; Darnell, Tim; Hall, David; Horn, Marshall; Jennings, Twyla; Parker, Melissa; Sharlot, Liz; Taylor, Kathryn; William McLeod; Ware, Daphne; Williams, Alisa; Young, Dorthy
Subject:	FW: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)
Date:	Wednesday, January 12, 2022 8:45:26 AM
Attachments:	image001.png image002.png N95 effectiveness as source control .pdf PARTNER ALERT CDC Expands Booster Shot Eligibility.msg COVID-19 Partner Updates January 10 2022.msg HHS Therapeutics Projected Allocations_7 Jan 2022.pdf HHS Update COVID-19 allocation projections for January .pdf Lindsley-2021-A comparison of performance metr.pdf Lindsley-2021-Efficacy of face masks, neck gai.pdf

Interesting studies on mask efficacy. Spoiler alert – while there is variability and more study needed, they work.

Jim

From: Byers, Paul <Paul.Byers@msdh.ms.gov>
Sent: Tuesday, January 11, 2022 4:27 PM
To: Dobbs, Thomas E <Thomas.Dobbs@msdh.ms.gov>; Central Office Epi COVID Team <CentralOfficeEpiCOVIDTeam@msdh.ms.gov>; Craig, Jim <Jim.Craig@msdh.ms.gov>; Broom, Sarah <Sarah.Broom@msdh.ms.gov>; Pearson, Meg <Meg.Pearson@msdh.ms.gov>; Smith, Elisabeth <elisabeth.smith@msdh.ms.gov>
Subject: FW: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)

Please see updates.

Paul Byers, MD
State Epidemiologist

From: CSTE Emergency Response <Preparedness@cste.org>
Sent: Tuesday, January 11, 2022 4:17 PM
To: CSTE Emergency Response <Preparedness@cste.org>
Cc: CSTE Novel Coronavirus 2019 <CSTEncov2019@cste.org>
Subject: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Partner Alert: N95 Effectiveness as Source Control [Attachments]
    - Today, **Tuesday, January 11**, CDC issued a partner update (attached) in response to numerous questions about N95 mask effectiveness as source control. The update shared two peer reviewed publications from National Institute for Occupational Safety and Health (NIOSH) researchers (both attached) on N95 mask effectiveness, including findings that a N95 respirator was 99% effective at blocking cough aerosols.
- HHS Update: COVID-19 Allocation Projections for January [Attachments]
    - On **Friday, January 7**, the U.S. Department of Health and Human Services (HHS) issued an update with a projected calendar of allocation amounts and cadence of COVID-19 therapeutics for the remainder of January (attached). Questions may be directed to us COVID19Therapetuics@hhs.gov.
- Partner Alert: CDC Expands Booster Shot Eligibility [Attachment, Link]
    - On **Saturday, January 6**, CDC issued a partner alert (attached) adjusting its recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months. CDC has extended this recommendation to recipients of a Moderna primary series. This means that people 12 years of age and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.
- CDC COCA Call: What Clinicians Need to Know About the New Oral Antiviral Medications for COVID-19 [Links]
    - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **tomorrow, Wednesday, January 12 at 2:00 pm EST** to discuss the recent emergency use authorizations (EUAs) for new oral antiviral medications intended to decrease hospitalizations, as well as prevent severe COVID-19 and death Call information is below:
        - Weblink: https://www.zoomgov.com/j/1612974214?pwd=VitYMEorako1YWhCaXpnaWdsc2Ixdz09
          Telephone: (660) 254-5252 or (646) 828-7666 or (669) 216-1590 or (551) 285-1373
          Webinar ID: 161 297 4214
          Passcode: 180866
          Post-Event Recording:
          https://emergency.cdc.gov/coca/calls/2021/callinfo_011222.asp
- Reminder: CDC Preventive Medicine Grand Rounds: "The Public Health System of the Future – Moving Ahead in Partnership with Health Care & Other Sectors" [Link]
    - CDC will host its monthly Preventive Medicine Grand Rounds **tomorrow, Wednesday, January 12** at **1:30 pm EST**. The session will focus on the public health system of the

future and the speaker is John Auerbach, Director of Intergovernmental and Strategic Affairs for CDC. Continuing education (CE) is available at no cost. Registration information is available here.

Standing Updates

- CDC Partner Update – January 10 [Attachment]
  - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – January 10 [Link]
  - Please click here for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
  - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am ET**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
  - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
  - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

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From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Monday, January 10, 2022 4:53 PM EST
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>
Subject: COVID-19 Partner Updates: January 10, 2022

Good afternoon Partners,
Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC at eocevent424@cdc.gov. Thank you for your partnership.

January 10, 2022

Morbidity and Mortality Weekly Report (MMWRs)

- Effectiveness of BNT162b2 (Pfizer-BioNTech) mRNA Vaccination Against Multisystem Inflammatory Syndrome in Children Among Persons Aged 12–18 Years — United States, July–December 2021. Link here.
- Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 years — United States, March 1, 2020–June 28, 2021. Link here.
- Risk Factors for Severe COVID-19 Outcomes Among Persons Aged ≥18 Years Who Completed a Primary COVID-19 Vaccination Series — 465 Health Care Facilities, United States, December 2020–October 2021. Link here.
- Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021. Link here.

CDC Resources

New & Updated

- CDC Recommends Moderna Booster at 5 Months: On January 4th, CDC made this recommendation for recipients of a Pfizer-BioNTech primary series. After FDA action on January 7th, we're extending this recommendation to recipients of a Moderna primary series. This means that people who initially received an mRNA vaccine series——two doses of Moderna or Pfizer-BioNTech —can now receive an mRNA booster shot 5 months after completing their initial series.
- Guidance for COVID-19 Prevention in K-12 Schools was recently updated to reflect new recommendations for isolation for people with COVID-19 and recommendations for people who have come into close contact with a person with COVID-19.
- CDC Expands Booster Shot Eligibility and Strengthens Recommendations for 12-17 Year Olds: CDC now recommends that adolescents age 12 to 17 years old should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccination series.
- CDC Recommends Pfizer Booster at 5 Months, Additional Primary Dose for Certain Immunocompromised Children: On January 4th, CDC updated its recommendation for when many people can receive a booster shot, shortening the interval from 6 months to 5 months for people who received the Pfizer-BioNTech COVID-19 Vaccine.
- Stay Up to Date with Your Vaccines: To align with standard language CDC uses about other vaccinations, CDC is now using the phrase "up to date" when talking about COVID-19 vaccination. CDC recommends that individuals stay "up to date" by receiving any additional doses they are eligible for, according to CDC's recommendations, to ensure they have optimal protection against COVID-19. The technical definition of "fully vaccinated"—two doses of an mRNA vaccine or one dose of the J&J vaccine—has not changed.
- What We Know About Quarantine and Isolation provides information on why CDC shortened quarantine and isolation guidance for the general population.

School and Work

- Guidance for COVID-19 Prevention in K-12 Schools
- Overview of COVID-19 Isolation for K-12 Schools
- Overview of COVID-19 Quarantine for K-12 Schools
- What you Should Know About COVID-19 Testing in Schools
- Responding to COVID-19 Cases in K-12 Schools: Resources for School Administrators
- Schools, Child Care, and Colleges
- Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2
- Strategies to Mitigate Healthcare Personnel Staffing Shortages
- School Learning Modalities (HHS Protect Public Data Hub)

Community

- Communication Resources for Travelers
- CDC COVID-19 Travel
- 12 COVID-19 Vaccination Strategies for Your Community
- Find a COVID-19 vaccine near you: Vaccines.gov
  - Individuals in the U.S. can utilize a text messaging service to locate vaccine locations, available in both English and Spanish. Individuals can text their ZIP code to 438829 (GETVAX) and 822862 (VACUNA) to find three locations nearby that have vaccines available.

Science and Data

COVID-19 Variants

- Science Brief: Omicron (B.1.1.529) Variant provides an overview of the current scientific information regarding the Omicron (B.1.1.529) variant. New data continue to emerge, and recommendations will be updated periodically, as needed.
- Omicron Variant: What You Need to Know provides information on what is currently known about the Omicron (B.1.1.529) variant.
- What You Need to Know About Variants

COVID-19 Testing Guidance

¡¤Testing Strategies for SARS-CoV-2 describes and compares different types of testing strategies for SARS-CoV-2.
¡¤Self-Testing provides information on when, why, and how to use a self-test for COVID-19.

Influenza (flu) Guidance

¡¤Increasing Seasonal Influenza A (H3N2) Activity, Especially Among Young Adults and in College and University Settings, During SARS-CoV-2 Co-Circulation
¡¤FAQ: CDC Distribution of COVID-19 Assays
¡¤CDC Digital Media Toolkit: 2021-22 Flu Season

COVID-19 Vaccines

¡¤CDC Endorses ACIP's Updated COVID-19 Vaccine Recommendations
¡¤CDC Expands COVID-19 Booster Recommendations to 16-and-17-year-olds
¡¤COVID-19 Vaccine Booster Shots
¡¤COVID-19 Vaccines for Children and Teens
¡¤COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19: CDC strongly recommends COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.
¡¤Science Brief: Evidence Used to Update the List of Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19
¡¤Quick Conversation Guide on COVID-19 Vaccines for Children
¡¤Resources to Promote the COVID-19 Vaccine for Children & Teens
¡¤Using the COVID-Vac Tool to Assess Your COVID-19 Vaccination Clinic Staffing and Operations Needs

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Kind regards,
Shyonna Johnson, MPH (She/Her)
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DRAFT – PRE-DECISIONAL & DELIBERATIVE

Therapeutic Allocation

	Drug Class	Allocation Cadence	Sweep Schedule	Allocation Jan 3	Planned Allocation Jan 10	Planned Allocation Jan 17	Planned Allocation Jan 24	Planned Allocation Jan 31
Paxlovid *Pfizer*	Oral antiviral	Bi-Weekly	N/A	0	100,000	0	100,000	0
Molnupirivir *Merck*	Oral antiviral	Bi-Weekly	N/A	0	400,000	0	400,000	0
Evusheld *AstraZeneca*	Monoclonal for prevention	Weekly	N/A	50,000	75,000	75,000	75,000	75,000
Sotrovimab *GSK/Vir*	Monoclonal for treatment	Weekly	N/A	50,000	52,250	52,250	52,250	52,250
Bamlanivimab/ Etesevimab *Lilly*	Monoclonal; omicron resistance	Weekly	Weekly; Saturday	45,000	**45,000*	**45,000*	**45,000*	**45,000*
REGEN-COV *Regeneron*	Monoclonal, omicron resistance	Weekly	Weekly; Saturday	55,000	**55,000*	**55,000*	**55,000*	**55,000*
Remdesivir *Gilead*	IV antiviral	N/A; Commercial Market	N/A	N/A	N/A	N/A	N/A	N/A

** With the rise of the omicron variant, clinically appropriate use should be considered for bam/ete and REGEN-COV. Allocations of these products are subject to change based on omicron prevalence data.*

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From: ASPR Stake Holder (OS/ASPR) <ASPRStakeholder@hhs.gov>
Sent: Friday, January 7, 2022 5:41:02 PM
Subject: HHS Update: COVID-19 allocation projections for January

Dear State and Territorial Health Officials,

Thank you for your continued partnership in this all-of-America approach to fighting the COVID-19 pandemic. It remains our goal to facilitate a fair and equitable process in the allocation of COVID-19 therapeutics, and we certainly couldn't do this without you. We know that providing a longer look ahead for expected allocation amounts will help further support your jurisdictional planning. As such, attached is a projected calendar of allocation amounts and cadence for the remainder of January. Of course, the COVID-19 environment is very dynamic; so, these projections could change based on daily analysis of related data.

Additionally, we wanted to provide you with an update regarding Gilead's product - VEKLURY(tm) (remdesivir), which is not allocated by the federal government but is available commercially. Following the recent statement from the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel regarding therapies for the COVID-19 Omicron variant, CMS created HCPCS code J0248 for the VEKLURY(tm) (remdesivir) antiviral medication when administered in an outpatient setting. This code is available for use by all payers and is effective for dates of service on or after December 23, 2021:

* Long descriptor: Injection, remdesivir, 1 mg
* Short descriptor: Inj, remdesivir, 1 mg

Medicare Administrative Contractors (MACs) determine Medicare coverage when there is no national coverage determination, including in cases when providers use FDA-approved drugs for indications other than what is on the approved label. The MACs consider the major drug compendia, authoritative medical literature and accepted standards of medical practice to determine medical necessity when considering coverage. Therefore, the MACs will determine Medicare coverage for HCPCS code J0248 for VEKLURY(tm) (remdesivir) administered in an outpatient setting.

Thank you, again, and please contact us at COVID19Therapetuics@hhs.gov with any questions.

Regards,
HHS - Coordination Operations and Response Element (H-CORE)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Aerosol Science and Technology

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A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols

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AEROSOL SCIENCE AND TECHNOLOGY
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A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols

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ABSTRACT

Universal mask wearing is recommended to help control the spread of COVID-19. Masks reduce the expulsion of aerosols of respiratory fluids into the environment (called source control) and offer some protection to the wearer. Masks are often characterized using filtration efficiency, airflow resistance, and manikin or human fit factors, which are standard metrics used for personal protective devices. However, none of these metrics are direct measurements of how effectively a mask blocks coughed and exhaled aerosols. We studied the source control performance of 15 cloth masks (face masks, neck gaiters, and bandanas), two medical masks, and two N95 filtering facepiece respirators by measuring their ability to block aerosols $\leq$7 µm expelled during simulated coughing and exhalation (called source control collection efficiency). These measurements were compared with filtration efficiencies, airflow resistances, and fit factors measured on manikin headforms and humans. Collection efficiencies for the cloth masks ranged from 17% to 71% for coughing and 35% to 66% for exhalation. Filtration efficiencies for the cloth masks ranged from 1.4% to 98%, while the fit factors were 1.3 to 7.4 on headforms and 1.0 to 4.0 on human subjects. The Spearman's rank correlation coefficients between the source control collection efficiencies and the standard metrics ranged from 0.03 to 0.68 and were significant in all but two cases. However, none of the standard metrics were strongly correlated with source control performance. A better understanding of the relationships between source control collection efficiency, filtration efficiency, airflow resistance, and fit factor is needed.

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Introduction

Humans infected with SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), can produce droplets and aerosols of respiratory fluids containing the virus when they cough, breathe, talk, sing and sneeze (Anderson et al. 2020; CDC 2020b; Hamner et al. 2020; Ma et al. 2020; Morawska and Milton 2020). To reduce the transmission of SARS-CoV-2, public health agencies have recommended that the general public wear cloth masks (CDC 2020c, 2020d, 2021; Edelstein and Ramakrishnan 2020; WHO 2020). The primary purpose of masks (which in this article includes face masks, neck gaiters, bandanas and other face coverings) is to block the expulsion of infectious droplets and aerosols from the wearer into the environment (called source control) and thereby reduce the exposure of other people to the virus (CDC 2020a). Laboratory studies using manikins and human subjects have shown that cloth face masks can partially block respiratory aerosols produced during coughing, breathing and talking (Asadi et al. 2020; Davies et al. 2013; Lindsley et al. 2021; Pan et al.

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2021). Wearing medical face masks (i.e., "surgical masks" as defined by the U.S. Food and Drug Administration [FDA 2004]) reduces the dispersion of potentially infectious aerosols from patients with respiratory infections (Leung et al. 2020; Milton et al. 2013). Masks may also provide some personal protection to the wearer by reducing their exposure to infectious droplets and aerosols produced by others, although they are not as effective as a respiratory protective device such as a NIOSH-approved N95 filtering facepiece respirator (N95 respirator) (CDC 2020a; Lawrence et al. 2006; Oberg and Brosseau 2008; Pan et al. 2021). Several community level studies have shown that universal masking helps reduce the spread of COVID-19 (CDC 2020a). For example, a comparison of counties in the US state of Kansas found that mask mandates were associated with lower incidence rates of COVID-19 (Van Dyke et al. 2020). A study of 10 US states found that statewide mask mandates were associated with a decline in weekly COVID-19–associated hospitalization growth compared to states without such mandates (Joo et al. 2021).

In response to the need for source control devices for the general public, manufacturers worldwide have produced a broad array of masks. Unfortunately, because of the many different designs and construction materials, it is not possible to predict how well a particular mask will perform as a source control device without testing, which is rarely done for non-medical masks not intended for occupational use. Although general guidelines have been developed (CDC 2020d), it is very difficult for public health organizations, governments, medical facilities, and the general public to know which of the available devices are most effective.

Test methods and performance standards do exist for regulated medical face masks and respiratory protective devices (Rengasamy et al. 2017). In the United States, respiratory protective devices, which are devices such as N95 filtering facepiece respirators that are intended to protect the wearer from airborne particles, must be approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 Code of Federal Regulations (CFR) Part 84 (NIOSH 1995). The approval process includes testing the filtration efficiency for the most-penetrating aerosol particle size and measuring the airflow resistance of the device (NIOSH 2019). Medical face masks that are not intended to be used as respiratory protective devices are cleared by the Food and Drug Administration (FDA), which reviews manufacturer-supplied information on filtration efficiency, airflow resistance, resistance to fluid penetration and flammability (FDA 2004). The FDA recommends that manufacturers use the ASTM standards F2299 for measuring particle filtration efficiency through the mask material using latex microspheres (ASTM 2003), and the F2101 Standard test method of evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of *Staphylococcus aureus* (ASTM 2019). Bacterial filtration efficiency can also be measured with the modified Greene and Vesley method using human test subjects (Greene and Vesley 1962; Quesnel 1975).

In addition to filtration performance, how well a respiratory protective device protects the wearer depends upon how well the device fits the face and whether the seal between the face and the device has gaps or leaks (Lawrence et al. 2006). ASTM Standard F3407-20 outlines procedures for testing respirators using a bivariate panel of human test subjects with different facial dimensions (ASTM 2020). The NIOSH approval test for respirators measures the filtration properties but does not include tests of how well the device fits faces of different shapes, although this has been proposed. Consequently, in the United States, when a worker is required to wear a respirator, the Occupational Safety and Health Administration (OSHA) requires that a respirator fit test be performed annually for each worker to determine how well the respirator protects the worker (OSHA 2020). Quantitative fit tests measure the aerosol particle concentration inside and outside the respirator during a series of exercises, and this information is used to calculate the fit factor (outside concentration/inside concentration) (Janssen and McKay 2017). The minimum acceptable fit factor for a respirator depends upon the exposure level and potential health consequences of the hazards to which the worker may be exposed (OSHA 2020).

The existing test methods for respirators and medical face masks provide a possible basis for developing standards for non-medical masks used as source control devices. The American Association of Textile Chemists and Colorists (AATCC) published guidelines for cloth face coverings that include the use of ASTM F2299 and other national and international performance standards (AATCC 2020). Leith, L'Orange, and Volckens (2021) proposed an estimated mask protection factor that is calculated based on tests of filtration efficiency and fit and on estimates of the average time spent speaking, inhaling, and exhaling. ASTM International has released a standard for testing barrier face coverings that includes tests of filtration efficiency and airflow resistance, and an assessment of leakage, which are standard metrics that are commonly used to test personal protective devices (ASTM 2021). The use of these standard performance metrics has many advantages, most notably that the equipment and procedures needed to conduct the tests are widely available. However, none of these metrics are

Table 1. Performance metrics used in this study. Outward mask airflow is in the direction of exhalation. Inward airflow is in the direction of inhalation.

Performance metric	**Parameter measured**	Mask airflow direction	Measurement instrument	**Measurement method**	Particle size	**Instrument airflow rate (liters/minute)**
Cough aerosol collection efficiency	Aerosol mass escaping beyond mask into collection chamber	Outward	Andersen impactor	Fluorescence of aerosol on impactor stages	0.1 to 7 μm	28.3
Exhaled aerosol collection efficiency	Aerosol mass escaping beyond mask into collection chamber	Cyclical	Andersen impactor	Fluorescence of aerosol on impactor stages	0.1 to 7 μm	28.3
Filtration efficiency	Aerosol mass concentration upstream & downstream of mask	Inward	TSI 8130 A	Photometer	75 nm count median diameter (GSD 1.86)	85
Airflow resistance	Pressure required for 85 lpm flow	Inward	TSI 8130 A	Manometer	n/a	85
Manikin fit factor	Aerosol particle count inside & outside mask	Cyclical	TSI PortaCount	Size classifier & condensation particle counter	55 nm (N95 mode)	0.35
Human fit factor	Aerosol particle count inside & outside mask	Cyclical	TSI PortaCount	Size classifier & condensation particle counter	55 nm (N95 mode) 0.02–1.0 μm (Class 100 mode)	0.35

direct measurements of the ability of a mask to block aerosols expelled during coughing and exhalation. To assist in the further development of these types of standards and guidelines, the relationship between the efficacy of masks as source control devices and their performance using standard metrics needs to be better understood. For example, it is possible to measure the filtration efficiency of the mask material, but it is not clear how that filtration efficiency translates to source control efficacy or what minimum performance level should be required.

The purpose of this study was to compare the performance of a variety of N95 respirators, medical masks, and cloth masks as source control devices with their filtration efficiencies, airflow resistances, fit factors measured using manikin headforms, and fit factors measured on humans. The results of these experiments will assist in the development of appropriate test methods and standardized performance metrics to evaluate the efficacy of cloth masks as source control devices for respiratory aerosols.

Materials and methods

Experimental design

A source control measurement system was used to assess the efficacy of N95 respirators, medical masks, and cloth masks as source control devices. The source control performance was determined by measuring the source control collection efficiency of the mask, which is the fraction of the mass of the coughed or exhaled test aerosol particles that were blocked by the mask from reaching the collection chamber. The filtration efficiencies and airflow resistance of the construction materials were measured using a modified version of the test method used for respirator approvals. Fit tests were performed both on a manikin headform with pliable skin and with human test subjects. The source control collection efficiencies were then compared with the fit factors, filtration efficiencies and airflow resistances measured on the same devices. A summary of the performance metrics used in the study is shown in Table 1.

Respiratory aerosol source control measurement system

The efficacy of respirators, medical masks, and cloth masks as source control devices for aerosols produced during coughing and exhalation was determined using a respiratory aerosol source control measurement system described previously (Lindsley et al. 2021). The system includes a coughing and breathing aerosol simulator, a manikin headform, an 136 L aerosol collection chamber, and a cascade impactor (Figure 1). The manikin headform used in the study has pliable skin that mimics the elastic properties of human skin in order to create a realistic simulation of how each source control device would fit a human face (Bergman et al. 2014).

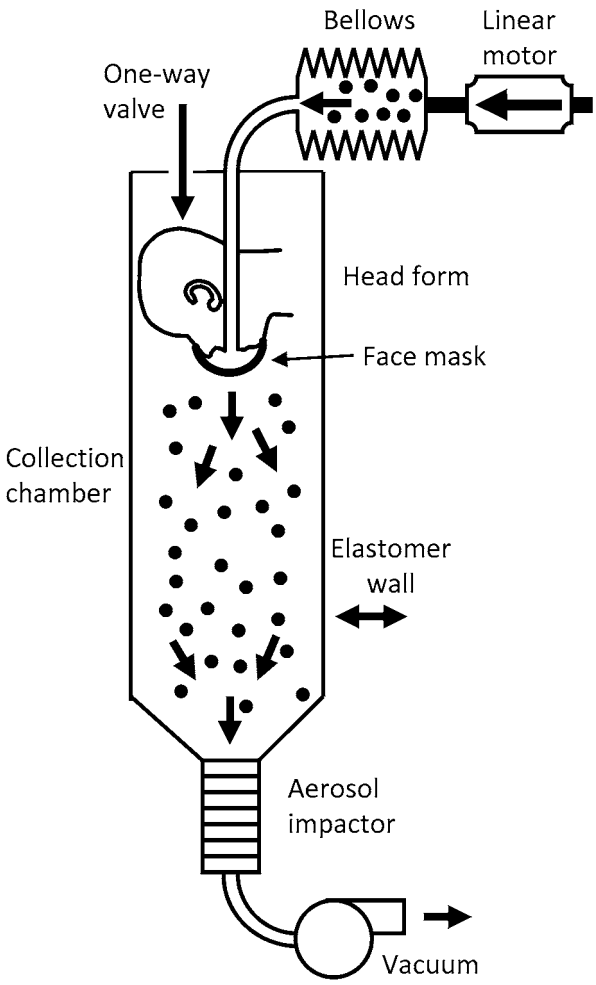

Figure 1. Source control measurement system. The system consists of an aerosol generation system, a bellows and linear motor to produce the simulated coughing and breathing, a pliable skin headform on which the source control device is placed, a 136 liter collection chamber into which the aerosol is coughed or exhaled, and a cascade impactor to separate the aerosol particles by size and collect them. The system is oriented vertically as shown to minimize the loss of aerosol particles due to settling before collection. The system is described in more detail in Lindsley et al. (2021).

The test aerosol was produced using a solution of 14% potassium chloride (KCl) and 0.4% sodium fluorescein in a single-jet Collison nebulizer (BGI, Butler, NJ, USA) at 103 kPa (15 lbs./in^2). The aerosol passed through a diffusion drier (Model 3062, TSI, Shoreview, MN, USA), mixed with dry filtered air flowing at 10 L/min for the cough tests and 15 L/min for the breathing tests, and neutralized using a bipolar ionizer (Model HPX-1, Electrostatics). An elastomeric bellows driven by a computer-controlled linear motor produced the coughing or breathing airflow.

For cough tests, the test aerosol was loaded into the elastomeric bellows and then coughed out using a single cough with a volume of 4.2 L and a peak flow rate of 11 L/s (Lindsley et al. 2013). An Andersen cascade impactor (Model TE-10-830, Tisch Environmental) collected all aerosol particles that traveled through or around the device for 20 min after each cough. For breathing tests, the system used a ventilation rate of 15 L/min with a breathing rate of 12 breathes/min and a tidal volume of 1.25 liters, which corresponds to the ISO standard for a female performing light work (ISO 2015). The test aerosol was only generated for the first 30 s of breathing to avoid overloading the impactor. The breathing continued for 20 min total. The impactor collected the aerosol particles in the chamber during the 20-minute breathing period followed by an additional five minutes of collection after the breathing had stopped.

The impactor operated at a flow rate of 28.3 liters/minute and had six collection stages and a filter that separated the aerosol particles into seven size fractions based on the aerodynamic diameter of the particles: <0.6 µm; 0.6–1.1 µm; 1.1–2.1 µm; 2.1–3.3 µm; 3.3–4.7 µm; 4.7–7.0 µm; and >7 µm. The impactor collection plates were coated with a solution of glycerol and Brij 35 to prevent particles from bouncing off the plates during collection (Mitchell 2003). Because the amount of aerosol in the largest size fraction was small (<0.7% of total aerosol mass) and because of possible losses due to settling of the large aerosol particles, data for the largest size fraction were not included in the analysis. After aerosol collection was completed, the aerosol particles were eluted from the impactor plates using a 0.1 M Tris solution and the fluorescence of the solution was read using a spectrofluorometer (SpectraMax M4, Molecular Devices).

To control for variations in the amount of aerosol in each experiment, a sample of each test aerosol was collected from the bellows prior to coughing or breathing using a 47 mm 5 µm PVC filter. The aerosol was eluted from the filter using 0.1 M Tris. An adjustment factor for the experiment (A) was calculated as:

$$A = \frac{Mass\ of\ aerosol\ on\ filter}{Mean\ (mass\ of\ aerosol\ on\ filter\ for\ all\ control\ experiments)} \quad (1)$$

The adjusted mass of aerosol on each impactor stage for the experiment was then calculated as:

$$M_{stage,\ adjusted} = \frac{M_{stage,\ unadjusted}}{A} \quad (2)$$

The adjusted masses were used for all subsequent calculations. The adjusted aerosol masses collected by the cascade impactor during the experiments are

Table 2. Source control devices used in experiments.

Type	Manufacturer	Product	Fastener	Material
Medical masks & respirators	3M	Model 1860 N95 respirator and surgical mask (TC-84A-0006)	Two elastic straps around head	Polypropylene and polyethylene composition
	BYD	N95 filtering facepiece respirator (TC-84A-9221)	Two elastic straps around head	IL and OL: Polypropylene spun-bound nonwoven fabric. ML: Polypropylene melt-blown nonwoven + hot air cotton
	3M	Model 1818 surgical mask	Two ties behind head	Poly(ethylene terephthalate) and polypropylene
	Excellent Artisan	Procedure mask	Ear loops	3-ply, Nonwoven. Fabric composition unknown
Reusable cloth face masks	Hanes	Defender 3-ply mask	Ear loops	100% cotton
	EnerPlex	3-ply mask	Ear loops	IL and ML: 65% polyester, 35% cotton. OL: 100% polyester
	Craft & Soul	2-ply mask	Ear loops	65% polyester, 35% cotton
	Lefty	2-ply face mask	Ear loops	92% polyester, 8% spandex
	Badger	4-ply mask	Ear loops	IL : 100% cotton. MLs: melt blown filters. OL: air mesh polyester
	Debrief Me	3-ply mask with PM 2.5 filter	Ear loops	IL 100% cotton, ML and OL: polyester blend
	Fabrique Innovations	Mask	Ear loops	100% cotton
	Besungo	Mask with PM 2.5 filter & exhalation valves	Ear loops and Velcro neck strap	Nylon
	Inspire	2-ply mask with PM 2.5 filter	Ear loops	Polyester/cotton blend
Neck gaiters	FKGIONG	Neck gaiter	Encircles head	95% polyester, 5% spandex
	AXBXCX	Neck gaiter	Encircles head	Polyester
	Retro Brand	Neck gaiter	Encircles head	100% polyester
	Givon	Neck gaiter	Encircles head	100% polyester fleece
Bandanas	L & M	Bandana	Ties behind head	100% cotton
	Underwear	Bandana/gaiter	Ear loops	Polyester blend

In this article, the reusable cloth face masks, neck gaiters and bandanas are referred to collectively as "cloth masks". IL is inner layer, ML is middle layer, and OL is outer layer. Photographs are shown in Figures S3–S5 (SI).

shown in Tables S1 and S2 in the supplemental information (SI).

The source control performance, or source control collection efficiency, of a face covering is defined as the fraction of the mass of the respiratory aerosol that is blocked from entering the environment around the wearer. For example, if 80% of the mass of the aerosol from a cough is blocked by a face mask and 20% of the aerosol mass is able to flow through or around the mask into the air around the wearer, then the mask is said to have a collection efficiency of 80%. The performance of each source control device was evaluated by calculating the collection efficiency as:

$$Collection\ efficiency = 1 - \frac{M_{mask}}{M_{control}} \qquad (3)$$

where:

M_{mask} = adjusted total mass of the aerosol particles that passed through or around the source control device and was collected by the impactor.

$M_{control}$ = adjusted total mass of the aerosol particles collected by the impactor while not wearing a source control device.

Note that the collection efficiency is based on the mass of the aerosol rather than a measure such as particle counts. Also, the aerosol is flowing from the inside of the mask toward the outside; that is, in our test system the aerosol flows in the same direction as it would flow during a cough or exhalation by a person wearing the mask.

Respirators, medical masks, and cloth masks

In our study, the term "cloth mask" refers to a cloth face mask, neck gaiter or bandana constructed from textiles or fabrics (both natural and synthetic) that is not a surgical mask or N95 respirator and is not intended for use as personal protective equipment. The term "medical masks" in this article refers to non-woven disposable masks that are held on the face with elastic ear loops. These masks are loose-fitting and are not expected to provide the wearer with as reliable a level of protection against airborne or aerosolized particles as N95 respirators regulated by NIOSH. Commercial manufacturers often refer to

masks held on by ear loops as procedure masks and masks that tie behind the head as surgical masks. However, the U.S. Food and Drug Administration uses the term "surgical mask" to describe commercially produced masks regulated by the under 21 CFR 878.4040 for performing medical procedures (FDA 2004). The FDA definition applies to all masks that cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials, and includes masks that are labeled as surgical, laser, isolation, dental or medical procedure masks with or without a face shield.

Nineteen commercially available N95 respirators, medical masks, and cloth masks were selected to provide a broad cross-section of the different types of source control devices that are available (Table 2). For the source control tests, each device was placed on the headform as it would normally be worn by a person. Three of the neck gaiters were tested both as a single layer of fabric and folded over to provide two layers of fabric. Before the source control test, the manikin fit factor (Janssen and McKay 2017) was measured by performing a respirator fit test (Bergman et al. 2015) for each device using a PortaCount® Pro + respirator fit tester (Model 8038, TSI, Shoreview, MN) in N95 mode with the system breathing at 36 L/min but not producing an aerosol. Each device was used for two consecutive tests. Photographs of the source control devices on the headform are shown in the SI (SI; Figures S1–S3).

Filtration efficiency and airflow resistance measurements

The filtration efficiency of the face covering is the fraction of the test aerosol that is collected as the aerosol passes through the mask material. For example, if 70% of the test aerosol is collected by the mask material and 30% of the aerosol passes through it, then the filtration efficiency is 70%. Note that the filtration efficiency tests are performed by fastening the mask to a holder so that all the aerosol flows through the mask material, and none can escape through face seal leaks. Thus, the filtration efficiency is a property of the mask material.

The filtration efficiency and airflow resistance of the construction materials were measured using automated filter testers (Models 8130 and 8130 A, TSI). Material samples were secured to a test plate using beeswax as shown in Figure S4 in the SI. Measurements were made using a modified version of the NIOSH standard testing procedure (STP) (NIOSH 2019). Under the modified STP, samples were tested at ambient temperature and humidity but were not subjected to conditioning at 38°C and 85% relative humidity for 25 h, and sample testing was limited to 10 min. The device to be tested was oriented in the filter tester so that the air and aerosol flowed from the exterior of the device toward the interior (that is, as if the wearer were inhaling, which is the same direction as when testing a respirator as a personal protective device). The challenge aerosol was generated using a 2% sodium chloride (NaCl) solution in distilled water, conditioned to 25 °C and 30% relative humidity and neutralized to the Boltzmann equilibrium state. The challenge aerosol had a count median diameter of 75 nm ± 20 nm, a mass mean diameter of 260 nm and a geometric standard deviation (GSD) $\leq$ 1.86 (TSI 8130 A specifications). The automated filter tester compares particle mass concentration readings from upstream and downstream light-scattering laser photometers to calculate the material filtration efficiency. An electronic pressure transducer measures the pressure difference across the material sample to indicate airflow resistance. Tests were performed with an airflow of 85 L/minute.

Fit tests on human subjects

A convenience sample of eleven subjects (six males and five females) participated in fit testing. Subjects complied with CDC/NIOSH guidelines for facial hair styles intended for workers who wear tight-fitting respirators (CDC 2017). Fit testing was performed with a PortaCount® fit tester (model 8038, TSI) using OSHA's modified ambient aerosol condensation nuclei counter (CNC) protocol for filtering facepiece respirators (OSHA 2019). Because only fit factors were measured and no identifiable private information was collected, the West Virginia University Office of Human Research Protections determined that Institutional Review Board approval was not required. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy (see e.g., 45 C.F.R. part 46; 21 C.F.R. part 56; 42 U.S.C. §241(d), 5 U.S.C. §552a, 44 U.S.C. §3501 et seq.). All measurements were performed in a room with volume of 43.4 m^3 (1531 ft^3) at 19 °C (67 °F).

An NaCl aerosol generator (Model 8026, TI) was used to supplement the naturally occurring particles in the air. The particle generator was placed 10 feet away from all sampling apparatus and fit testing equipment. The generator was turned on ten minutes prior to testing to seed aerosols and turned off while

a triplicate series of fit tests were performed (around 7 min). As the aerosol concentration in the room had started to slightly decline at this point, the generator was turned on between tests (around 7 min) and then turned off during subsequent tests. This process was repeated until testing for the day was completed.

To verify that suitable aerosol concentrations were present during testing, particle concentrations were measured with a condensation particle counter (CPC Model 3775, TSI) for 25 min beginning at 2 min prior to the nebulizer being initially turned on. Particle size distributions were measured for 20 min with a scanning mobility particle sizer (SMPS Model 3938, TSI) and an electrical low-pressure impactor (ELPI+, Dakati). Information on the aerosol particle size distribution and concentration are shown in the SI (Figures S5 and S6).

Each source control device was tested by three subjects; for each subject three replicate measurements were made using each of the two protocols described below. One individual administered all fit tests. Subjects were instructed in the proper donning of medical masks and respirators, and they were asked to don cloth masks in the manner that they ordinarily don similar coverings for public use. If a cloth mask was too large, it was modified using materials that would be accessible to most lay individuals: tape was used to shorten mask ear loops or head straps, and a binder clip was used to decrease the circumference of neck gaiters. These adjustments were made so that the covering was held flush to the face, but the materials were not under tension.

Two particle measurement protocols were performed on all source control devices: the PortaCount® N95 Companion protocol (referred to here as N95 mode), which counts negatively charged particles 40–70 nm (mean 55 nm) in diameter; and the PortaCount® standard protocol (referred to here as Class 100 mode), which counts all particles from 0.02–1.0 µm (TSI 2010). The "Class 100 mode" is also called "N99 mode". For both modes, the fit factor (FF) was calculated by the PortaCount® software as (Janssen and McKay 2017; TSI 2015):

$$FF = \frac{C_B + C_A}{2C_R} \quad (4)$$

where:

C_B = ambient particle concentration measured before the particle concentration is measured inside the respirator.

C_A = ambient particle concentration measured after the particle concentration is measured inside the respirator.

C_R = particle concentration measured inside the respirator.

Note that the TSI PortaCount instrument used in our experiments measures the aerosol concentration based on the number of aerosol particles rather than the particle mass.

Data analysis

The source control results were compared with the filtration efficiencies, airflow resistances, and fit factor measurements by calculating the Spearman's rank correlation coefficients (ρ) between the metrics. Fit factors were transformed into fit efficiencies (= 1-1/fit factor) to allow for a direct comparison with the other parameters. For example, a fit factor of 5 corresponds to a fit efficiency of 80%, indicating that the mask blocked 80% of the ambient aerosol from being inhaled by the wearer. Because the replicate numbers were different for the different performance metrics, the correlations were calculated based on the mean results for each device. When analyzing the human fit factor results, we did not attempt to account for differences among test subjects. The p-value was calculated based on ρ and the number of types of devices that were tested (22 for all source control devices and 18 for the cloth masks alone, with the 1-layer and 2-layer gaiter tests counted separately). Correlations were considered significant if $p \leq 0.05$.

Results

Efficacy of N95 respirators, medical masks, and cloth masks as source control devices for respiratory aerosols

Twenty-six cough experiments were performed without a source control device to measure the cough aerosol output from the source control measurement system. The cough aerosol had a geometric mean aerodynamic diameter of 1.3 µm with a GSD of 2.3 and a mean mass of 525 µg (standard deviation [SD] 65; Figure 2 and SI Figure S7). Thirty-five breathing aerosol experiments were performed without a source control device to measure the exhaled aerosol output. The exhaled aerosol had a geometric mean aerodynamic diameter of 1.3 µm with a GSD of 2.3 and a mean mass of 495 µg (SD 68; Figure 2 and SI Figure S8). The experiments without source control devices were used as control experiments when evaluating performance of the devices.

The collection efficiencies of the 19 source control devices are shown in Figure 3 and Table 3. The mean

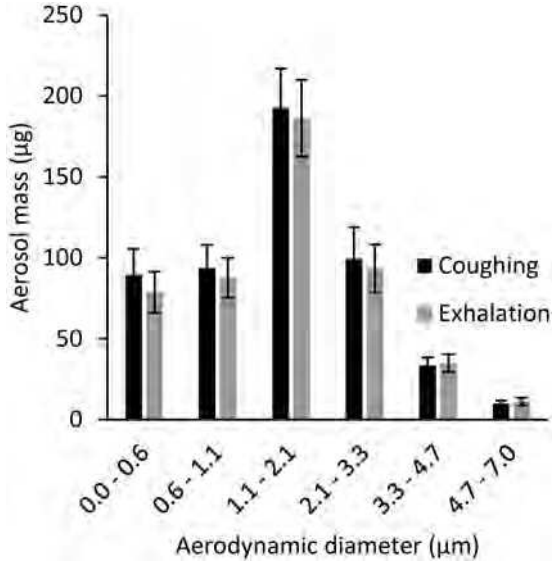

Figure 2. Mass of aerosol expelled by the source control measurement system during coughs and exhalations. The size bins correspond to the stages of the Andersen impactor. The size distribution is shown in units of µg/µm in Figures S7 and S8 in the SI.

collection efficiencies of the N95 respirators and the surgical mask ranged from 83% to 99% for aerosol particles during coughing and exhalation. For the procedure and cloth masks, the mean collection efficiencies ranged from 35% to 71% for coughing (except for the bandana at 17%) and 35% to 66% for exhalation. The collection efficiencies for the coughing and breathing source control experiments were correlated, with a Spearman's correlation coefficient (ρ) of 0.76 ($p < 0.001$; Table 4) when considering all the devices and 0.67 ($p = 0.003$; Table 4) when considering only the cloth face masks, gaiters and bandanas. The amounts of aerosol collected on each stage of the impactor are shown in Tables S1 and S2 in the SI.

Filtration efficiencies and inhalation airflow resistance

The mean material filtration efficiencies were >99% for the respirators, 80% to 93% for the medical masks, and 1.4% to 36% for the cloth face masks, neck gaiters, and bandanas, except for the Besungo sports mask at 98% (Figure 4 and Table 3). The inhalation

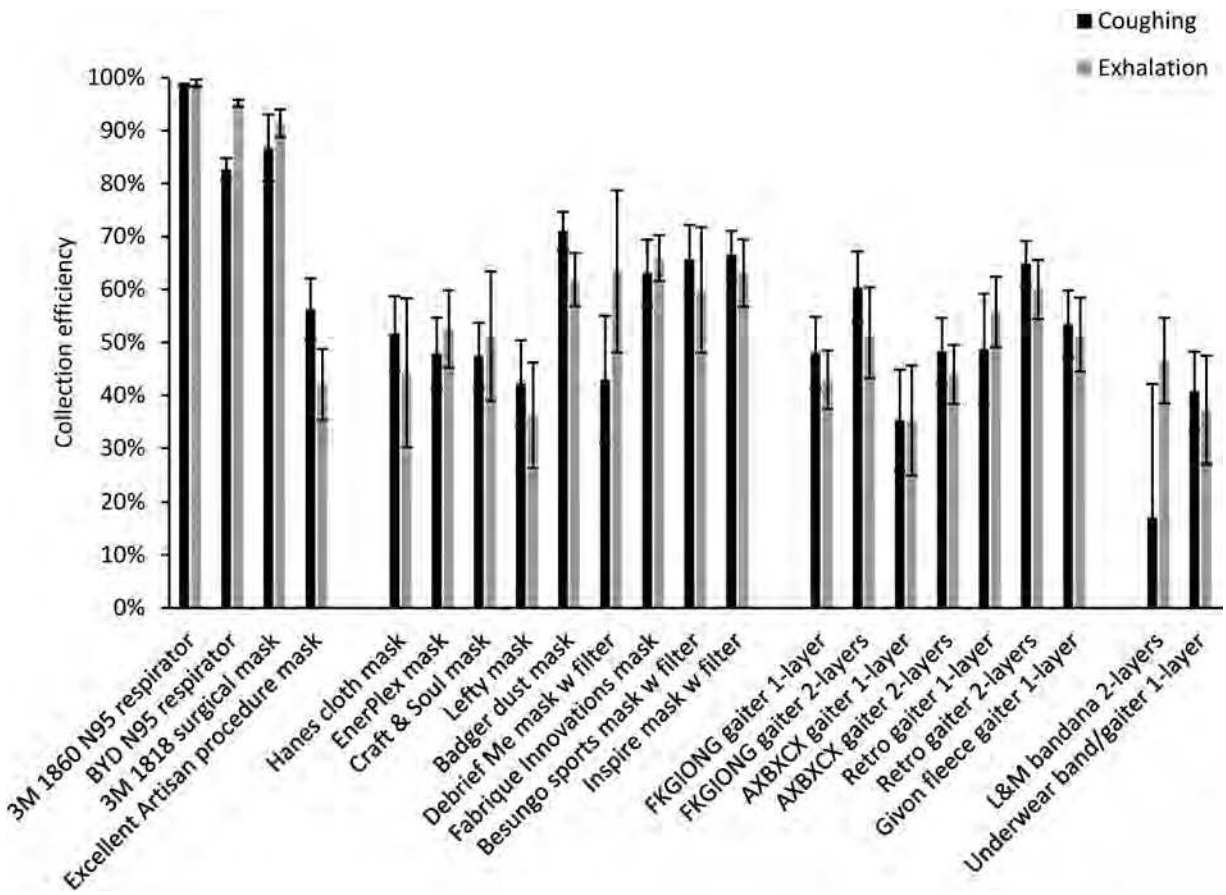

Figure 3. Source control collection efficiencies of N95 respirators, medical masks, cloth face masks, neck gaiters and bandanas during coughing and exhalation aerosol tests with the respiratory aerosol source control measurement system. Each bar is the mean of 4 or 6 experiments. Error bars show the standard deviation.

Table 3. Results for all performance metrics for source control devices.

Face covering	COUGHING				EXHALATION				Filtration Efficiency (%)		Inhalation airflow resistance (Pa)		Human fit factor			
	Collection efficiency (%)		Manikin fit factor		Collection efficiency (%)		Manikin fit factor						N95 mode		Class 100 mode	
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
3M 1860 N95 respirator	98.6%	0.3%	198.0	3.5	99.0%	0.7%	132.5	78.5	99.1%	0.1%	72.2	8.1	163.8	56.2	45.3	10.9
BYD N95 respirator	82.7%	2.1%	25.0	11.3	95.2%	0.6%	113.5	122.3	99.1%	0.1%	150.8	14.5	147.9	33.5	54.9	7.8
3M 1818 surgical mask	86.8%	6.3%	26.1	26.7	91.4%	2.6%	27.5	12.0	92.7%	0.6%	48.0	7.8	78.6	92.0	9.6	5.8
Excellent Artisan procedure mask	56.3%	5.8%	7.4	3.4	42.0%	6.7%	6.1	5.5	79.7%	3.6%	108.0	34.3	3.3	0.7	1.7	0.5
Hanes cloth mask	51.7%	7.1%	1.3	0.1	44.3%	14.0%	2.3	1.1	18.8%	2.7%	64.1	9.5	1.7	0.5	1.0	0
EnerPlex mask	48.0%	6.7%	5.1	1.3	52.6%	7.3%	2.5	0.4	19.9%	3.9%	23.8	10.7	2.1	1.2	1.8	0.7
Craft & Soul mask	47.4%	6.2%	2.5	1.2	51.2%	12.2%	2.3	1.0	9.7%	3.9%	11.4	8.2	2.0	0.5	1.3	0.5
Lefty mask	42.3%	8.1%	2.4	0.7	36.3%	9.9%	1.9	n/a	20.2%	0.8%	96.3	5.9	1.8	0.7	1.6	0.5
Badger dust mask	71.1%	3.5%	5.0	0.1	61.8%	5.0%	3.2	0.6	36.0%	9.9%	92.1	1.0	2.8	1.6	1.7	0.5
Debrief Me mask w filter	43.0%	12.0%	4.6	1.8	63.4%	15.3%	3.0	1.5	30.8%	1.5%	154.1	34.9	2.9	0.9	2.1	0.8
Fabrique Innovations mask	63.2%	6.2%	2.1	n/a	65.9%	4.4%	2.2	0.4	14.8%	n/a	61.7	n/a	1.4	0.7	1.1	0.3
Besungo sports mask w filter	65.7%	6.5%	4.8	n/a	59.9%	11.9%	3.2	0.3	97.8%	0.3%	142.7	22.9	2.7	1.7	1.9	1.4
Inspire mask w filter	66.5%	4.5%	4.3	3.0	63.1%	6.4%	2.7	0.5	27.1%	5.1%	149.8	85.4	4.0	1.4	2.4	0.5
FKGIONG gaiter 1-layer	48.1%	6.7%	1.7	0.5	42.9%	5.5%	1.5	0.2	3.3%	4.3%	13.1	8.0	1.1	0.3	1.0	0
FKGIONG gaiter 2-layers	60.5%	6.7%	1.9	0.4	51.8%	8.6%	1.7	n/a	7.9%	0.5%	23.8	8.4	1.0	0	1.4	0.5
AXBXCX gaiter 1-layer	35.4%	9.5%	1.7	0.1	35.3%	10.3%	1.4	0.1	2.7%	1.1%	14.4	5.7	1.3	0.7	1.0	0
AXBXCX gaiter 2-layers	48.3%	6.3%	1.8	0.1	43.9%	5.6%	1.9	0.5	3.6%	0.3%	29.4	4.5	1.3	0.5	1.3	0.5
Retro gaiter 1-layer	48.7%	10.5%	2.6	n/a	55.8%	6.6%	2.5	0.6	2.2%	n/a	40.2	n/a	1.6	0.7	1.3	0.5
Retro gaiter 2-layers	64.9%	4.2%	2.3	0.4	60.0%	5.5%	2.1	0.4	8.6%	n/a	69.5	n/a	1.7	1.0	1.7	0.5
Givon fleece gaiter 1-layer	53.5%	6.3%	2.1	0.5	51.4%	7.0%	2.3	0.8	8.4%	0.8%	19.3	7.4	1.0	0	1.3	0.5
L&M Bandana 2-layers	17.1%	25.0%	1.3	0.2	46.5%	8.1%	1.6	0.1	1.4%	0.4%	5.2	8.2	1.1	0.3	1.0	0
Underwear Bandana/gaiter 1-layer	40.8%	7.5%	6.9	7.3	37.3%	10.2%	1.4	0.1	3.5%	1.1%	19.3	8.2	1.1	0.7	1.0	0

Manikin fit factors were measured with the fit tester in N95 mode only (as described in the Discussion). Human fit factors were measured using both the N95 mode and Class 100 mode.

Table 4. Correlations between different performance metrics for all source control devices.

		All source control devices		Cloth face masks, gaiters, and bandanas only	
Correlation parameter #1	Correlation parameter #2	ρ	*p*-value	ρ	*p*-value
Cough aerosol collection efficiency	Exhaled aerosol collection efficiency	0.76	<0.001	0.67	0.003
	Filtration efficiency of material	0.69	0.001	0.51	0.032
	Airflow resistance of material	0.55	0.009	0.54	0.020
	Human subject fit (N95 mode)	0.57	0.005	0.30	0.208
	Human subject fit (Class 100 mode)	0.68	<0.001	0.48	0.035
	Manikin fit before coughing	0.39	0.076	0.03	0.890
Exhaled aerosol collection efficiency	Filtration efficiency of material	0.60	0.004	0.54	0.023
	Airflow resistance of material	0.51	0.016	0.58	0.012
	Human subject fit (N95 mode)	0.60	0.003	0.51	0.024
	Human subject fit (Class 100 mode)	0.71	<0.001	0.63	0.003
	Manikin fit before breathing	0.72	<0.001	0.68	0.002
Manikin fit before coughing	Manikin fit before breathing	0.61	0.003	0.38	0.112
Filtration efficiency of material	Airflow resistance of material	0.78	<0.001	0.78	<0.001

Each Spearman's rank coefficient (ρ) was calculated based on data from 22 experiments for all source control devices and 18 experiments for cloth masks (cloth face masks, gaiters, and bandanas). A correlogram of the ρ values in shown in Figure S9 in the SI.

airflow resistances were from 5.2 to 154 Pa (Table 3). When comparing the data for all devices, the filtration efficiencies were correlated with cough aerosol collection efficiency ($\rho = 0.69$, $p = 0.001$) and exhaled aerosol collection efficiency ($\rho = 0.60$, $p = 0.004$; Table 4). For the group of cloth masks, the correlations were not as strong; the cough aerosol collection efficiency and filtration efficiency had an ρ of 0.51 ($p = 0.032$) while the exhaled aerosol collection efficiency and filtration efficiency had an ρ of 0.54 ($p = 0.023$; Table 4). The airflow resistance did not correlate as well as the filtration efficiency when all devices were considered ($\rho = 0.55$ and $p = 0.009$ for coughing; $\rho = 0.51$ and $p = 0.016$ for exhalation). However, when examining the cloth masks alone, the airflow resistance was slightly better correlated than filtration efficiency ($\rho = 0.54$ and $p = 0.020$ for coughing; $\rho = 0.58$ and $p = 0.012$ for exhalation).

Human fit tests

The fit factors measured on the human test subjects are shown in Table 3 and Figure 5. The mean fit factors for the two N95 respirators were 148 and 164

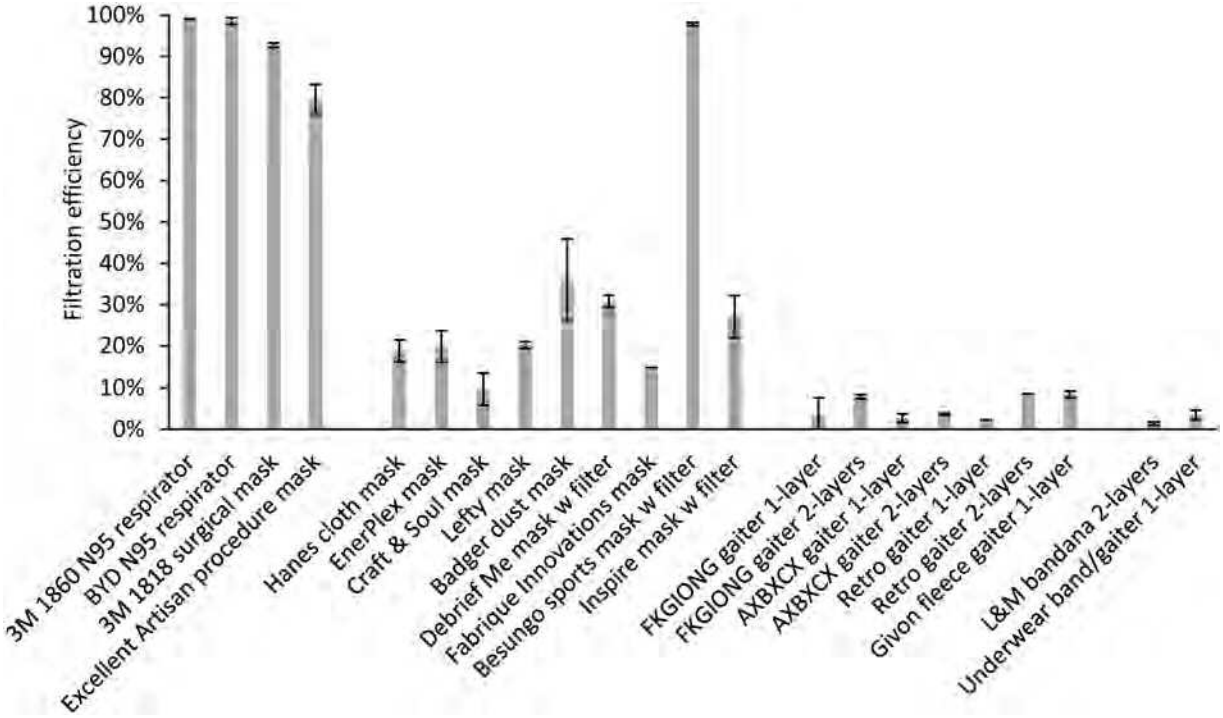

Figure 4. Filtration efficiencies for the source control devices used in the study. Three samples of each device were tested, except for the 3 M 1860 N95 respirator and Hanes cloth mask (10 samples each) and the Fabrique Innovations mask, Retro gaiter 1-layer, and Retro gaiter 2-layers (one sample each). Error bars show the standard deviation.

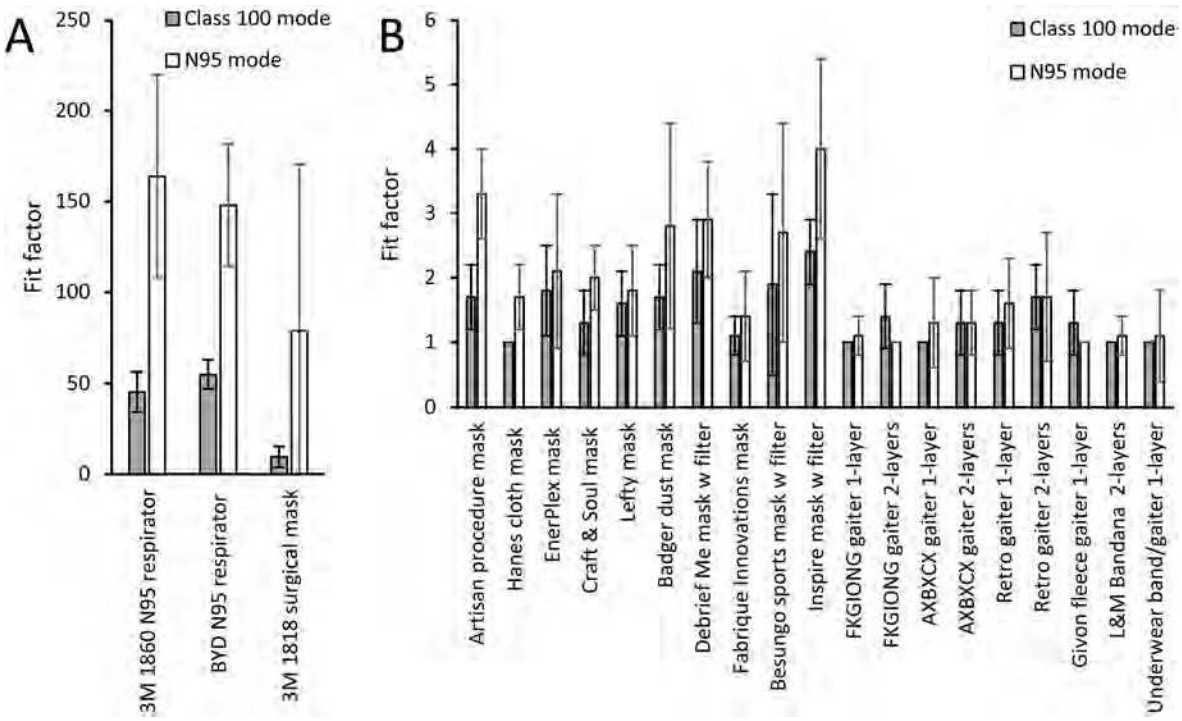

Figure 5. Fit factors measured with human subjects for (a) N95 respirators and surgical mask and (b) procedure mask, cloth face masks, gaiters and bandanas. The plot shows the means and standard deviations. Results for all human fit tests are given in Table S3 in the SI.

when using the N95 mode on the fit tester and 55 and 45 with the Class 100 mode. The surgical mask provided a mean N95 mode fit factor of 79 and a much lower mean fit factor of 9.6 in Class 100 mode. The mean N95 mode fit factor of the reusable cloth face masks ranged from 1.4 to 4.0, and the all sizes

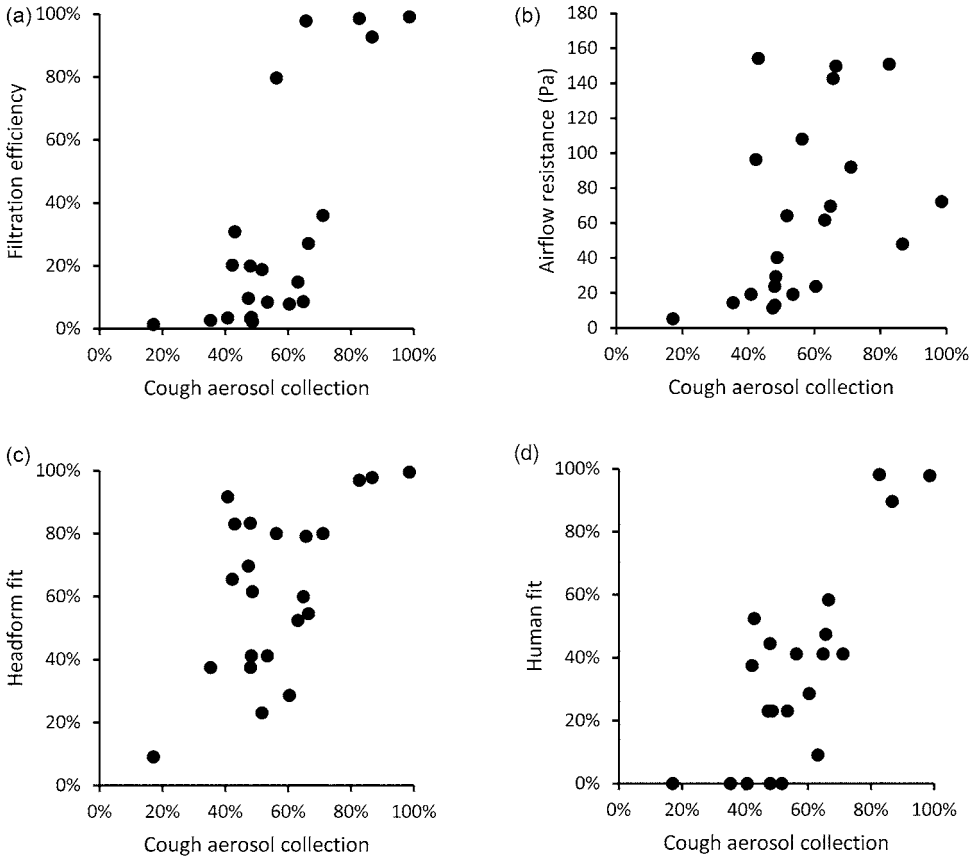

Figure 6. Comparison of collection efficiencies for aerosols from coughs to (a) filtration efficiency of construction material; (b) airflow resistance; (c) fit on manikin headform (using N95 mode); and (d) fit on human test subjects (using Class 100 mode). Each dot corresponds to the mean result for one type of source control device.

mode mean fit factors ranged from 1.0 to 2.4. Neck gaiters and bandanas demonstrated N95 mode fit factors ranging from 1.0 to 1.7 and all particle size mode mean fit factors from 1.0 to 1.7. The performance of cloth masks sometimes varied considerably when worn by different subjects. The fit test results for individual subjects are shown in Table S3 in the SI.

The cough and exhalation aerosol collection efficiencies for all devices were well correlated with the fit factors when measured using the Class 100 mode ($\rho = 0.68$ and $p < 0.001$ for coughing, $\rho = 0.71$ and $p < 0.001$ for exhalation, Table 4). When looking at the results for the cloth masks, gaiters, and bandanas in the all sizes mode, the correlations were not as strong, with $\rho = 0.48$ for coughing ($p = 0.035$), and $\rho = 0.63$ for exhalation ($p = 0.003$; Table 4). In all cases, the correlation coefficients were higher when the fit tester was in the Class 100 mode than when the tester was in N95 mode.

Manikin fit tests

The manikin fit factor measurements found using the source control measurement system before the cough tests were 25 to 198 for the N95 respirators and the surgical mask and 1.3 to 7.4 for the procedure mask and cloth masks (Table 3). Before the breathing tests, the manikin fit factors were 28 to 133 for the N95 respirators and the surgical mask and 1.4 to 6.1 for the procedure mask and cloth masks. The cough aerosol collection efficiencies and the pre-cough manikin fit factors were not significantly correlated, with a ρ of 0.39 ($p = 0.076$) for all devices (Table 4 and Figure 6) and a ρ of only 0.03 ($p = 0.890$) for the cloth masks (Table 4). The correlation was better between the exhaled aerosol collection efficiency and pre-breathing manikin fit factors, with a ρ of 0.72 ($p < 0.001$) for all devices (Table 4 and Figure 7) and 0.68 ($p = 0.002$) for the cloth masks (Table 4).

Discussion

The COVID-19 pandemic has resulted in considerable interest in the performance characteristics of masks and respirators as a means of reducing the person-to-person transmission of SARS-CoV-2. Some studies have looked at the emission of particles from human volunteers wearing different face coverings, which has

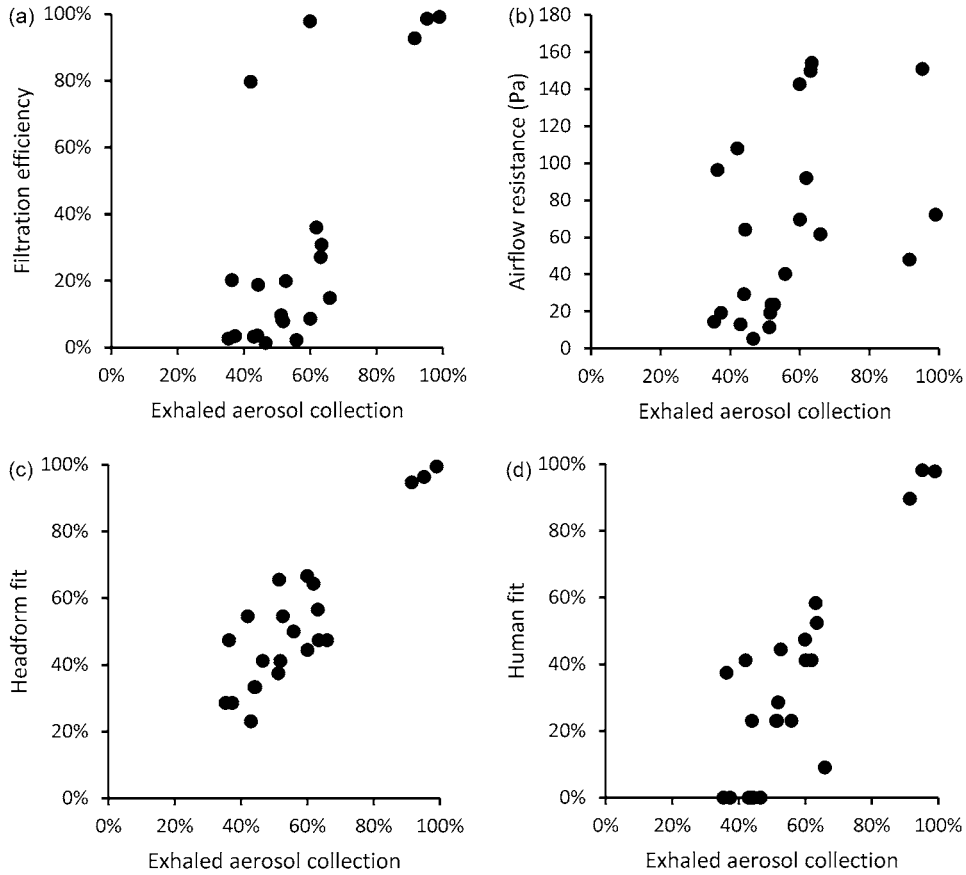

Figure 7. Comparison of collection efficiencies for exhaled aerosols from simulated breathing to (a) filtration efficiency of construction material; (b) airflow resistance; (c) fit on manikin headform (using N95 mode); and (d) fit on human test subjects (using Class 100 mode). Each dot shows the mean result for one type of source control device.

the advantage of directly examining the expulsion of aerosols into the environment by people (Asadi et al. 2020; Davies et al. 2013; Leung et al. 2020; Li, Niu, and Zhu 2021). However, the collection and measurement of human-generated respiratory aerosols is challenging and can be hazardous when the subject has a contagious respiratory infection. In addition, the amount and size distribution of aerosol particles produced by people during coughing, breathing and other respiratory activities varies tremendously from person to person and even for a particular person over time, which makes it difficult to compare results (Asadi et al. 2019; Fennelly 2020; Gralton et al. 2011; Lindsley et al. 2012). Consequently, lab-based surrogate techniques are more frequently used to study source control devices. The most commonly reported methods have been tests of filtration efficiencies and fit factors (Clapp et al. 2021; Guha et al. 2021; Konda et al. 2020; Wang et al. 2020; Zhao et al. 2020). Other studies have used manikins in a chamber or room to assess the efficacy of medical masks and cloth masks both as source control devices and as personal protective equipment (Pan et al. 2021; Patel et al. 2016; Rothamer et al. 2021). Experimental data have also been used to develop computational fluid dynamics models of medical and cloth masks performance (Dbouk and Drikakis 2020; Mittal, Ni, and Seo 2020). These studies have provided valuable information about the properties of masks and respirators. However, it is unclear how the various metrics used in these studies are related to source control performance.

The source control measurement system used in this study allows for a direct quantitative comparison of the ability of different types of source control devices to block the expulsion of simulated cough and exhaled breath aerosol particles into the environment (Lindsley et al. 2021). However, the system is complex and requires expertise to operate, and it is neither commercially sold nor easily constructed. In contrast, filtration measurement systems and respirator fit testers are widely available. If a methodology could be developed to gauge source control performance using existing commercially available equipment, it could be rapidly expanded and adopted by manufacturers and public health entities.

The filtration efficiency of a mask or respirator is a measurement of the ability of the mask material to remove aerosol particles from an airstream traveling through the fabric. Filtration efficiency tests typically use aerosol particles at or near the most-penetrating aerosol particle size, which is around 300 nm for an uncharged filter at low air velocities but shifts to smaller sizes at higher velocities and when the filter and particles are electrostatically charged (Martin and Moyer 2000; Rengasamy, BerryAnn, and Szalajda 2013; Rengasamy et al. 2017). The mechanisms by which filters collect aerosol particles are strongly dependent upon the size of the particles; for example, large particles are more likely to be collected by impaction or interception while small particles are more likely to be collected by diffusion (Lindsley 2016). Although the SARS-CoV-2 virus is about 100 nm in diameter, contagious humans do not shed bare viral particles. Instead, they expel aerosols and droplets of respiratory fluids that contain respiratory virus, and the size of these virus-laden aerosols and droplets can range from hundreds of nanometers to visible droplets of 1 mm or more (Fennelly 2020; Gralton et al. 2011). Thus, the collection efficiencies for 100-300 nm particles may not predict the performance for larger particles (Drewnick et al. 2021). In our experiments, the coughing and exhalation source control collection efficiencies increased as the particle size increased (Tables S1 and S2 in the SI) and in most cases were higher than the filtration efficiencies, likely because our coughing and exhalation test aerosols were much larger than the 75 nm aerosol used for filtration tests.

The fit factor is normally used to determine how well a respiratory protective device fits the wearer by measuring the degree to which aerosol particles can enter through gaps between the wearer's face and the respirator (face seal leaks). It is determined by placing the device on a person or on a manikin headform and measuring the ratio of the aerosol concentration outside the respirator to the aerosol concentration inside the respirator (Janssen and McKay 2017). For example, a fit factor of 10 means that the ambient aerosol concentration is 10 times higher than the concentration inside the respirator. Fit factor measurements are not intended to test the filtration efficiency of the device itself. In fact, the calculation of the fit factor for a respirator assumes that any ambient aerosol particles passing through respirator material are filtered out and that any particles detected inside the respirator are due to face seal leaks, not penetration of particles through the filter material (Halvorsen 1998). For example, a fit factor of 10 is interpreted as indicating that 90% of the air inside the respirator has passed through the respirator filtration media (with aerosol particles being completely removed) and that 10% of the air bypassed the media and entered through face seal leaks.

For high efficiency filters such as P100 respirator filters, which filter out 99.97% of airborne particles, a respirator fit test is performed by measuring the concentrations of aerosol particles of all sizes inside and outside the respirator (referred to here as Class 100 mode). However, N95 respirators can allow up to 5% of aerosol particles of the most penetrating size to pass through the filtration media. These particles would reduce the apparent fit factor if they were included in the calculation. Thus, when fit testing N95 respirators, the respirator fit tester used in our experiments has a size classifier to count only negatively charged aerosol particles near 55 nm in size (referred to here as N95 mode). For an N95 respirator, these charged 55 nm particles are almost entirely filtered out by the filtration media, and thus any particles detected inside the respirator can then be assumed to have entered through face seal leaks and not through the respirator (Halvorsen 1998; Han and Prell 2010).

It is important to note, however, that this assumption is not correct when using the fit tester with cloth masks. As can be seen in Table 3, the filtration efficiencies of most cloth masks are much lower than those of respirators, and ambient particles therefore can penetrate more easily through the cloth material. Thus, the fit factor for a cloth mask is not a true measurement of face seal leakage alone; instead, it represents a combination of face seal leakage and particle penetration through the mask material.

Our findings suggest that the results from filtration efficiency, airflow resistance and fit factor tests are correlated with measurements made using our source control measurement system. For the cloth masks, all but two of the standard performance metrics were significantly correlated with the cough and exhaled aerosol collection efficiencies, which suggests that these other measures could be useful as part of a method for testing the performance of cloth masks. However, none of the standard metrics were strong predictors of source control performance, and no metric was clearly superior to the others.

The limited correlations between the different test methods in our study likely have several explanations. First, filtration efficiency and airflow resistance measurements do not account for how well the devices fit the wearer or for face seal leaks around the edges of

the device. Thus, for example, the Artisan procedure mask had an 80% filtration efficiency but a 56% collection efficiency for cough aerosols and a 42% collection efficiency for exhaled aerosols. The most likely explanation is that this mask's material is an efficient filter but that aerosol particles were able to travel around the mask through face seal leaks because the Artisan mask fits loosely on the headform. On the other hand, the Hanes Defender cloth mask had only a 19% filtration efficiency but had similar aerosol collection efficiencies of 52% for coughs and 44% for exhalations. In this case, the cloth mask was not an effective filter for the 75 nm aerosol used in filtration testing, but the Hanes mask fit the manikin headform more tightly. Thus, much of the aerosol then flowed through the mask rather than around it during coughing and breathing tests and the larger aerosol particles that were used in the coughing and breathing tests were filtered out more effectively than the 75 nm particles used in filtration testing. The results presented here are consistent with a previous study by our group in which knotting the Artisan procedure mask to improve the fit increased the cough aerosol collection efficiency to 77%, while wearing a Hanes Defender cloth mask on top of an Artisan procedure mask increased the cough collection efficiency to 85% (Brooks et al. 2021). Together, these results also support the recommendation by Gandhi and Marr that members of the public wear a high-quality mask that fits tightly or wear a tight-fitting cloth mask over a surgical mask in order to reduce face seal leaks and improve the source control performance and protection offered by the masks (Gandhi and Marr 2021).

Fit tests are designed to measure the effects of face seal leaks but have their own limitations when applied to cloth masks. As noted above, fit factor measurements for cloth masks reflect some combination of particle penetration through the media and face seal leakage which will likely vary from mask to mask. Thus, it is neither clear how to interpret fit factor measurements for cloth masks nor is it clear how this relates to the effectiveness of the mask as a source control device. In addition, fit test results can vary greatly from person to person and even somewhat for the same person during repeated tests (Lawrence et al. 2006). Similarly, a comparison of fit tests between humans and a pliable skin manikin headform found significant differences (Bergman et al. 2015). Much of this discrepancy is likely due to facial variations and differences in how the mask is placed on the person or manikin headform. It is possible to shift, stretch, tighten, loosen, or adjust the masks in many ways,

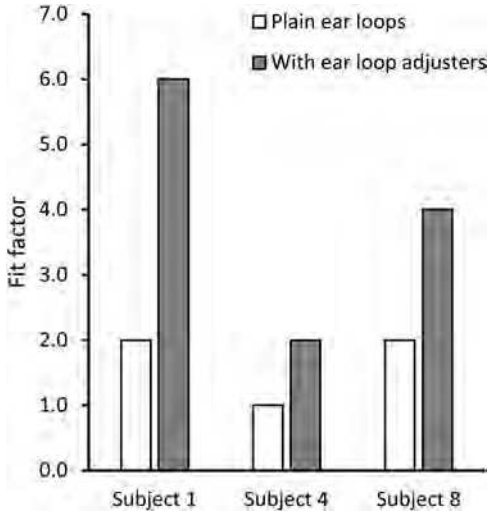

Figure 8. Effect on mask fit factor of adding ear loop adjusters to tighten the mask fit. Subjects were wearing the Excellent Artisan procedure mask. Tests were conducted with the fit tester in Class 100 mode. Each bar is the mean of three trials. All standard deviations were zero.

and small differences in how the mask is worn may have substantial effects on the fit test results. For example, in tests with three subjects using the Artisan procedure mask, we found that tightening the mask against the face by using silicone ear loop adjusters increased the mean fit factor from 1.7 to 4.0 (Figure 8). In experiments with cloth masks, the ρ value for the manikin headform fit tests done before coughing experiments compared with tests done before exhalation experiments was only 0.38, suggesting that differences were occurring even when the same model of mask was being placed on the same headform.

Finally, our study has several limitations. The source control measurement system produced a test aerosol with particles $\leq$7 µm in diameter, which is the size range of aerosol particles most likely to remain airborne and most difficult to block with source control devices. However, humans expel aerosol particles in a much broader range of sizes, particularly when coughing. We used a single cough flowrate profile and a single breathing ventilation rate for our studies; these parameters can vary greatly from person to person under different physiological conditions. Some internal losses of the test aerosol particles likely occurred due to settling or impaction on the surfaces of the collection chamber, which may affect the estimates of the collection efficiencies. We used representative examples of different types of source control devices, but many such devices are available with a wide range of shapes and compositions, which would be expected to affect their individual performance. As shown in Table 1, the instrumentation used for the

different performance metrics are based on different operating principles and thus caution should be used when comparing results; for example, the collection efficiency results from the impactors are based on aerosol mass, while the fit factor results from the PortaCount are based on particle counts. Lastly, because of the need to rapidly produce results in response to the COVID-19 pandemic, we only tested 2-3 samples of each source control device (each sample was used in two consecutive tests). By comparison, for example, the NIOSH procedure for evaluating N95 respirators calls for 20 samples to be tested (NIOSH 2019).

Current evidence indicates that masks like those tested in our experiments can substantially decrease the amount of respiratory aerosols released by the wearer, and also help reduce what the wearer breathes in (CDC 2020a). Both effects vary depending upon the material and construction of the mask, as well as how it is worn. In addition to consistent and correct mask use when in the company of others, other measures such as physical separation are important, particularly during brief exposures. In a room where someone sneezes, being six feet or further away is better than being closer. However, with prolonged exposure in the same space for more than a few minutes, the benefit of distance fades as exhaled respiratory aerosols drift, mix, and accumulate in the enclosed air space. Optimizing ventilation, air filtration, and the introduction of fresh air can help counter this effect, but at every distance, correct mask use reduces the risk for everyone.

Conclusions

The ongoing COVID-19 pandemic has created an urgent need for simple methods to evaluate cloth masks as respiratory aerosol source control devices and to produce meaningful performance metrics that can be used to determine the effectiveness of different materials and designs. Our results suggest that test methods such as filtration efficiency testing, airflow resistance testing, and fit factor measurements on manikin headforms or human subjects have potential as ways to estimate the performance of masks as source control devices for respiratory aerosols. However, more research and improvements in the test methodologies are needed before such methods can be reliably implemented. Until the factors controlling the performance of source control devices are better understood and better testing methodologies are developed, results from test methods such as filtration efficiency testing, airflow resistance testing, and fit factor measurements should be interpreted cautiously when used to evaluate source control devices for respiratory aerosols.

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Declaration of interests statement

The authors declare no competing interests.

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Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols

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ABSTRACT

Face masks are recommended to reduce community transmission of SARS-CoV-2. One of the primary benefits of face masks and other coverings is as source control devices to reduce the expulsion of respiratory aerosols during coughing, breathing, and speaking. Face shields and neck gaiters have been proposed as an alternative to face masks, but information about face shields and neck gaiters as source control devices is limited. We used a cough aerosol simulator with a pliable skin headform to propel small aerosol particles (0 to 7 μm) into different face coverings. An N95 respirator blocked 99% (standard deviation (SD) 0.3%) of the cough aerosol, a medical grade procedure mask blocked 59% (SD 6.9%), a 3-ply cotton cloth face mask blocked 51% (SD 7.7%), and a polyester neck gaiter blocked 47% (SD 7.5%) as a single layer and 60% (SD 7.2%) when folded into a double layer. In contrast, the face shield blocked 2% (SD 15.3%) of the cough aerosol. Our results suggest that face masks and neck gaiters are preferable to face shields as source control devices for cough aerosols.

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Introduction

SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), can be transmitted from person-to-person by large respiratory aerosols (airborne liquid droplets and dried particles greater than about 10 μm in diameter) produced by people who are infectious while they are talking, singing, coughing, breathing or sneezing (CDC 2020a; Hamner et al. 2020). Smaller aerosols also are emitted by people during these activities, suggesting that short-range airborne transmission of SARS-CoV-2 might be possible under some circumstances (Anderson et al. 2020; CDC 2020a; Fennelly 2020; Ma et al. 2020; Morawska and Milton 2020).

To interrupt this potential transmission route, the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and other public health organizations recommend the wearing of face masks or other face coverings by the general public during the ongoing COVID-19 pandemic (CDC 2020b, 2020c; Edelstein and Ramakrishnan 2020; WHO 2020). One of the primary benefits of face coverings is to act as source control devices to reduce the expulsion of aerosols containing the virus from people who are infectious during coughing, breathing, and speaking. Source control devices are intended to protect other people from infectious aerosols emitted by the wearer, as compared with personal protective equipment such as N95 respirators which are primarily intended to protect the wearer. A face covering can provide source control in two ways (Diaz and Smaldone 2010). First, and most importantly, the covering may collect aerosol particles by filtration, impaction, or other mechanisms, and thus prevent infectious aerosols from entering the environment. Second, the face covering may change the direction of travel and the velocity of the aerosol stream and thus possibly divert the aerosol away from a potential recipient. However, deflection is more uncertain as a source control mechanism. For example, if large aerosols are deflected downward, they may settle to the floor or otherwise be unable to reach the breathing zones of other people. However, since exhaled breath is often warmer than the surrounding air, this

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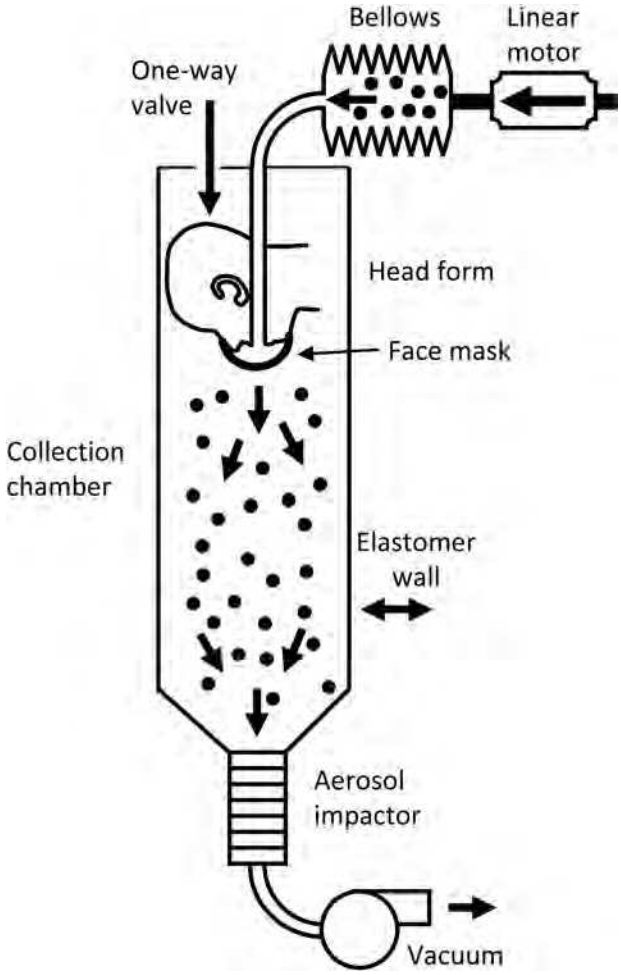

Figure 1. Cough aerosol simulator system for source control measurements. The system consists of an aerosol generation system, a bellows and linear motor to produce the simulated cough, a pliable skin head form on which the face mask, neck gaiter or face shield is placed, a 105 liter collection chamber into which the aerosol is coughed, and an Andersen impactor to separate the aerosol particles by size and collect them. More information about the cough aerosol simulator is provided in the SI.

downward deflection may be counteracted by the buoyancy of the breath for smaller aerosols. In addition, if the respiratory aerosols are deflected sideways, they may be diverted away from a person directly in front of the wearer but toward someone to the side or behind the wearer.

Studies using manikins (Lai, Poon, and Cheung 2012; Patel et al. 2016) and patients with respiratory infections (Leung et al. 2020; Milton et al. 2013) have shown that wearing medical face masks can reduce the dispersion of potentially infectious aerosols from patients. Two studies in which face masks were required for visitors and healthcare workers interacting with patients in bone marrow transplant centers found a reduction in respiratory viral infections among patients (Sokol et al. 2016; Sung et al. 2016). Studies of cloth face masks have suggested that they also can be effective at reducing the release of respiratory aerosols into the environment (Asadi et al. 2020; Davies et al. 2013; Konda et al. 2020). Several computational fluid dynamics studies have examined the generation and expulsion of respiratory aerosols and have provided important insights into the ability of face coverings to reduce the dispersion of large and small aerosols from the wearer (Dbouk and Drikakis 2020; Mittal, Ni, and Seo 2020).

Unfortunately, the use of face masks and other face coverings by the general public can present challenges. People often dislike wearing masks, and compliance can be low and inconsistent (Longtin et al. 2009). Mask wearers may repeatedly don, doff and adjust face masks, which can contaminate the hands and potentially lead to disease transmission, especially when the masks are reused (Brady et al. 2017; Casanova et al. 2008). For cloth masks, the filtration efficiency and air flow resistance of different textiles varies widely (Konda et al. 2020; Teesing et al. 2020; Wilson et al. 2020). Alternative face coverings such as neck gaiters (an elastic fabric tube that fits snugly around the head and neck) are commonly used, but information about their performance as source control devices is limited. Factors such as how well the mask fits the face and the coverage provided by a mask can have a substantial impact on the effectiveness of face masks (Davies et al. 2013; Lawrence et al. 2006). Comparisons of face coverings have found substantial differences in the ability of different types of these devices to reduce the release of respiratory aerosols (Asadi et al. 2020; Davies et al. 2013).

An opinion article in JAMA proposed that face shields would be more effective than face masks at reducing community disease transmission, in large part because the authors felt that face shields were more comfortable and thus that they were more likely to be widely adopted by the public (Perencevich, Diekema, and Edmond 2020). A previous study by our group of face shields used as personal protective devices showed that face shields protect the wearer from large cough aerosols directed at the face but are much less effective against smaller aerosols which were able to flow around the edges of the shield and be inhaled (Lindsley et al. 2014). However, very little work has been done examining face shields as source control devices. Two qualitative flow visualization studies of face shields and masks found that, although face shields deflected the air flow from the mouth, they did not stop aerosol particles from traveling around the face shield and entering the environment

(Verma, Dhanak, and Frankenfield 2020; Viola et al. 2020). Beyond these studies, quantitative data on the efficacy of face shields for source control are lacking.

The objective of our study was to conduct a quantitative comparison of the efficacy of an N95 respirator, a medical procedure mask, a commercial 3-ply cloth face mask, a single and double layer fabric neck gaiter, and a commercial disposable face shield as source control devices to reduce the expulsion of small cough-generated aerosol particles into the environment. Our results provide more information about the effectiveness of different types of source control devices and will help the public health community make recommendations about the best ways to use these devices to help reduce the spread of COVID-19.

Materials and methods

Experimental design

In our experiments, a cough aerosol simulator propelled a test aerosol through a headform into a collection chamber (Figure 1), and the amount of aerosol in the collection chamber was measured in each of six size fractions. The collection efficiency of each face mask, neck gaiter, or face shield was determined by comparing the amount of aerosol that was collected from the chamber with and without the device. Our test method was similar to the modified Greene and Vesley method used to test medical masks (Quesnel 1975), with the human test subject replaced by the cough aerosol simulator.

Cough aerosol simulator

The cough aerosol simulator is a modified version of the NIOSH cough aerosol simulator described previously (Lindsley et al. 2019; Lindsley et al. 2014; Lindsley et al. 2013). The experimental cough aerosol was generated by nebulizing a solution of 14% KCl and 0.4% sodium fluorescein using a single-jet Collison nebulizer (BGI, Butler, NJ, USA) at 103 kPa (15 lbs./in^2), passing the aerosol through a diffusion drier (Model 3062, TSI, Shoreview, MN, USA), and mixing it with 10 L/min of dry filtered air. The test aerosol was loaded into an elastomeric bellows, and the cough airflow was produced by a computer-controlled linear motor that compresses the bellows. The cough aerosol was expelled through the mouth of a headform into a collection chamber. The headform used in the study has pliable skin that mimics the elastic properties of human skin in order to create a realistic simulation of how each face covering or shield would fit a human face (Bergman et al. 2014).

Source control devices

The source control devices tested were an N95 medical respirator (3 M model 1860), a medical grade (ASTM Level 3) procedure mask with ear loops (Kimberly Clark model 47107), a cloth face mask with 3 layers of cotton fabric and ear loops (Hanes Defender), a fabric neck gaiter (FKGIONG Sun UV Protection Neck Gaiter, 95% polyester, 5% Spandex) and a disposable face shield (Fisher Scientific # 19-181-600 A). The neck gaiter was tested both as a single layer of fabric and doubled over to provide two layers of fabric. The masks and respirator were not equipped with exhalation valves. The face shield was 25 cm tall and extended from the forehead of the headform to 3 cm below the chin and around the side to 3 cm before the front of the ear. Photographs of the source control devices on the headform are shown in the online supplementary information (SI).

Mask fit test

For the experiments, either no device, a face mask, a neck gaiter, or a face shield were placed on the head form. Each device was used for two consecutive tests. For face masks and gaiters, a respirator fit test was performed using a PortaCount (TSI). The fit factor is a measure of the protection against airborne particles that is provided by a respiratory protective device. It is defined as the ratio of the aerosol concentration outside the respiratory protective device to the aerosol concentration inside the device (i.e., the aerosol concentration that is inhaled by the wearer). For example, a fit factor of 10 means that the ambient aerosol concentration is 10 times higher than the concentration inside the mask, and that the mask is therefore filtering out 90% of the ambient aerosol.

Aerosol collection and analysis

After placing the device on the headform and performing the fit test, the system was sealed. The test aerosol was then generated and propelled with a simulated cough through the headform and into the collection chamber. The Andersen impactor at the bottom of the collection chamber collected the aerosol particles that traveled through or around the device for 20 min after each cough. The Andersen impactor operates at a flow rate of 28.3 liters/minute and has six collection stages and a filter that separate the aerosol particles into seven size fractions based on the aerodynamic diameter of the particles: <0.6 µm; 0.6–1.1 µm; 1.1–2.1 µm; 2.1–3.3 µm; 3.3–4.7 µm;

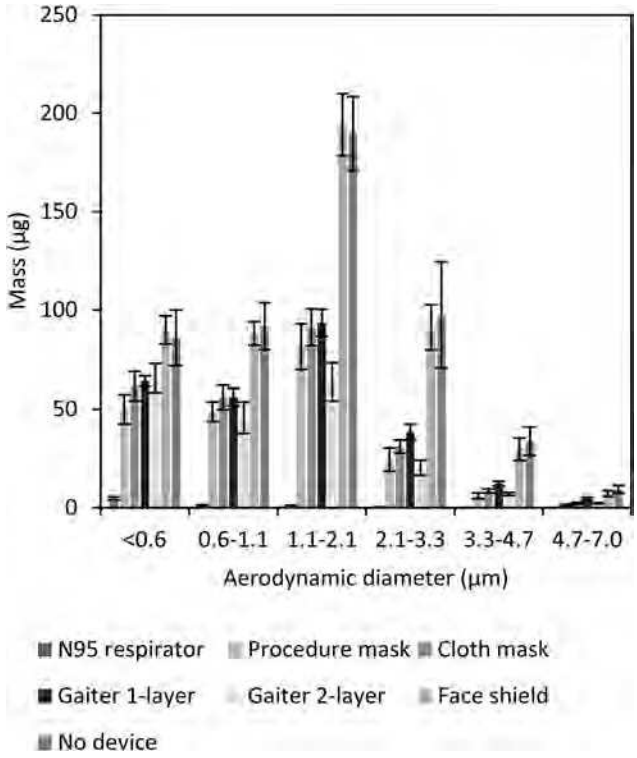

Figure 2. Mass of aerosol collected in each size fraction. The graph shows the amount of simulated respiratory aerosol that was collected from the collection chamber in each aerosol particle size fraction after a single simulated cough. The bars show the mean and standard deviation. A larger color version of this figure is shown in the SI.

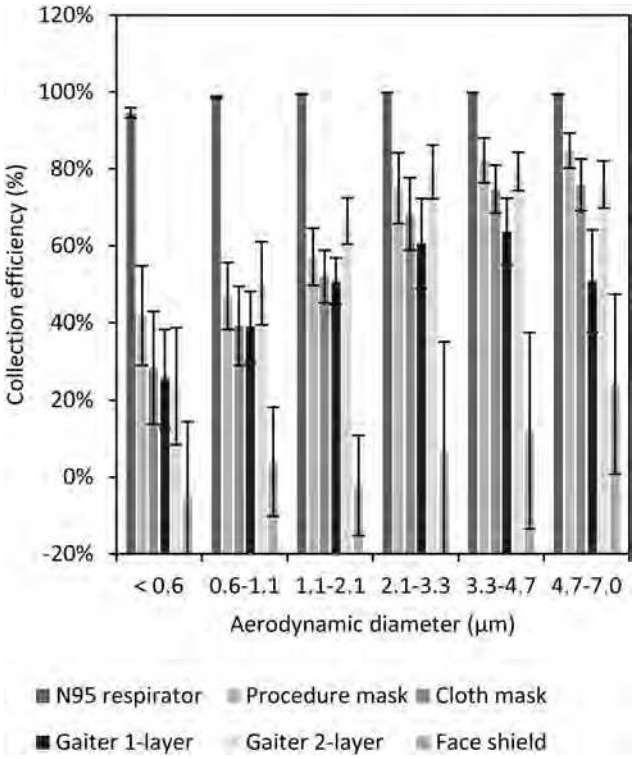

Figure 3. Collection efficiency of face masks, neck gaiter and face shield. The collection efficiency is the percentage of aerosol particles that were blocked by the face mask, neck gaiter or face shield compared with experiments without a device. The plot shows the means and standard deviations of the collection efficiency in each size fraction. A larger version of this figure is shown in color in the SI.

4.7–7.0 µm; and >7 µm. Because the amount of aerosol in the largest size fraction was small and because of possible losses due to settling of the large aerosol particles, data for the largest size fraction was not included in the analysis. The impactor collection plates were coated with a solution of glycerol and Brij 35 to prevent particles from bouncing off the plates during collection (Mitchell 2003). After aerosol collection was completed, the impactor plates were rinsed with 0.1 M Tris solution and the fluorescence of the solution was measured using a fluorometer (SpectraMax M4, Molecular Devices). The complete experimental protocol is given in the SI.

Statistical analysis

The performance of each device was evaluated by comparing the total mass of the aerosol particles from a single cough that passed through or around the device and was collected by the Andersen impactor. The results were evaluated using a one-way ANOVA and multiple comparisons among the different devices and the control experiments without a device were conducted using a Tukey-Kramer test. To control for variations in the amount of aerosol in each cough, a sample of each cough aerosol was collected from the bellows prior to coughing and used to normalize the aerosol mass collection results for each experiment.

Results

The cough aerosol simulator provides a cough with a controlled cough airflow rate containing a test aerosol with a consistent aerosol size distribution. The simulator allows for a direct quantitative comparison of the ability of different types of source control devices to block the expulsion of simulated cough aerosol particles of different sizes into the environment. The flow rate of the simulated cough used in our experiments was based on cough flow profiles recorded from influenza patients and had a volume of 4.2 L with a peak flow rate of 11 L/s (Lindsley et al. 2013). The cough aerosol collected from the control experiments without a face covering had a mass median aerodynamic diameter of 1.3 µm, a geometric standard deviation of 2.3 and a total aerosol mass of 505 µg (standard deviation 69).

For our study, we tested the collection efficiencies (that is, the fraction of the cough aerosol that was

Table 1. Total mass of aerosol expelled into collection chamber and device collection efficiencies.

Device tested	Number of experiments	Fit factor	Aerosol mass (μg)	Collection efficiency
No device	12	n/a	512 (64)	n/a
Procedure mask	6	2.9 (0.5)	212 (23)	58.5% (6.9%)
Cloth mask	6	1.3 (0.1)	251 (23)	50.9% (7.7%)
Neck gaiter (single layer)	6	1.7 (0.5)	270 (18)	47.2% (7.5%)
Neck gaiter (double layer)	6	1.9 (0.4)	206 (26)	59.8% (7.2%)
Face shield	6	n/a	502 (46)	1.8% (15.3%)
N95 respirator	6	198 (3.5)	7.2 (1.2)	98.6% (0.3%)

Note: The fit factor, aerosol mass, and collection efficiency are given as mean (standard deviation).

blocked) of a medical grade procedure mask, a cotton cloth face mask, a polyester neck gaiter, an N95 medical respirator and a disposable face shield. These source control devices were chosen to provide representative samples of the different types of face coverings and face shields that are in common use during the pandemic. Neck gaiters are typically worn either as a single layer of fabric over the mouth and nose or doubled over to provide two layers of fabric; for our experiments, we tested both configurations. The quantity of aerosol particles in six size fractions that were able to travel through or around each source control device are shown in Figure 2. The collection efficiencies of the devices are shown as a function of aerosol size in Figure 3. All the devices showed increased collection efficiencies as the aerosol size increased.

On average, the N95 respirator blocked 99% of the total mass of test aerosol from being released into the environment, while the medical procedure mask blocked 59%, the cloth face mask blocked 51%, the single-layer gaiter blocked 47%, the double-layer gaiter blocked 60%, and the face shield blocked 2% of the total aerosol (Table 1). The N95 respirator, procedure mask, cloth mask, and the single-layer and double-layer gaiters all significantly reduced the aerosol emitted into the environment compared with no device ($P < 0.0001$ for each), but the face shield did not ($P = 0.9993$). The collection efficiencies of the procedure mask, cloth mask, and the single and double-layer gaiters did not differ significantly from each other, but all blocked cough aerosols significantly better than did the face shield ($P < 0.0001$). The N95 respirator outperformed all the other devices ($P < 0.0001$) (Table 2).

Discussion

Humans continuously emit aerosols of respiratory fluids as they breathe, talk, cough, sneeze, sing, or carry out other respiratory activities. These respiratory aerosols can have a very broad size range, from tens of nanometers in diameter to visible droplets of a millimeter or more (Bourouiba, Dehandschoewercker, and Bush 2014; Fennelly 2020; Gralton et al. 2011; Morawska et al. 2009). Airborne particles larger than 100 μm are ballistic; that is, they are affected primarily by gravity and fall quickly to the ground. Respiratory aerosol particles in this size range tend to deposit within a few meters of the source (Prather et al. 2020). As the aerosol particle diameter decreases from 100 μm, a gradual transition occurs where the settling velocity rapidly decreases and the particles remain airborne for longer times. For example, a 100 μm aerosol particle takes 4 s to fall 1 m in still air, while a 10 μm aerosol particle takes 5.4 min and a 1 μm aerosol particle takes 8 h to settle the same distance (Hinds 1999). Air currents such as plumes of warm air rising from the body can lift these particles and extend the time for which they stay in the air. Thus, small aerosol particles can remain airborne for minutes to hours and can accumulate over time in environments with poor ventilation (Bahl et al. 2020). Small aerosol particles also are easier to inhale and can travel more deeply into the lungs (Vincent 2005).

The amount and sizes of aerosol particles containing SARS-CoV-2 that are expelled by people who are infected are not yet known. Two studies of aerosol samples collected in patient rooms found infectious (replication-competent) SARS-CoV-2 in aerosol particles <4 μm in diameter (Santarpia et al. 2020a) and <10 μm in diameter (Lednicky et al. 2020). Other studies have reported SARS-CoV-2 RNA in exhaled breath from infected patients (Ma et al. 2020), aerosol samples from biocontainment and quarantine units housing SARS-CoV-2 infected persons (Santarpia et al. 2020b), and in aerosol samples at multiple locations throughout two hospitals in Wuhan, China during a COVID-19 outbreak (Liu et al. 2020). The presence of small aerosol particles containing

Table 2. Comparison of aerosol mass expelled into the collection chamber while wearing face masks, neck gaiters and face shields.

		95% confidence intervals for mean differences (μg)			
PPE types compared		Lower limit	Mean difference	Upper limit	P-value
N95 respirator	No device	−567	−504	−442	<0.0001
Procedure mask	No device	−361	−299	−237	<0.0001
Cloth mask	No device	−322	−260	−198	<0.0001
Gaiter (single layer)	No device	−304	−241	−179	<0.0001
Gaiter (double layer)	No device	−368	−306	−243	<0.0001
Face shield	No device	−71	−9	53	0.9993
N95 respirator	Face shield	−567	−495	−423	<0.0001
Procedure mask	Face shield	−362	−290	−218	<0.0001
Cloth mask	Face shield	−323	−251	−179	<0.0001
Gaiter (single layer)	Face shield	−304	−232	−160	<0.0001
Gaiter (double layer)	Face shield	−369	−297	−225	<0.0001
N95 respirator	Gaiter (double layer)	−271	−199	−127	<0.0001
Procedure mask	Gaiter (double layer)	−65	7	79	0.9999
Cloth mask	Gaiter (double layer)	−26	46	118	0.4505
Gaiter (single layer)	Gaiter (double layer)	−7	64	136	0.1051
N95 respirator	Gaiter (single layer)	−335	−263	−191	<0.0001
Procedure mask	Gaiter (single layer)	−130	−58	14	0.1900
Cloth mask	Gaiter (single layer)	−91	−19	53	0.9825
N95 respirator	Cloth mask	−316	−244	−172	<0.0001
Procedure mask	Cloth mask	−111	−39	33	0.6336
N95 respirator	Procedure mask	−277	−205	−133	<0.0001

infectious SARS-CoV-2 detected in these studies suggests that in addition to large aerosols, these small aerosols might play a role in SARS-CoV-2 transmission (Anderson et al. 2020; Bahl et al. 2020; Ma et al. 2020; Morawska and Milton 2020).

Source control devices like face coverings and face shields collect respiratory particles larger than 0.3 μm primarily by impaction and interception of the aerosol particles against the fibers or solid surfaces of the device. As noted earlier, source control devices may also deflect aerosols, but this mechanism can be problematic as a means of source control because the infectious aerosol is not prevented from entering the surrounding environment; it is merely sent in a different direction which may or may not be protective depending upon local airflows and the locations of other people. Our experimental system measures particle collection only; any particles that are deflected but not collected by the face covering are still collected by the Andersen impactor. Thus, we are able to measure the particle collection efficiency of the face coverings without the potentially confounding variable of particle deflection. On the other hand, this does means that any potential benefits from, for example, deflecting large aerosol particles toward the ground were not measured by our system.

Small aerosols require much higher air velocities to deposit by impaction than do larger aerosols, and thus are more difficult to block with source control devices (Hinds 1999; Lindsley 2016). Consequently, small aerosols present the most challenging scenario for testing source control devices since devices that block small aerosol particles would be expected to block larger ones as well. Our results show that face masks and neck gaiters can significantly reduce the expulsion of small respiratory aerosol particles during coughing. This suggests that various types of face coverings can make an important contribution to reducing the quantity of aerosol particles containing SARS-CoV-2 released into the environment by people who are infected. N95 respirators, which are worn for personal protection by healthcare workers and others at highest risk of exposure, are also very effective source control devices. In contrast, the face shield blocked very little of the cough aerosol, indicating that face shields are not effective as source control devices for small respiratory aerosols.

The collection efficiencies of all the devices tested increased as the aerosol particle size increased, and this trend would be expected to continue for larger aerosol particles than were tested here. For example, the collection efficiency of the cloth face mask was 28% for the <0.6 μm particles and increased to 76% for the 4.7 to 7 μm particles. Similarly, the double-layer gaiter blocked 24% of the <0.6 μm particles and 76% of the 4.7 to 7 μm particles. These results suggest that cloth face coverings would be effective as source control devices against the large respiratory aerosols that are thought to play an important role in SARS-CoV-2 transmission.

Our study has several limitations. We used a single cough volume, air flow profile, and aerosol size distribution for our studies; these parameters can vary greatly from person to person. We examined the

performance of these devices during simulated coughing but not breathing or speaking, which have different air flow rates and aerosol size distributions. Some internal losses of the test aerosol particles likely occurred due to settling or impaction on the surfaces of the collection chamber, which may affect the estimates of the collection efficiencies. We only used a single representative example of each type of device. The shape and composition of face coverings vary widely, and this would be expected to affect the performance of individual devices. Some face masks have exhalation valves or vents which could reduce their efficacy as source control devices. The fit of a particular mask to an individual wearer and compliance in wearing the mask correctly (i.e., over the nose and mouth) also are important factors in how well the mask performs as a source control device. Because we used a < 0.6 to 7 µm test aerosol, our results do not indicate if face shields would be more effective as source control devices for large droplets. The face shield that we tested has a widely used design, but alternative designs are being marketed that provide greater facial coverage and, in some cases, include fabric skirts between the shield and the face. These alternative face shield designs might perform better as source control devices.

Previous studies have shown that face shields provide eye and facial protection to the wearer from droplets and splashes (Lindsley et al. 2014; Roberge 2016). When a face shield is worn in addition to a face mask, the face shield can also help reduce surface contamination of the mask by large aerosols and reduce the likelihood of hand contamination when the mask is removed or inadvertently touched (Lindsley et al. 2014). Our previous study showed that face shields provide some benefits as personal protective equipment when face masks cannot be worn (Lindsley et al. 2014), but as with all personal protection and source control devices, their limitations must be respected. Our results suggest that face masks and neck gaiters are more effective than face shields as source control devices to reduce the expulsion of respiratory aerosols into the environment as a public health measure to reduce the community transmission of SARS-CoV-2.

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Declaration of interests statement

The authors declare no competing interests.

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From: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>
Sent: Tuesday, January 11, 2022 2:05 PM
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
Cc: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>; McCalla, Haley (CDC/OD/OCS) <LNO3@cdc.gov>; Brunson, Juanita (CDC/DDNID/NCBDDD/DBDID) (CTR) <qrl8@cdc.gov>
Subject: N95 effectiveness as source control

Dear Partners,

We have had a number of questions from you and others about N95 effectiveness as source control and wanted to share some information back with you.

National Institute for Occupational Safety and Health (NIOSH) researchers have evaluated N95s as source control in two different peer reviewed publications. In the first paper (Lindsley et al. 2021a- attached), NIOSH researchers found that a N95 respirator (3M model 1860) was 99% effective at blocking cough aerosols. In a second paper (Lindsley et al. 2021b- attached), NIOSH researchers found that one N95 respirator (3M 1860 N95) was 99% effective at blocking coughed and exhaled aerosols, and a second N95 Respirator (BYD) was 83% effective at blocking cough aerosols and 95% effective at blocking exhaled aerosols.

References (attached)
Lindsley WG, et al. (2021a). Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols. AEROSOL SCIENCE AND TECHNOLOGY, VOL. 55, NO. 4, 449–457
https://doi.org/10.1080/02786826.2020.1862409

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Many thanks,
Aliki

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Coronavirus Disease 2019 (COVID-19) | CDC

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Saturday, January 08, 2022 1:55 PM EST
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
Subject: PARTNER ALERT: CDC Expands Booster Shot Eligibility

Dear Partners –

Yesterday, CDC adjusted our recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months.

Earlier this week CDC made this recommendation for recipients of a Pfizer-BioNTech primary seriesand, after FDA action this morning, we're extending this recommendation to recipients of a Moderna primary series. This means that people 12 and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.

Recently CDC strengthened our COVID-19 vaccination recommendations for children, now recommending that:

- Moderately to severely immunocompromised children ages 5–11 years receive an additional primary dose of Pfizer-BioNTech to ensure optimal protection from the vaccine.
- Children and teens ages 12–17 years should receive a booster shot.

Thank you,

Vaccine Task Force
COVID-19 Response

From:	Byers, Paul
To:	Dobbs, Thomas E; Central Office Epi COVID Team; Craig, Jim; Broom, Sarah; Pearson, Meg; Smith, Elisabeth
Subject:	FW: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)
Date:	Tuesday, January 11, 2022 4:26:53 PM
Attachments:	image001.png image002.png N95 effectiveness as source control .pdf PARTNER ALERT CDC Expands Booster Shot Eligibility.msg COVID-19 Partner Updates January 10 2022.msg HHS Therapeutics Projected Allocations_7 Jan 2022.pdf HHS Update COVID-19 allocation projections for January .pdf Lindsley-2021-A comparison of performance metr.pdf Lindsley-2021-Efficacy of face masks, neck gai.pdf

Please see updates.

Paul Byers, MD
State Epidemiologist

From: CSTE Emergency Response <Preparedness@cste.org>
Sent: Tuesday, January 11, 2022 4:17 PM
To: CSTE Emergency Response <Preparedness@cste.org>
Cc: CSTE Novel Coronavirus 2019 <CSTEncov2019@cste.org>
Subject: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Partner Alert: N95 Effectiveness as Source Control [Attachments]
    - Today, **Tuesday, January 11**, CDC issued a partner update (attached) in response to numerous questions about N95 mask effectiveness as source control. The update shared two peer reviewed publications from National Institute for Occupational Safety and Health (NIOSH) researchers (both attached) on N95 mask effectiveness, including findings that a N95 respirator was 99% effective at blocking cough aerosols.

HHS Update: COVID-19 Allocation Projections for January [Attachments]

- On **Friday, January 7**, the U.S. Department of Health and Human Services (HHS) issued an update with a projected calendar of allocation amounts and cadence of COVID-19 therapeutics for the remainder of January (attached). Questions may be directed to us COVID19Therapetuics@hhs.gov.

- Partner Alert: CDC Expands Booster Shot Eligibility [Attachment, Link]
  - On **Saturday, January 6**, CDC issued a partner alert (attached) adjusting its recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months. CDC has extended this recommendation to recipients of a Moderna primary series. This means that people 12 years of age and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.
- CDC COCA Call: What Clinicians Need to Know About the New Oral Antiviral Medications for COVID-19 [Links]
  - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **tomorrow, Wednesday, January 12 at 2:00 pm EST** to discuss the recent emergency use authorizations (EUAs) for new oral antiviral medications intended to decrease hospitalizations, as well as prevent severe COVID-19 and death Call information is below:
    - Weblink: https://www.zoomgov.com/j/1612974214?pwd=VitYMEorako1YWhCaXpnaWdsc2Ixdz09
      Telephone: (660) 254-5252 or (646) 828-7666 or (669) 216-1590 or (551) 285-1373
      Webinar ID: 161 297 4214
      Passcode: 180866
      Post-Event Recording:
      https://emergency.cdc.gov/coca/calls/2021/callinfo_011222.asp
- Reminder: CDC Preventive Medicine Grand Rounds: "The Public Health System of the Future – Moving Ahead in Partnership with Health Care & Other Sectors" [Link]
  - CDC will host its monthly Preventive Medicine Grand Rounds **tomorrow, Wednesday, January 12** at **1:30 pm EST**. The session will focus on the public health system of the future and the speaker is John Auerbach, Director of Intergovernmental and Strategic Affairs for CDC. Continuing education (CE) is available at no cost. Registration information is available here.

Standing Updates

- CDC Partner Update – January 10 [Attachment]
  - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – January 10 [Link]
  - Please click here for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.

- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am ET**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
    - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

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From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Monday, January 10, 2022 4:53 PM EST
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>
Subject: COVID-19 Partner Updates: January 10, 2022

Good afternoon Partners,
Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC at eocevent424@cdc.gov. Thank you for your partnership.

January 10, 2022

Morbidity and Mortality Weekly Report (MMWRs)

- Effectiveness of BNT162b2 (Pfizer-BioNTech) mRNA Vaccination Against Multisystem Inflammatory Syndrome in Children Among Persons Aged 12–18 Years — United States, July–December 2021. Link here.
- Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 years — United States, March 1, 2020–June 28, 2021. Link here.
- Risk Factors for Severe COVID-19 Outcomes Among Persons Aged ≥18 Years Who Completed a Primary COVID-19 Vaccination Series — 465 Health Care Facilities, United States, December 2020–October 2021. Link here.
- Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021. Link here.

CDC Resources

New & Updated

- CDC Recommends Moderna Booster at 5 Months: On January 4th, CDC made this recommendation for recipients of a Pfizer-BioNTech primary series. After FDA action on January 7th, we're extending this recommendation to recipients of a Moderna primary series. This means that people who initially received an mRNA vaccine series——two doses of Moderna or Pfizer-BioNTech —can now receive an mRNA booster shot 5 months after completing their initial series.
- Guidance for COVID-19 Prevention in K-12 Schools was recently updated to reflect new recommendations for isolation for people with COVID-19 and recommendations for people who have come into close contact with a person with COVID-19.
- CDC Expands Booster Shot Eligibility and Strengthens Recommendations for 12-17 Year Olds: CDC now recommends that adolescents age 12 to 17 years old should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccination series.
- CDC Recommends Pfizer Booster at 5 Months, Additional Primary Dose for Certain Immunocompromised Children: On January 4th, CDC updated its recommendation for when many people can receive a booster shot, shortening the interval from 6 months to 5 months for people who received the Pfizer-BioNTech COVID-19 Vaccine.
- Stay Up to Date with Your Vaccines: To align with standard language CDC uses about other vaccinations, CDC is now using the phrase "up to date" when talking about COVID-19 vaccination. CDC recommends that individuals stay "up to date" by receiving any additional doses they are eligible for, according to CDC's recommendations, to ensure they have optimal protection against COVID-19. The technical definition of "fully vaccinated"—two doses of an mRNA vaccine or one dose of the J&J vaccine—has not changed.
- What We Know About Quarantine and Isolation provides information on why CDC shortened quarantine and isolation guidance for the general population.

School and Work

- Guidance for COVID-19 Prevention in K-12 Schools
- Overview of COVID-19 Isolation for K-12 Schools
- Overview of COVID-19 Quarantine for K-12 Schools
- What you Should Know About COVID-19 Testing in Schools
- Responding to COVID-19 Cases in K-12 Schools: Resources for School Administrators
- Schools, Child Care, and Colleges
- Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2
- Strategies to Mitigate Healthcare Personnel Staffing Shortages
- School Learning Modalities (HHS Protect Public Data Hub)

Community

- Communication Resources for Travelers
- CDC COVID-19 Travel
- 12 COVID-19 Vaccination Strategies for Your Community
- Find a COVID-19 vaccine near you: Vaccines.gov
  - Individuals in the U.S. can utilize a text messaging service to locate vaccine locations, available in both English and Spanish. Individuals can text their ZIP code to 438829 (GETVAX) and 822862 (VACUNA) to find three locations nearby that have vaccines available.

Science and Data

COVID-19 Variants

- Science Brief: Omicron (B.1.1.529) Variant provides an overview of the current scientific information regarding the Omicron (B.1.1.529) variant. New data continue to emerge, and recommendations will be updated periodically, as needed.
- Omicron Variant: What You Need to Know provides information on what is currently known about the Omicron (B.1.1.529) variant.
- What You Need to Know About Variants

COVID-19 Testing Guidance

¡¤Testing Strategies for SARS-CoV-2 describes and compares different types of testing strategies for SARS-CoV-2.
¡¤Self-Testing provides information on when, why, and how to use a self-test for COVID-19.

Influenza (flu) Guidance

¡¤Increasing Seasonal Influenza A (H3N2) Activity, Especially Among Young Adults and in College and University Settings, During SARS-CoV-2 Co-Circulation
¡¤FAQ: CDC Distribution of COVID-19 Assays
¡¤CDC Digital Media Toolkit: 2021-22 Flu Season

COVID-19 Vaccines

¡¤CDC Endorses ACIP's Updated COVID-19 Vaccine Recommendations
¡¤CDC Expands COVID-19 Booster Recommendations to 16-and-17-year-olds
¡¤COVID-19 Vaccine Booster Shots
¡¤COVID-19 Vaccines for Children and Teens
¡¤COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19: CDC strongly recommends COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.
¡¤Science Brief: Evidence Used to Update the List of Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19
¡¤Quick Conversation Guide on COVID-19 Vaccines for Children
¡¤Resources to Promote the COVID-19 Vaccine for Children & Teens
¡¤Using the COVID-Vac Tool to Assess Your COVID-19 Vaccination Clinic Staffing and Operations Needs

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Kind regards,
Shyonna Johnson, MPH (She/Her)
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CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

DRAFT – PRE-DECISIONAL & DELIBERATIVE

Therapeutic Allocation

	Drug Class	Allocation Cadence	Sweep Schedule	Allocation Jan 3	Planned Allocation Jan 10	Planned Allocation Jan 17	Planned Allocation Jan 24	Planned Allocation Jan 31
Paxlovid *Pfizer*	Oral antiviral	Bi-Weekly	N/A	0	100,000	0	100,000	0
Molnupirivir *Merck*	Oral antiviral	Bi-Weekly	N/A	0	400,000	0	400,000	0
Evusheld *AstraZeneca*	Monoclonal for prevention	Weekly	N/A	50,000	75,000	75,000	75,000	75,000
Sotrovimab *GSK/Vir*	Monoclonal for treatment	Weekly	N/A	50,000	52,250	52,250	52,250	52,250
Bamlanivimab/ Etesevimab *Lilly*	Monoclonal; omicron resistance	Weekly	Weekly; Saturday	45,000	**45,000*	**45,000*	**45,000*	**45,000*
REGEN-COV *Regeneron*	Monoclonal, omicron resistance	Weekly	Weekly; Saturday	55,000	**55,000*	**55,000*	**55,000*	**55,000*
Remdesivir *Gilead*	IV antiviral	N/A; Commercial Market	N/A	N/A	N/A	N/A	N/A	N/A

** With the rise of the omicron variant, clinically appropriate use should be considered for bam/ete and REGEN-COV. Allocations of these products are subject to change based on omicron prevalence data.*

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From: ASPR Stake Holder (OS/ASPR) <ASPRStakeholder@hhs.gov>
Sent: Friday, January 7, 2022 5:41:02 PM
Subject: HHS Update: COVID-19 allocation projections for January

Dear State and Territorial Health Officials,

Thank you for your continued partnership in this all-of-America approach to fighting the COVID-19 pandemic. It remains our goal to facilitate a fair and equitable process in the allocation of COVID-19 therapeutics, and we certainly couldn't do this without you. We know that providing a longer look ahead for expected allocation amounts will help further support your jurisdictional planning. As such, attached is a projected calendar of allocation amounts and cadence for the remainder of January. Of course, the COVID-19 environment is very dynamic; so, these projections could change based on daily analysis of related data.

Additionally, we wanted to provide you with an update regarding Gilead's product - VEKLURY(tm) (remdesivir), which is not allocated by the federal government but is available commercially. Following the recent statement from the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel regarding therapies for the COVID-19 Omicron variant, CMS created HCPCS code J0248 for the VEKLURY(tm) (remdesivir) antiviral medication when administered in an outpatient setting. This code is available for use by all payers and is effective for dates of service on or after December 23, 2021:

* Long descriptor: Injection, remdesivir, 1 mg
* Short descriptor: Inj, remdesivir, 1 mg

Medicare Administrative Contractors (MACs) determine Medicare coverage when there is no national coverage determination, including in cases when providers use FDA-approved drugs for indications other than what is on the approved label. The MACs consider the major drug compendia, authoritative medical literature and accepted standards of medical practice to determine medical necessity when considering coverage. Therefore, the MACs will determine Medicare coverage for HCPCS code J0248 for VEKLURY(tm) (remdesivir) administered in an outpatient setting.

Thank you, again, and please contact us at COVID19Therapetuics@hhs.gov with any questions.

Regards,
HHS - Coordination Operations and Response Element (H-CORE)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Aerosol Science and Technology

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A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols

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AEROSOL SCIENCE AND TECHNOLOGY
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A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols

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ABSTRACT

Universal mask wearing is recommended to help control the spread of COVID-19. Masks reduce the expulsion of aerosols of respiratory fluids into the environment (called source control) and offer some protection to the wearer. Masks are often characterized using filtration efficiency, airflow resistance, and manikin or human fit factors, which are standard metrics used for personal protective devices. However, none of these metrics are direct measurements of how effectively a mask blocks coughed and exhaled aerosols. We studied the source control performance of 15 cloth masks (face masks, neck gaiters, and bandanas), two medical masks, and two N95 filtering facepiece respirators by measuring their ability to block aerosols $\leq$7 µm expelled during simulated coughing and exhalation (called source control collection efficiency). These measurements were compared with filtration efficiencies, airflow resistances, and fit factors measured on manikin headforms and humans. Collection efficiencies for the cloth masks ranged from 17% to 71% for coughing and 35% to 66% for exhalation. Filtration efficiencies for the cloth masks ranged from 1.4% to 98%, while the fit factors were 1.3 to 7.4 on headforms and 1.0 to 4.0 on human subjects. The Spearman's rank correlation coefficients between the source control collection efficiencies and the standard metrics ranged from 0.03 to 0.68 and were significant in all but two cases. However, none of the standard metrics were strongly correlated with source control performance. A better understanding of the relationships between source control collection efficiency, filtration efficiency, airflow resistance, and fit factor is needed.

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Introduction

Humans infected with SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), can produce droplets and aerosols of respiratory fluids containing the virus when they cough, breathe, talk, sing and sneeze (Anderson et al. 2020; CDC 2020b; Hamner et al. 2020; Ma et al. 2020; Morawska and Milton 2020). To reduce the transmission of SARS-CoV-2, public health agencies have recommended that the general public wear cloth masks (CDC 2020c, 2020d, 2021; Edelstein and Ramakrishnan 2020; WHO 2020). The primary purpose of masks (which in this article includes face masks, neck gaiters, bandanas and other face coverings) is to block the expulsion of infectious droplets and aerosols from the wearer into the environment (called source control) and thereby reduce the exposure of other people to the virus (CDC 2020a). Laboratory studies using manikins and human subjects have shown that cloth face masks can partially block respiratory aerosols produced during coughing, breathing and talking (Asadi et al. 2020; Davies et al. 2013; Lindsley et al. 2021; Pan et al.

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2021). Wearing medical face masks (i.e., "surgical masks" as defined by the U.S. Food and Drug Administration [FDA 2004]) reduces the dispersion of potentially infectious aerosols from patients with respiratory infections (Leung et al. 2020; Milton et al. 2013). Masks may also provide some personal protection to the wearer by reducing their exposure to infectious droplets and aerosols produced by others, although they are not as effective as a respiratory protective device such as a NIOSH-approved N95 filtering facepiece respirator (N95 respirator) (CDC 2020a; Lawrence et al. 2006; Oberg and Brosseau 2008; Pan et al. 2021). Several community level studies have shown that universal masking helps reduce the spread of COVID-19 (CDC 2020a). For example, a comparison of counties in the US state of Kansas found that mask mandates were associated with lower incidence rates of COVID-19 (Van Dyke et al. 2020). A study of 10 US states found that statewide mask mandates were associated with a decline in weekly COVID-19–associated hospitalization growth compared to states without such mandates (Joo et al. 2021).

In response to the need for source control devices for the general public, manufacturers worldwide have produced a broad array of masks. Unfortunately, because of the many different designs and construction materials, it is not possible to predict how well a particular mask will perform as a source control device without testing, which is rarely done for non-medical masks not intended for occupational use. Although general guidelines have been developed (CDC 2020d), it is very difficult for public health organizations, governments, medical facilities, and the general public to know which of the available devices are most effective.

Test methods and performance standards do exist for regulated medical face masks and respiratory protective devices (Rengasamy et al. 2017). In the United States, respiratory protective devices, which are devices such as N95 filtering facepiece respirators that are intended to protect the wearer from airborne particles, must be approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 Code of Federal Regulations (CFR) Part 84 (NIOSH 1995). The approval process includes testing the filtration efficiency for the most-penetrating aerosol particle size and measuring the airflow resistance of the device (NIOSH 2019). Medical face masks that are not intended to be used as respiratory protective devices are cleared by the Food and Drug Administration (FDA), which reviews manufacturer-supplied information on filtration efficiency, airflow resistance, resistance to fluid penetration and flammability (FDA 2004). The FDA recommends that manufacturers use the ASTM standards F2299 for measuring particle filtration efficiency through the mask material using latex microspheres (ASTM 2003), and the F2101 Standard test method of evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of *Staphylococcus aureus* (ASTM 2019). Bacterial filtration efficiency can also be measured with the modified Greene and Vesley method using human test subjects (Greene and Vesley 1962; Quesnel 1975).

In addition to filtration performance, how well a respiratory protective device protects the wearer depends upon how well the device fits the face and whether the seal between the face and the device has gaps or leaks (Lawrence et al. 2006). ASTM Standard F3407-20 outlines procedures for testing respirators using a bivariate panel of human test subjects with different facial dimensions (ASTM 2020). The NIOSH approval test for respirators measures the filtration properties but does not include tests of how well the device fits faces of different shapes, although this has been proposed. Consequently, in the United States, when a worker is required to wear a respirator, the Occupational Safety and Health Administration (OSHA) requires that a respirator fit test be performed annually for each worker to determine how well the respirator protects the worker (OSHA 2020). Quantitative fit tests measure the aerosol particle concentration inside and outside the respirator during a series of exercises, and this information is used to calculate the fit factor (outside concentration/inside concentration) (Janssen and McKay 2017). The minimum acceptable fit factor for a respirator depends upon the exposure level and potential health consequences of the hazards to which the worker may be exposed (OSHA 2020).

The existing test methods for respirators and medical face masks provide a possible basis for developing standards for non-medical masks used as source control devices. The American Association of Textile Chemists and Colorists (AATCC) published guidelines for cloth face coverings that include the use of ASTM F2299 and other national and international performance standards (AATCC 2020). Leith, L'Orange, and Volckens (2021) proposed an estimated mask protection factor that is calculated based on tests of filtration efficiency and fit and on estimates of the average time spent speaking, inhaling, and exhaling. ASTM International has released a standard for testing barrier face coverings that includes tests of filtration efficiency and airflow resistance, and an assessment of leakage, which are standard metrics that are commonly used to test personal protective devices (ASTM 2021). The use of these standard performance metrics has many advantages, most notably that the equipment and procedures needed to conduct the tests are widely available. However, none of these metrics are

Table 1. Performance metrics used in this study. Outward mask airflow is in the direction of exhalation. Inward airflow is in the direction of inhalation.

Performance metric	**Parameter measured**	Mask airflow direction	Measurement instrument	**Measurement method**	Particle size	**Instrument airflow rate (liters/minute)**
Cough aerosol collection efficiency	Aerosol mass escaping beyond mask into collection chamber	Outward	Andersen impactor	Fluorescence of aerosol on impactor stages	0.1 to 7 μm	28.3
Exhaled aerosol collection efficiency	Aerosol mass escaping beyond mask into collection chamber	Cyclical	Andersen impactor	Fluorescence of aerosol on impactor stages	0.1 to 7 μm	28.3
Filtration efficiency	Aerosol mass concentration upstream & downstream of mask	Inward	TSI 8130 A	Photometer	75 nm count median diameter (GSD 1.86)	85
Airflow resistance	Pressure required for 85 lpm flow	Inward	TSI 8130 A	Manometer	n/a	85
Manikin fit factor	Aerosol particle count inside & outside mask	Cyclical	TSI PortaCount	Size classifier & condensation particle counter	55 nm (N95 mode)	0.35
Human fit factor	Aerosol particle count inside & outside mask	Cyclical	TSI PortaCount	Size classifier & condensation particle counter	55 nm (N95 mode) 0.02–1.0 μm (Class 100 mode)	0.35

direct measurements of the ability of a mask to block aerosols expelled during coughing and exhalation. To assist in the further development of these types of standards and guidelines, the relationship between the efficacy of masks as source control devices and their performance using standard metrics needs to be better understood. For example, it is possible to measure the filtration efficiency of the mask material, but it is not clear how that filtration efficiency translates to source control efficacy or what minimum performance level should be required.

The purpose of this study was to compare the performance of a variety of N95 respirators, medical masks, and cloth masks as source control devices with their filtration efficiencies, airflow resistances, fit factors measured using manikin headforms, and fit factors measured on humans. The results of these experiments will assist in the development of appropriate test methods and standardized performance metrics to evaluate the efficacy of cloth masks as source control devices for respiratory aerosols.

Materials and methods

Experimental design

A source control measurement system was used to assess the efficacy of N95 respirators, medical masks, and cloth masks as source control devices. The source control performance was determined by measuring the source control collection efficiency of the mask, which is the fraction of the mass of the coughed or exhaled test aerosol particles that were blocked by the mask from reaching the collection chamber. The filtration efficiencies and airflow resistance of the construction materials were measured using a modified version of the test method used for respirator approvals. Fit tests were performed both on a manikin headform with pliable skin and with human test subjects. The source control collection efficiencies were then compared with the fit factors, filtration efficiencies and airflow resistances measured on the same devices. A summary of the performance metrics used in the study is shown in Table 1.

Respiratory aerosol source control measurement system

The efficacy of respirators, medical masks, and cloth masks as source control devices for aerosols produced during coughing and exhalation was determined using a respiratory aerosol source control measurement system described previously (Lindsley et al. 2021). The system includes a coughing and breathing aerosol simulator, a manikin headform, an 136 L aerosol collection chamber, and a cascade impactor (Figure 1). The manikin headform used in the study has pliable skin that mimics the elastic properties of human skin in order to create a realistic simulation of how each source control device would fit a human face (Bergman et al. 2014).

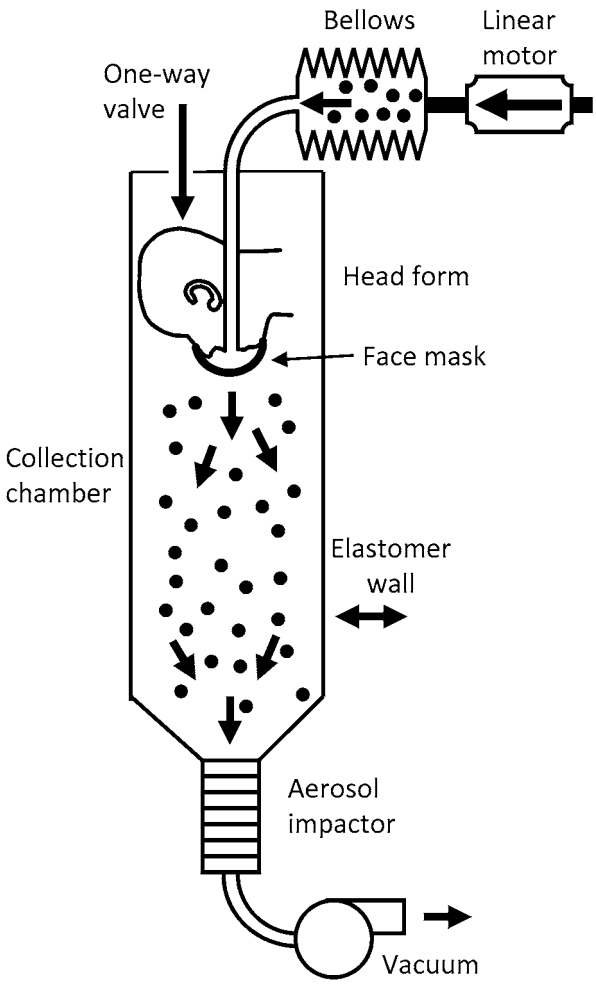

Figure 1. Source control measurement system. The system consists of an aerosol generation system, a bellows and linear motor to produce the simulated coughing and breathing, a pliable skin headform on which the source control device is placed, a 136 liter collection chamber into which the aerosol is coughed or exhaled, and a cascade impactor to separate the aerosol particles by size and collect them. The system is oriented vertically as shown to minimize the loss of aerosol particles due to settling before collection. The system is described in more detail in Lindsley et al. (2021).

The test aerosol was produced using a solution of 14% potassium chloride (KCl) and 0.4% sodium fluorescein in a single-jet Collison nebulizer (BGI, Butler, NJ, USA) at 103 kPa (15 lbs./in^2). The aerosol passed through a diffusion drier (Model 3062, TSI, Shoreview, MN, USA), mixed with dry filtered air flowing at 10 L/min for the cough tests and 15 L/min for the breathing tests, and neutralized using a bipolar ionizer (Model HPX-1, Electrostatics). An elastomeric bellows driven by a computer-controlled linear motor produced the coughing or breathing airflow.

For cough tests, the test aerosol was loaded into the elastomeric bellows and then coughed out using a single cough with a volume of 4.2 L and a peak flow rate of 11 L/s (Lindsley et al. 2013). An Andersen cascade impactor (Model TE-10-830, Tisch Environmental) collected all aerosol particles that traveled through or around the device for 20 min after each cough. For breathing tests, the system used a ventilation rate of 15 L/min with a breathing rate of 12 breathes/min and a tidal volume of 1.25 liters, which corresponds to the ISO standard for a female performing light work (ISO 2015). The test aerosol was only generated for the first 30 s of breathing to avoid overloading the impactor. The breathing continued for 20 min total. The impactor collected the aerosol particles in the chamber during the 20-minute breathing period followed by an additional five minutes of collection after the breathing had stopped.

The impactor operated at a flow rate of 28.3 liters/minute and had six collection stages and a filter that separated the aerosol particles into seven size fractions based on the aerodynamic diameter of the particles: <0.6 µm; 0.6–1.1 µm; 1.1–2.1 µm; 2.1–3.3 µm; 3.3–4.7 µm; 4.7–7.0 µm; and >7 µm. The impactor collection plates were coated with a solution of glycerol and Brij 35 to prevent particles from bouncing off the plates during collection (Mitchell 2003). Because the amount of aerosol in the largest size fraction was small (<0.7% of total aerosol mass) and because of possible losses due to settling of the large aerosol particles, data for the largest size fraction were not included in the analysis. After aerosol collection was completed, the aerosol particles were eluted from the impactor plates using a 0.1 M Tris solution and the fluorescence of the solution was read using a spectrofluorometer (SpectraMax M4, Molecular Devices).

To control for variations in the amount of aerosol in each experiment, a sample of each test aerosol was collected from the bellows prior to coughing or breathing using a 47 mm 5 µm PVC filter. The aerosol was eluted from the filter using 0.1 M Tris. An adjustment factor for the experiment (A) was calculated as:

$$A = \frac{Mass\ of\ aerosol\ on\ filter}{Mean\ (mass\ of\ aerosol\ on\ filter\ for\ all\ control\ experiments)} \quad (1)$$

The adjusted mass of aerosol on each impactor stage for the experiment was then calculated as:

$$M_{stage,\ adjusted} = \frac{M_{stage,\ unadjusted}}{A} \quad (2)$$

The adjusted masses were used for all subsequent calculations. The adjusted aerosol masses collected by the cascade impactor during the experiments are

Table 2. Source control devices used in experiments.

Type	Manufacturer	Product	Fastener	Material
Medical masks & respirators	3M	Model 1860 N95 respirator and surgical mask (TC-84A-0006)	Two elastic straps around head	Polypropylene and polyethylene composition
	BYD	N95 filtering facepiece respirator (TC-84A-9221)	Two elastic straps around head	IL and OL: Polypropylene spun-bound nonwoven fabric. ML: Polypropylene melt-blown nonwoven + hot air cotton
	3M	Model 1818 surgical mask	Two ties behind head	Poly(ethylene terephthalate) and polypropylene
	Excellent Artisan	Procedure mask	Ear loops	3-ply, Nonwoven. Fabric composition unknown
Reusable cloth face masks	Hanes	Defender 3-ply mask	Ear loops	100% cotton
	EnerPlex	3-ply mask	Ear loops	IL and ML: 65% polyester, 35% cotton. OL: 100% polyester
	Craft & Soul	2-ply mask	Ear loops	65% polyester, 35% cotton
	Lefty	2-ply face mask	Ear loops	92% polyester, 8% spandex
	Badger	4-ply mask	Ear loops	IL : 100% cotton. MLs: melt blown filters. OL: air mesh polyester
	Debrief Me	3-ply mask with PM 2.5 filter	Ear loops	IL 100% cotton, ML and OL: polyester blend
	Fabrique Innovations	Mask	Ear loops	100% cotton
	Besungo	Mask with PM 2.5 filter & exhalation valves	Ear loops and Velcro neck strap	Nylon
	Inspire	2-ply mask with PM 2.5 filter	Ear loops	Polyester/cotton blend
Neck gaiters	FKGIONG	Neck gaiter	Encircles head	95% polyester, 5% spandex
	AXBXCX	Neck gaiter	Encircles head	Polyester
	Retro Brand	Neck gaiter	Encircles head	100% polyester
	Givon	Neck gaiter	Encircles head	100% polyester fleece
Bandanas	L & M	Bandana	Ties behind head	100% cotton
	Underwear	Bandana/gaiter	Ear loops	Polyester blend

In this article, the reusable cloth face masks, neck gaiters and bandanas are referred to collectively as "cloth masks". IL is inner layer, ML is middle layer, and OL is outer layer. Photographs are shown in Figures S3–S5 (SI).

shown in Tables S1 and S2 in the supplemental information (SI).

The source control performance, or source control collection efficiency, of a face covering is defined as the fraction of the mass of the respiratory aerosol that is blocked from entering the environment around the wearer. For example, if 80% of the mass of the aerosol from a cough is blocked by a face mask and 20% of the aerosol mass is able to flow through or around the mask into the air around the wearer, then the mask is said to have a collection efficiency of 80%. The performance of each source control device was evaluated by calculating the collection efficiency as:

$$Collection\ efficiency = 1 - \frac{M_{mask}}{M_{control}} \qquad (3)$$

where:

M_{mask} = adjusted total mass of the aerosol particles that passed through or around the source control device and was collected by the impactor.

$M_{control}$ = adjusted total mass of the aerosol particles collected by the impactor while not wearing a source control device.

Note that the collection efficiency is based on the mass of the aerosol rather than a measure such as particle counts. Also, the aerosol is flowing from the inside of the mask toward the outside; that is, in our test system the aerosol flows in the same direction as it would flow during a cough or exhalation by a person wearing the mask.

Respirators, medical masks, and cloth masks

In our study, the term "cloth mask" refers to a cloth face mask, neck gaiter or bandana constructed from textiles or fabrics (both natural and synthetic) that is not a surgical mask or N95 respirator and is not intended for use as personal protective equipment. The term "medical masks" in this article refers to non-woven disposable masks that are held on the face with elastic ear loops. These masks are loose-fitting and are not expected to provide the wearer with as reliable a level of protection against airborne or aerosolized particles as N95 respirators regulated by NIOSH. Commercial manufacturers often refer to

masks held on by ear loops as procedure masks and masks that tie behind the head as surgical masks. However, the U.S. Food and Drug Administration uses the term "surgical mask" to describe commercially produced masks regulated by the under 21 CFR 878.4040 for performing medical procedures (FDA 2004). The FDA definition applies to all masks that cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials, and includes masks that are labeled as surgical, laser, isolation, dental or medical procedure masks with or without a face shield.

Nineteen commercially available N95 respirators, medical masks, and cloth masks were selected to provide a broad cross-section of the different types of source control devices that are available (Table 2). For the source control tests, each device was placed on the headform as it would normally be worn by a person. Three of the neck gaiters were tested both as a single layer of fabric and folded over to provide two layers of fabric. Before the source control test, the manikin fit factor (Janssen and McKay 2017) was measured by performing a respirator fit test (Bergman et al. 2015) for each device using a PortaCount® Pro + respirator fit tester (Model 8038, TSI, Shoreview, MN) in N95 mode with the system breathing at 36 L/min but not producing an aerosol. Each device was used for two consecutive tests. Photographs of the source control devices on the headform are shown in the SI (SI; Figures S1–S3).

Filtration efficiency and airflow resistance measurements

The filtration efficiency of the face covering is the fraction of the test aerosol that is collected as the aerosol passes through the mask material. For example, if 70% of the test aerosol is collected by the mask material and 30% of the aerosol passes through it, then the filtration efficiency is 70%. Note that the filtration efficiency tests are performed by fastening the mask to a holder so that all the aerosol flows through the mask material, and none can escape through face seal leaks. Thus, the filtration efficiency is a property of the mask material.

The filtration efficiency and airflow resistance of the construction materials were measured using automated filter testers (Models 8130 and 8130 A, TSI). Material samples were secured to a test plate using beeswax as shown in Figure S4 in the SI. Measurements were made using a modified version of the NIOSH standard testing procedure (STP) (NIOSH 2019). Under the modified STP, samples were tested at ambient temperature and humidity but were not subjected to conditioning at 38°C and 85% relative humidity for 25 h, and sample testing was limited to 10 min. The device to be tested was oriented in the filter tester so that the air and aerosol flowed from the exterior of the device toward the interior (that is, as if the wearer were inhaling, which is the same direction as when testing a respirator as a personal protective device). The challenge aerosol was generated using a 2% sodium chloride (NaCl) solution in distilled water, conditioned to 25 °C and 30% relative humidity and neutralized to the Boltzmann equilibrium state. The challenge aerosol had a count median diameter of 75 nm ± 20 nm, a mass mean diameter of 260 nm and a geometric standard deviation (GSD) $\leq$ 1.86 (TSI 8130 A specifications). The automated filter tester compares particle mass concentration readings from upstream and downstream light-scattering laser photometers to calculate the material filtration efficiency. An electronic pressure transducer measures the pressure difference across the material sample to indicate airflow resistance. Tests were performed with an airflow of 85 L/minute.

Fit tests on human subjects

A convenience sample of eleven subjects (six males and five females) participated in fit testing. Subjects complied with CDC/NIOSH guidelines for facial hair styles intended for workers who wear tight-fitting respirators (CDC 2017). Fit testing was performed with a PortaCount® fit tester (model 8038, TSI) using OSHA's modified ambient aerosol condensation nuclei counter (CNC) protocol for filtering facepiece respirators (OSHA 2019). Because only fit factors were measured and no identifiable private information was collected, the West Virginia University Office of Human Research Protections determined that Institutional Review Board approval was not required. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy (see e.g., 45 C.F.R. part 46; 21 C.F.R. part 56; 42 U.S.C. §241(d), 5 U.S.C. §552a, 44 U.S.C. §3501 et seq.). All measurements were performed in a room with volume of 43.4 m^3 (1531 ft^3) at 19 °C (67 °F).

An NaCl aerosol generator (Model 8026, TI) was used to supplement the naturally occurring particles in the air. The particle generator was placed 10 feet away from all sampling apparatus and fit testing equipment. The generator was turned on ten minutes prior to testing to seed aerosols and turned off while

a triplicate series of fit tests were performed (around 7 min). As the aerosol concentration in the room had started to slightly decline at this point, the generator was turned on between tests (around 7 min) and then turned off during subsequent tests. This process was repeated until testing for the day was completed.

To verify that suitable aerosol concentrations were present during testing, particle concentrations were measured with a condensation particle counter (CPC Model 3775, TSI) for 25 min beginning at 2 min prior to the nebulizer being initially turned on. Particle size distributions were measured for 20 min with a scanning mobility particle sizer (SMPS Model 3938, TSI) and an electrical low-pressure impactor (ELPI+, Dakati). Information on the aerosol particle size distribution and concentration are shown in the SI (Figures S5 and S6).

Each source control device was tested by three subjects; for each subject three replicate measurements were made using each of the two protocols described below. One individual administered all fit tests. Subjects were instructed in the proper donning of medical masks and respirators, and they were asked to don cloth masks in the manner that they ordinarily don similar coverings for public use. If a cloth mask was too large, it was modified using materials that would be accessible to most lay individuals: tape was used to shorten mask ear loops or head straps, and a binder clip was used to decrease the circumference of neck gaiters. These adjustments were made so that the covering was held flush to the face, but the materials were not under tension.

Two particle measurement protocols were performed on all source control devices: the PortaCount® N95 Companion protocol (referred to here as N95 mode), which counts negatively charged particles 40–70 nm (mean 55 nm) in diameter; and the PortaCount® standard protocol (referred to here as Class 100 mode), which counts all particles from 0.02–1.0 µm (TSI 2010). The "Class 100 mode" is also called "N99 mode". For both modes, the fit factor (FF) was calculated by the PortaCount® software as (Janssen and McKay 2017; TSI 2015):

$$FF = \frac{C_B + C_A}{2C_R} \quad (4)$$

where:

C_B = ambient particle concentration measured before the particle concentration is measured inside the respirator.

C_A = ambient particle concentration measured after the particle concentration is measured inside the respirator.

C_R = particle concentration measured inside the respirator.

Note that the TSI PortaCount instrument used in our experiments measures the aerosol concentration based on the number of aerosol particles rather than the particle mass.

Data analysis

The source control results were compared with the filtration efficiencies, airflow resistances, and fit factor measurements by calculating the Spearman's rank correlation coefficients (ρ) between the metrics. Fit factors were transformed into fit efficiencies (= 1-1/fit factor) to allow for a direct comparison with the other parameters. For example, a fit factor of 5 corresponds to a fit efficiency of 80%, indicating that the mask blocked 80% of the ambient aerosol from being inhaled by the wearer. Because the replicate numbers were different for the different performance metrics, the correlations were calculated based on the mean results for each device. When analyzing the human fit factor results, we did not attempt to account for differences among test subjects. The p-value was calculated based on ρ and the number of types of devices that were tested (22 for all source control devices and 18 for the cloth masks alone, with the 1-layer and 2-layer gaiter tests counted separately). Correlations were considered significant if $p \leq 0.05$.

Results

Efficacy of N95 respirators, medical masks, and cloth masks as source control devices for respiratory aerosols

Twenty-six cough experiments were performed without a source control device to measure the cough aerosol output from the source control measurement system. The cough aerosol had a geometric mean aerodynamic diameter of 1.3 µm with a GSD of 2.3 and a mean mass of 525 µg (standard deviation [SD] 65; Figure 2 and SI Figure S7). Thirty-five breathing aerosol experiments were performed without a source control device to measure the exhaled aerosol output. The exhaled aerosol had a geometric mean aerodynamic diameter of 1.3 µm with a GSD of 2.3 and a mean mass of 495 µg (SD 68; Figure 2 and SI Figure S8). The experiments without source control devices were used as control experiments when evaluating performance of the devices.

The collection efficiencies of the 19 source control devices are shown in Figure 3 and Table 3. The mean

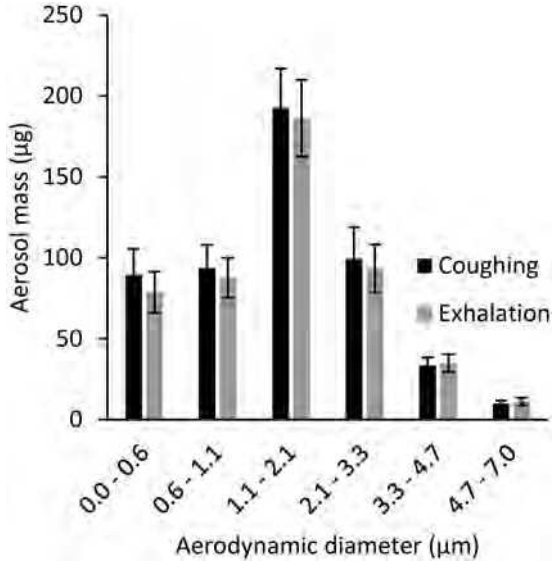

Figure 2. Mass of aerosol expelled by the source control measurement system during coughs and exhalations. The size bins correspond to the stages of the Andersen impactor. The size distribution is shown in units of µg/µm in Figures S7 and S8 in the SI.

collection efficiencies of the N95 respirators and the surgical mask ranged from 83% to 99% for aerosol particles during coughing and exhalation. For the procedure and cloth masks, the mean collection efficiencies ranged from 35% to 71% for coughing (except for the bandana at 17%) and 35% to 66% for exhalation. The collection efficiencies for the coughing and breathing source control experiments were correlated, with a Spearman's correlation coefficient (ρ) of 0.76 ($p < 0.001$; Table 4) when considering all the devices and 0.67 ($p = 0.003$; Table 4) when considering only the cloth face masks, gaiters and bandanas. The amounts of aerosol collected on each stage of the impactor are shown in Tables S1 and S2 in the SI.

Filtration efficiencies and inhalation airflow resistance

The mean material filtration efficiencies were >99% for the respirators, 80% to 93% for the medical masks, and 1.4% to 36% for the cloth face masks, neck gaiters, and bandanas, except for the Besungo sports mask at 98% (Figure 4 and Table 3). The inhalation

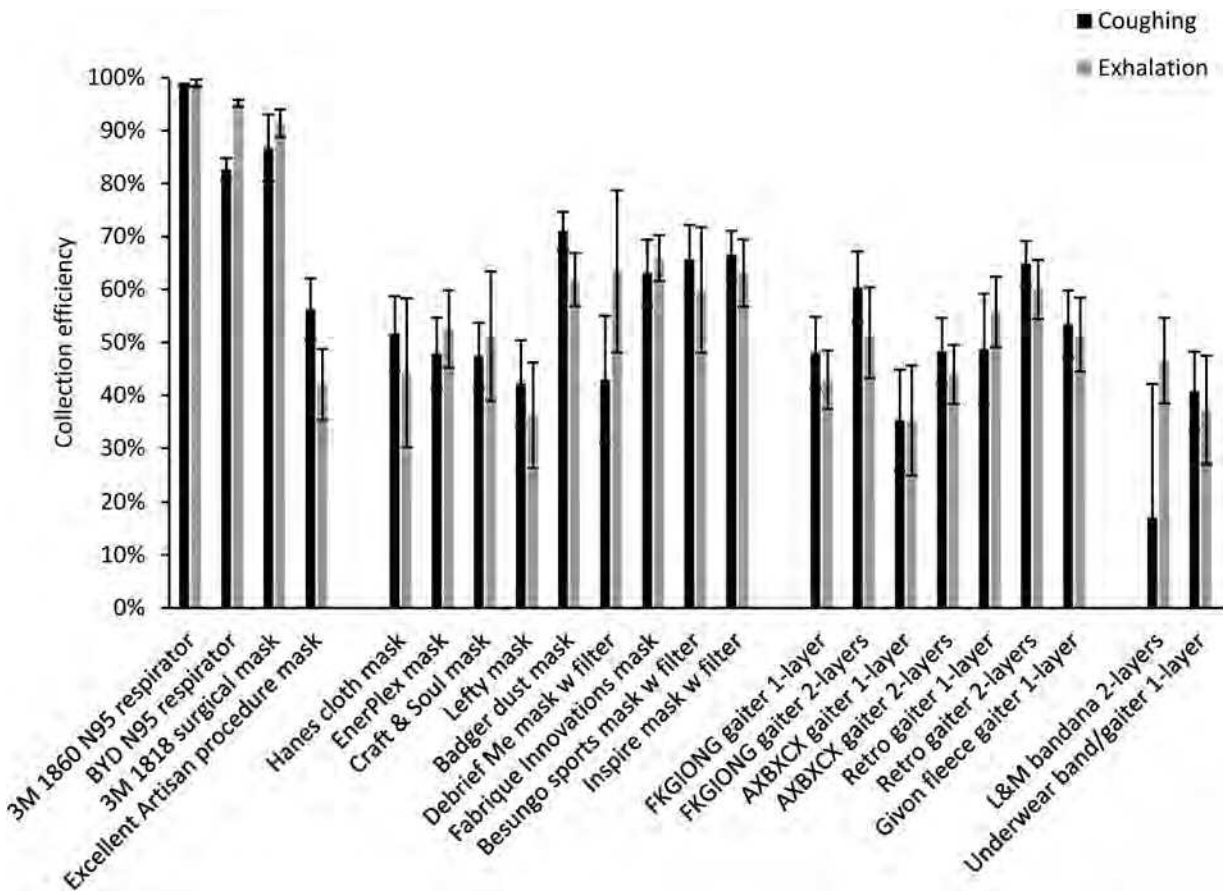

Figure 3. Source control collection efficiencies of N95 respirators, medical masks, cloth face masks, neck gaiters and bandanas during coughing and exhalation aerosol tests with the respiratory aerosol source control measurement system. Each bar is the mean of 4 or 6 experiments. Error bars show the standard deviation.

Table 3. Results for all performance metrics for source control devices.

Face covering	COUGHING				EXHALATION				Filtration Efficiency (%)		Inhalation airflow resistance (Pa)		Human fit factor			
	Collection efficiency (%)		Manikin fit factor		Collection efficiency (%)		Manikin fit factor						N95 mode		Class 100 mode	
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
3M 1860 N95 respirator	98.6%	0.3%	198.0	3.5	99.0%	0.7%	132.5	78.5	99.1%	0.1%	72.2	8.1	163.8	56.2	45.3	10.9
BYD N95 respirator	82.7%	2.1%	25.0	11.3	95.2%	0.6%	113.5	122.3	99.1%	0.1%	150.8	14.5	147.9	33.5	54.9	7.8
3M 1818 surgical mask	86.8%	6.3%	26.1	26.7	91.4%	2.6%	27.5	12.0	92.7%	0.6%	48.0	7.8	78.6	92.0	9.6	5.8
Excellent Artisan procedure mask	56.3%	5.8%	7.4	3.4	42.0%	6.7%	6.1	5.5	79.7%	3.6%	108.0	34.3	3.3	0.7	1.7	0.5
Hanes cloth mask	51.7%	7.1%	1.3	0.1	44.3%	14.0%	2.3	1.1	18.8%	2.7%	64.1	9.5	1.7	0.5	1.0	0
EnerPlex mask	48.0%	6.7%	5.1	1.3	52.6%	7.3%	2.5	0.4	19.9%	3.9%	23.8	10.7	2.1	1.2	1.8	0.7
Craft & Soul mask	47.4%	6.2%	2.5	1.2	51.2%	12.2%	2.3	1.0	9.7%	3.9%	11.4	8.2	2.0	0.5	1.3	0.5
Lefty mask	42.3%	8.1%	2.4	0.7	36.3%	9.9%	1.9	n/a	20.2%	0.8%	96.3	5.9	1.8	0.7	1.6	0.5
Badger dust mask	71.1%	3.5%	5.0	0.1	61.8%	5.0%	3.2	0.6	36.0%	9.9%	92.1	1.0	2.8	1.6	1.7	0.5
Debrief Me mask w filter	43.0%	12.0%	4.6	1.8	63.4%	15.3%	3.0	1.5	30.8%	1.5%	154.1	34.9	2.9	0.9	2.1	0.8
Fabrique Innovations mask	63.2%	6.2%	2.1	n/a	65.9%	4.4%	2.2	0.4	14.8%	n/a	61.7	n/a	1.4	0.7	1.1	0.3
Besungo sports mask w filter	65.7%	6.5%	4.8	n/a	59.9%	11.9%	3.2	0.3	97.8%	0.3%	142.7	22.9	2.7	1.7	1.9	1.4
Inspire mask w filter	66.5%	4.5%	4.3	3.0	63.1%	6.4%	2.7	0.5	27.1%	5.1%	149.8	85.4	4.0	1.4	2.4	0.5
FKGIONG gaiter 1-layer	48.1%	6.7%	1.7	0.5	42.9%	5.5%	1.5	0.2	3.3%	4.3%	13.1	8.0	1.1	0.3	1.0	0
FKGIONG gaiter 2-layers	60.5%	6.7%	1.9	0.4	51.8%	8.6%	1.7	n/a	7.9%	0.5%	23.8	8.4	1.0	0	1.4	0.5
AXBXCX gaiter 1-layer	35.4%	9.5%	1.7	0.1	35.3%	10.3%	1.4	0.1	2.7%	1.1%	14.4	5.7	1.3	0.7	1.0	0
AXBXCX gaiter 2-layers	48.3%	6.3%	1.8	0.1	43.9%	5.6%	1.9	0.5	3.6%	0.3%	29.4	4.5	1.3	0.5	1.3	0.5
Retro gaiter 1-layer	48.7%	10.5%	2.6	n/a	55.8%	6.6%	2.5	0.6	2.2%	n/a	40.2	n/a	1.6	0.7	1.3	0.5
Retro gaiter 2-layers	64.9%	4.2%	2.3	0.4	60.0%	5.5%	2.1	0.4	8.6%	n/a	69.5	n/a	1.7	1.0	1.7	0.5
Givon fleece gaiter 1-layer	53.5%	6.3%	2.1	0.5	51.4%	7.0%	2.3	0.8	8.4%	0.8%	19.3	7.4	1.0	0	1.3	0.5
L&M Bandana 2-layers	17.1%	25.0%	1.3	0.2	46.5%	8.1%	1.6	0.1	1.4%	0.4%	5.2	8.2	1.1	0.3	1.0	0
Underwear Bandana/gaiter 1-layer	40.8%	7.5%	6.9	7.3	37.3%	10.2%	1.4	0.1	3.5%	1.1%	19.3	8.2	1.1	0.7	1.0	0

Manikin fit factors were measured with the fit tester in N95 mode only (as described in the Discussion). Human fit factors were measured using both the N95 mode and Class 100 mode.

Table 4. Correlations between different performance metrics for all source control devices.

		All source control devices		Cloth face masks, gaiters, and bandanas only	
Correlation parameter #1	Correlation parameter #2	ρ	*p*-value	ρ	*p*-value
Cough aerosol collection efficiency	Exhaled aerosol collection efficiency	0.76	<0.001	0.67	0.003
	Filtration efficiency of material	0.69	0.001	0.51	0.032
	Airflow resistance of material	0.55	0.009	0.54	0.020
	Human subject fit (N95 mode)	0.57	0.005	0.30	0.208
	Human subject fit (Class 100 mode)	0.68	<0.001	0.48	0.035
	Manikin fit before coughing	0.39	0.076	0.03	0.890
Exhaled aerosol collection efficiency	Filtration efficiency of material	0.60	0.004	0.54	0.023
	Airflow resistance of material	0.51	0.016	0.58	0.012
	Human subject fit (N95 mode)	0.60	0.003	0.51	0.024
	Human subject fit (Class 100 mode)	0.71	<0.001	0.63	0.003
	Manikin fit before breathing	0.72	<0.001	0.68	0.002
Manikin fit before coughing	Manikin fit before breathing	0.61	0.003	0.38	0.112
Filtration efficiency of material	Airflow resistance of material	0.78	<0.001	0.78	<0.001

Each Spearman's rank coefficient (ρ) was calculated based on data from 22 experiments for all source control devices and 18 experiments for cloth masks (cloth face masks, gaiters, and bandanas). A correlogram of the ρ values in shown in Figure S9 in the SI.

airflow resistances were from 5.2 to 154 Pa (Table 3). When comparing the data for all devices, the filtration efficiencies were correlated with cough aerosol collection efficiency ($\rho = 0.69$, $p = 0.001$) and exhaled aerosol collection efficiency ($\rho = 0.60$, $p = 0.004$; Table 4). For the group of cloth masks, the correlations were not as strong; the cough aerosol collection efficiency and filtration efficiency had an ρ of 0.51 ($p = 0.032$) while the exhaled aerosol collection efficiency and filtration efficiency had an ρ of 0.54 ($p = 0.023$; Table 4). The airflow resistance did not correlate as well as the filtration efficiency when all devices were considered ($\rho = 0.55$ and $p = 0.009$ for coughing; $\rho = 0.51$ and $p = 0.016$ for exhalation). However, when examining the cloth masks alone, the airflow resistance was slightly better correlated than filtration efficiency ($\rho = 0.54$ and $p = 0.020$ for coughing; $\rho = 0.58$ and $p = 0.012$ for exhalation).

Human fit tests

The fit factors measured on the human test subjects are shown in Table 3 and Figure 5. The mean fit factors for the two N95 respirators were 148 and 164

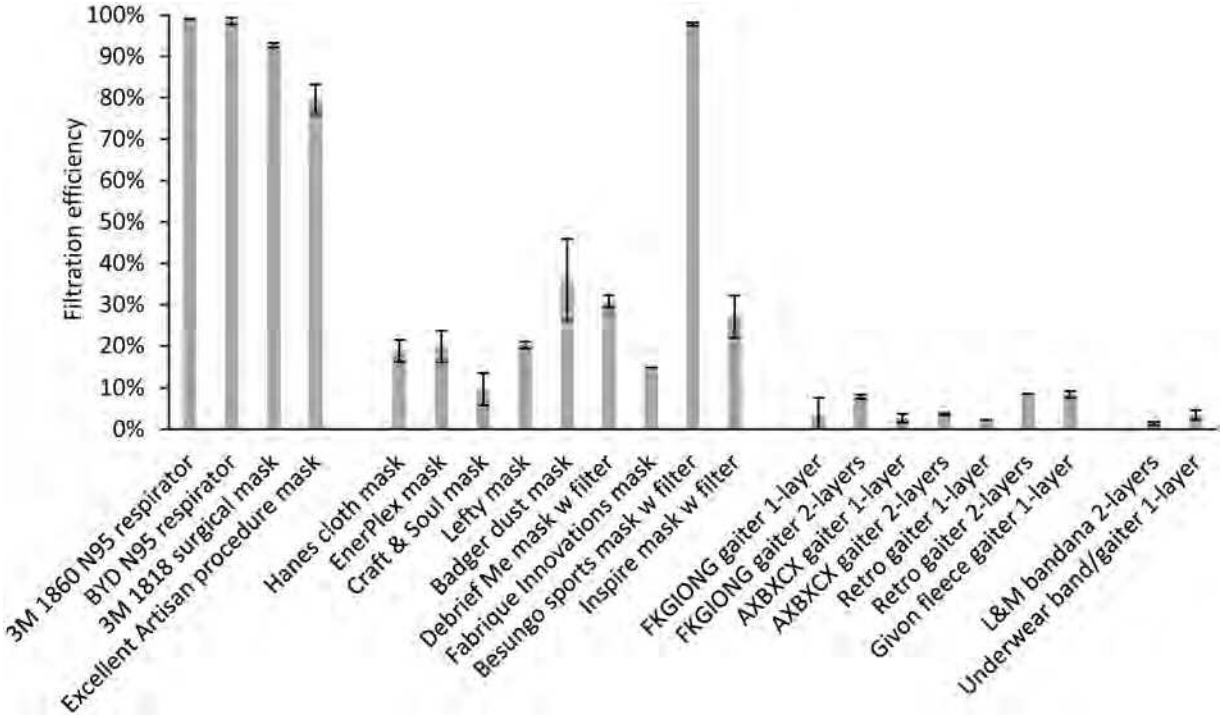

Figure 4. Filtration efficiencies for the source control devices used in the study. Three samples of each device were tested, except for the 3 M 1860 N95 respirator and Hanes cloth mask (10 samples each) and the Fabrique Innovations mask, Retro gaiter 1-layer, and Retro gaiter 2-layers (one sample each). Error bars show the standard deviation.

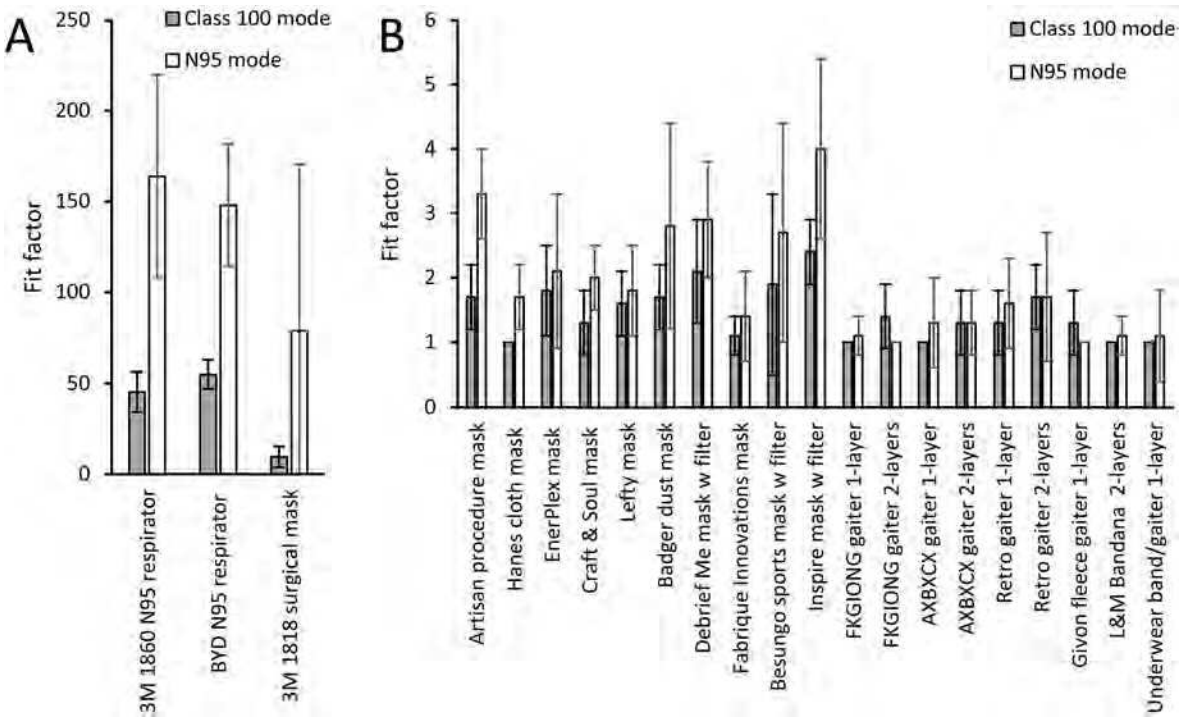

Figure 5. Fit factors measured with human subjects for (a) N95 respirators and surgical mask and (b) procedure mask, cloth face masks, gaiters and bandanas. The plot shows the means and standard deviations. Results for all human fit tests are given in Table S3 in the SI.

when using the N95 mode on the fit tester and 55 and 45 with the Class 100 mode. The surgical mask provided a mean N95 mode fit factor of 79 and a much lower mean fit factor of 9.6 in Class 100 mode. The mean N95 mode fit factor of the reusable cloth face masks ranged from 1.4 to 4.0, and the all sizes

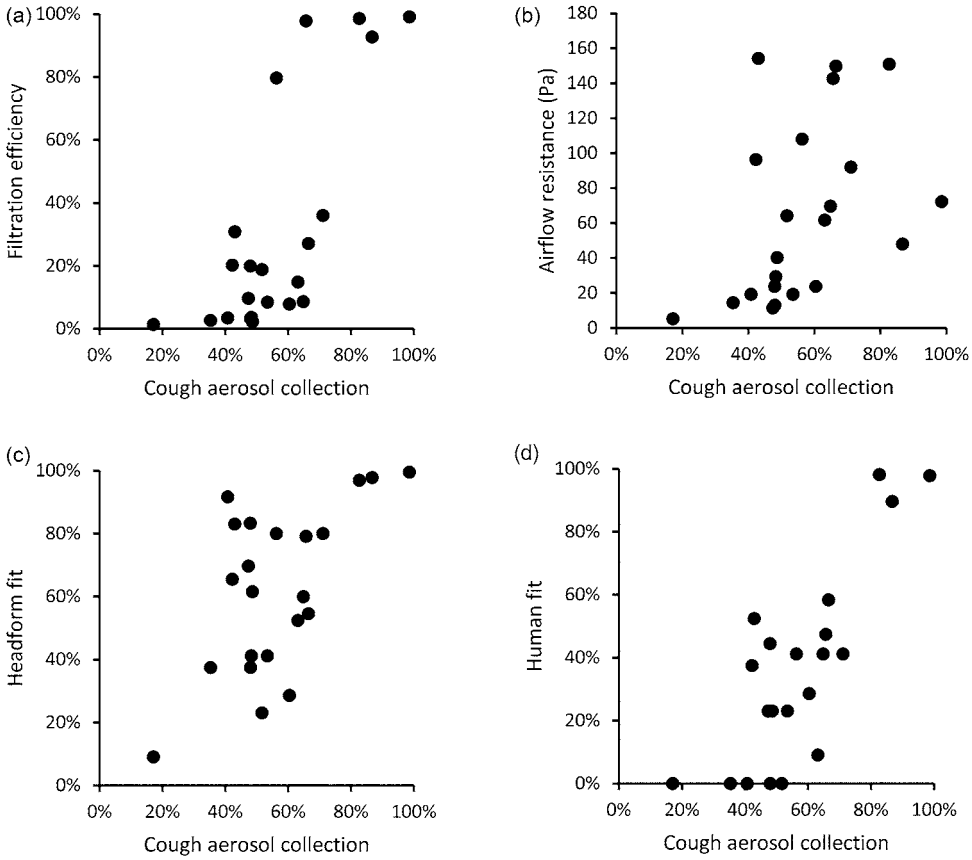

Figure 6. Comparison of collection efficiencies for aerosols from coughs to (a) filtration efficiency of construction material; (b) airflow resistance; (c) fit on manikin headform (using N95 mode); and (d) fit on human test subjects (using Class 100 mode). Each dot corresponds to the mean result for one type of source control device.

mode mean fit factors ranged from 1.0 to 2.4. Neck gaiters and bandanas demonstrated N95 mode fit factors ranging from 1.0 to 1.7 and all particle size mode mean fit factors from 1.0 to 1.7. The performance of cloth masks sometimes varied considerably when worn by different subjects. The fit test results for individual subjects are shown in Table S3 in the SI.

The cough and exhalation aerosol collection efficiencies for all devices were well correlated with the fit factors when measured using the Class 100 mode ($\rho = 0.68$ and $p < 0.001$ for coughing, $\rho = 0.71$ and $p < 0.001$ for exhalation, Table 4). When looking at the results for the cloth masks, gaiters, and bandanas in the all sizes mode, the correlations were not as strong, with $\rho = 0.48$ for coughing ($p = 0.035$), and $\rho = 0.63$ for exhalation ($p = 0.003$; Table 4). In all cases, the correlation coefficients were higher when the fit tester was in the Class 100 mode than when the tester was in N95 mode.

Manikin fit tests

The manikin fit factor measurements found using the source control measurement system before the cough tests were 25 to 198 for the N95 respirators and the surgical mask and 1.3 to 7.4 for the procedure mask and cloth masks (Table 3). Before the breathing tests, the manikin fit factors were 28 to 133 for the N95 respirators and the surgical mask and 1.4 to 6.1 for the procedure mask and cloth masks. The cough aerosol collection efficiencies and the pre-cough manikin fit factors were not significantly correlated, with a ρ of 0.39 ($p = 0.076$) for all devices (Table 4 and Figure 6) and a ρ of only 0.03 ($p = 0.890$) for the cloth masks (Table 4). The correlation was better between the exhaled aerosol collection efficiency and pre-breathing manikin fit factors, with a ρ of 0.72 ($p < 0.001$) for all devices (Table 4 and Figure 7) and 0.68 ($p = 0.002$) for the cloth masks (Table 4).

Discussion

The COVID-19 pandemic has resulted in considerable interest in the performance characteristics of masks and respirators as a means of reducing the person-to-person transmission of SARS-CoV-2. Some studies have looked at the emission of particles from human volunteers wearing different face coverings, which has

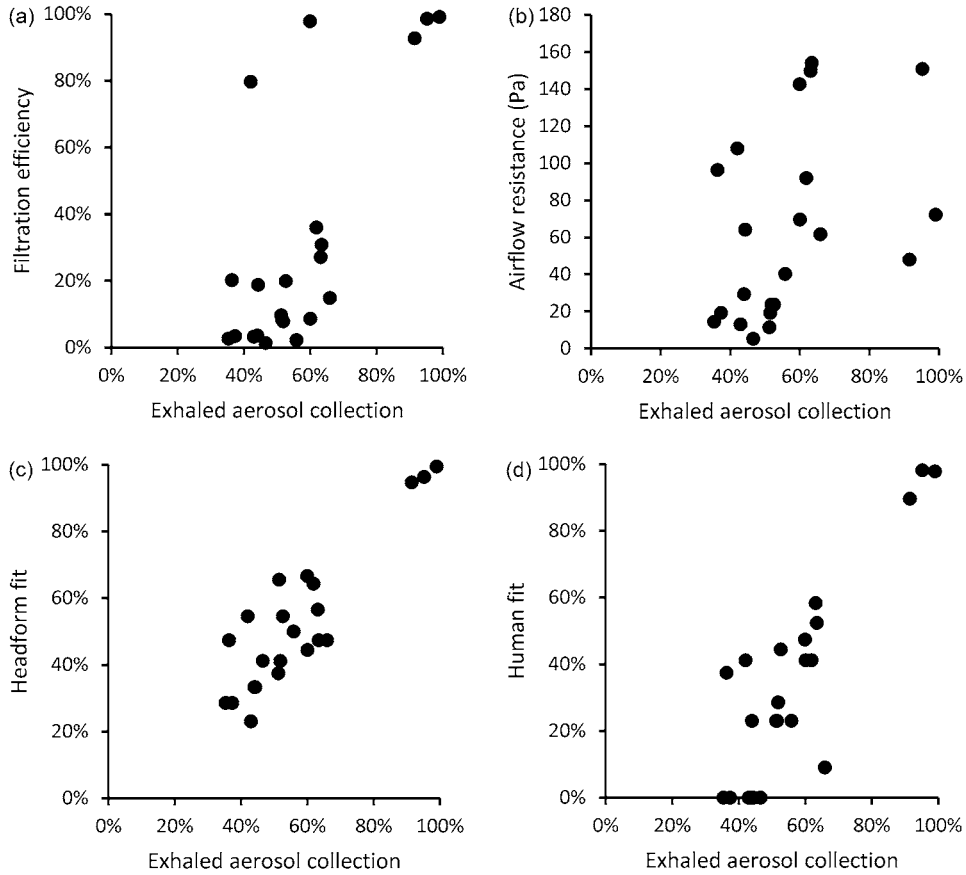

Figure 7. Comparison of collection efficiencies for exhaled aerosols from simulated breathing to (a) filtration efficiency of construction material; (b) airflow resistance; (c) fit on manikin headform (using N95 mode); and (d) fit on human test subjects (using Class 100 mode). Each dot shows the mean result for one type of source control device.

the advantage of directly examining the expulsion of aerosols into the environment by people (Asadi et al. 2020; Davies et al. 2013; Leung et al. 2020; Li, Niu, and Zhu 2021). However, the collection and measurement of human-generated respiratory aerosols is challenging and can be hazardous when the subject has a contagious respiratory infection. In addition, the amount and size distribution of aerosol particles produced by people during coughing, breathing and other respiratory activities varies tremendously from person to person and even for a particular person over time, which makes it difficult to compare results (Asadi et al. 2019; Fennelly 2020; Gralton et al. 2011; Lindsley et al. 2012). Consequently, lab-based surrogate techniques are more frequently used to study source control devices. The most commonly reported methods have been tests of filtration efficiencies and fit factors (Clapp et al. 2021; Guha et al. 2021; Konda et al. 2020; Wang et al. 2020; Zhao et al. 2020). Other studies have used manikins in a chamber or room to assess the efficacy of medical masks and cloth masks both as source control devices and as personal protective equipment (Pan et al. 2021; Patel et al. 2016; Rothamer et al. 2021). Experimental data have also been used to develop computational fluid dynamics models of medical and cloth masks performance (Dbouk and Drikakis 2020; Mittal, Ni, and Seo 2020). These studies have provided valuable information about the properties of masks and respirators. However, it is unclear how the various metrics used in these studies are related to source control performance.

The source control measurement system used in this study allows for a direct quantitative comparison of the ability of different types of source control devices to block the expulsion of simulated cough and exhaled breath aerosol particles into the environment (Lindsley et al. 2021). However, the system is complex and requires expertise to operate, and it is neither commercially sold nor easily constructed. In contrast, filtration measurement systems and respirator fit testers are widely available. If a methodology could be developed to gauge source control performance using existing commercially available equipment, it could be rapidly expanded and adopted by manufacturers and public health entities.

The filtration efficiency of a mask or respirator is a measurement of the ability of the mask material to remove aerosol particles from an airstream traveling through the fabric. Filtration efficiency tests typically use aerosol particles at or near the most-penetrating aerosol particle size, which is around 300 nm for an uncharged filter at low air velocities but shifts to smaller sizes at higher velocities and when the filter and particles are electrostatically charged (Martin and Moyer 2000; Rengasamy, BerryAnn, and Szalajda 2013; Rengasamy et al. 2017). The mechanisms by which filters collect aerosol particles are strongly dependent upon the size of the particles; for example, large particles are more likely to be collected by impaction or interception while small particles are more likely to be collected by diffusion (Lindsley 2016). Although the SARS-CoV-2 virus is about 100 nm in diameter, contagious humans do not shed bare viral particles. Instead, they expel aerosols and droplets of respiratory fluids that contain respiratory virus, and the size of these virus-laden aerosols and droplets can range from hundreds of nanometers to visible droplets of 1 mm or more (Fennelly 2020; Gralton et al. 2011). Thus, the collection efficiencies for 100-300 nm particles may not predict the performance for larger particles (Drewnick et al. 2021). In our experiments, the coughing and exhalation source control collection efficiencies increased as the particle size increased (Tables S1 and S2 in the SI) and in most cases were higher than the filtration efficiencies, likely because our coughing and exhalation test aerosols were much larger than the 75 nm aerosol used for filtration tests.

The fit factor is normally used to determine how well a respiratory protective device fits the wearer by measuring the degree to which aerosol particles can enter through gaps between the wearer's face and the respirator (face seal leaks). It is determined by placing the device on a person or on a manikin headform and measuring the ratio of the aerosol concentration outside the respirator to the aerosol concentration inside the respirator (Janssen and McKay 2017). For example, a fit factor of 10 means that the ambient aerosol concentration is 10 times higher than the concentration inside the respirator. Fit factor measurements are not intended to test the filtration efficiency of the device itself. In fact, the calculation of the fit factor for a respirator assumes that any ambient aerosol particles passing through respirator material are filtered out and that any particles detected inside the respirator are due to face seal leaks, not penetration of particles through the filter material (Halvorsen 1998). For example, a fit factor of 10 is interpreted as indicating that 90% of the air inside the respirator has passed through the respirator filtration media (with aerosol particles being completely removed) and that 10% of the air bypassed the media and entered through face seal leaks.

For high efficiency filters such as P100 respirator filters, which filter out 99.97% of airborne particles, a respirator fit test is performed by measuring the concentrations of aerosol particles of all sizes inside and outside the respirator (referred to here as Class 100 mode). However, N95 respirators can allow up to 5% of aerosol particles of the most penetrating size to pass through the filtration media. These particles would reduce the apparent fit factor if they were included in the calculation. Thus, when fit testing N95 respirators, the respirator fit tester used in our experiments has a size classifier to count only negatively charged aerosol particles near 55 nm in size (referred to here as N95 mode). For an N95 respirator, these charged 55 nm particles are almost entirely filtered out by the filtration media, and thus any particles detected inside the respirator can then be assumed to have entered through face seal leaks and not through the respirator (Halvorsen 1998; Han and Prell 2010).

It is important to note, however, that this assumption is not correct when using the fit tester with cloth masks. As can be seen in Table 3, the filtration efficiencies of most cloth masks are much lower than those of respirators, and ambient particles therefore can penetrate more easily through the cloth material. Thus, the fit factor for a cloth mask is not a true measurement of face seal leakage alone; instead, it represents a combination of face seal leakage and particle penetration through the mask material.

Our findings suggest that the results from filtration efficiency, airflow resistance and fit factor tests are correlated with measurements made using our source control measurement system. For the cloth masks, all but two of the standard performance metrics were significantly correlated with the cough and exhaled aerosol collection efficiencies, which suggests that these other measures could be useful as part of a method for testing the performance of cloth masks. However, none of the standard metrics were strong predictors of source control performance, and no metric was clearly superior to the others.

The limited correlations between the different test methods in our study likely have several explanations. First, filtration efficiency and airflow resistance measurements do not account for how well the devices fit the wearer or for face seal leaks around the edges of

the device. Thus, for example, the Artisan procedure mask had an 80% filtration efficiency but a 56% collection efficiency for cough aerosols and a 42% collection efficiency for exhaled aerosols. The most likely explanation is that this mask's material is an efficient filter but that aerosol particles were able to travel around the mask through face seal leaks because the Artisan mask fits loosely on the headform. On the other hand, the Hanes Defender cloth mask had only a 19% filtration efficiency but had similar aerosol collection efficiencies of 52% for coughs and 44% for exhalations. In this case, the cloth mask was not an effective filter for the 75 nm aerosol used in filtration testing, but the Hanes mask fit the manikin headform more tightly. Thus, much of the aerosol then flowed through the mask rather than around it during coughing and breathing tests and the larger aerosol particles that were used in the coughing and breathing tests were filtered out more effectively than the 75 nm particles used in filtration testing. The results presented here are consistent with a previous study by our group in which knotting the Artisan procedure mask to improve the fit increased the cough aerosol collection efficiency to 77%, while wearing a Hanes Defender cloth mask on top of an Artisan procedure mask increased the cough collection efficiency to 85% (Brooks et al. 2021). Together, these results also support the recommendation by Gandhi and Marr that members of the public wear a high-quality mask that fits tightly or wear a tight-fitting cloth mask over a surgical mask in order to reduce face seal leaks and improve the source control performance and protection offered by the masks (Gandhi and Marr 2021).

Fit tests are designed to measure the effects of face seal leaks but have their own limitations when applied to cloth masks. As noted above, fit factor measurements for cloth masks reflect some combination of particle penetration through the media and face seal leakage which will likely vary from mask to mask. Thus, it is neither clear how to interpret fit factor measurements for cloth masks nor is it clear how this relates to the effectiveness of the mask as a source control device. In addition, fit test results can vary greatly from person to person and even somewhat for the same person during repeated tests (Lawrence et al. 2006). Similarly, a comparison of fit tests between humans and a pliable skin manikin headform found significant differences (Bergman et al. 2015). Much of this discrepancy is likely due to facial variations and differences in how the mask is placed on the person or manikin headform. It is possible to shift, stretch, tighten, loosen, or adjust the masks in many ways,

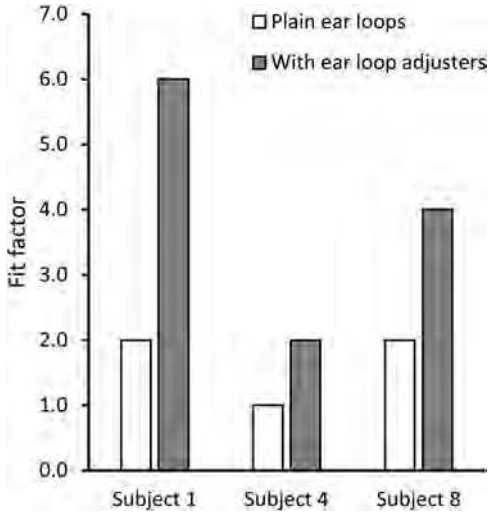

Figure 8. Effect on mask fit factor of adding ear loop adjusters to tighten the mask fit. Subjects were wearing the Excellent Artisan procedure mask. Tests were conducted with the fit tester in Class 100 mode. Each bar is the mean of three trials. All standard deviations were zero.

and small differences in how the mask is worn may have substantial effects on the fit test results. For example, in tests with three subjects using the Artisan procedure mask, we found that tightening the mask against the face by using silicone ear loop adjusters increased the mean fit factor from 1.7 to 4.0 (Figure 8). In experiments with cloth masks, the ρ value for the manikin headform fit tests done before coughing experiments compared with tests done before exhalation experiments was only 0.38, suggesting that differences were occurring even when the same model of mask was being placed on the same headform.

Finally, our study has several limitations. The source control measurement system produced a test aerosol with particles $\leq$7 µm in diameter, which is the size range of aerosol particles most likely to remain airborne and most difficult to block with source control devices. However, humans expel aerosol particles in a much broader range of sizes, particularly when coughing. We used a single cough flowrate profile and a single breathing ventilation rate for our studies; these parameters can vary greatly from person to person under different physiological conditions. Some internal losses of the test aerosol particles likely occurred due to settling or impaction on the surfaces of the collection chamber, which may affect the estimates of the collection efficiencies. We used representative examples of different types of source control devices, but many such devices are available with a wide range of shapes and compositions, which would be expected to affect their individual performance. As shown in Table 1, the instrumentation used for the

different performance metrics are based on different operating principles and thus caution should be used when comparing results; for example, the collection efficiency results from the impactors are based on aerosol mass, while the fit factor results from the PortaCount are based on particle counts. Lastly, because of the need to rapidly produce results in response to the COVID-19 pandemic, we only tested 2-3 samples of each source control device (each sample was used in two consecutive tests). By comparison, for example, the NIOSH procedure for evaluating N95 respirators calls for 20 samples to be tested (NIOSH 2019).

Current evidence indicates that masks like those tested in our experiments can substantially decrease the amount of respiratory aerosols released by the wearer, and also help reduce what the wearer breathes in (CDC 2020a). Both effects vary depending upon the material and construction of the mask, as well as how it is worn. In addition to consistent and correct mask use when in the company of others, other measures such as physical separation are important, particularly during brief exposures. In a room where someone sneezes, being six feet or further away is better than being closer. However, with prolonged exposure in the same space for more than a few minutes, the benefit of distance fades as exhaled respiratory aerosols drift, mix, and accumulate in the enclosed air space. Optimizing ventilation, air filtration, and the introduction of fresh air can help counter this effect, but at every distance, correct mask use reduces the risk for everyone.

Conclusions

The ongoing COVID-19 pandemic has created an urgent need for simple methods to evaluate cloth masks as respiratory aerosol source control devices and to produce meaningful performance metrics that can be used to determine the effectiveness of different materials and designs. Our results suggest that test methods such as filtration efficiency testing, airflow resistance testing, and fit factor measurements on manikin headforms or human subjects have potential as ways to estimate the performance of masks as source control devices for respiratory aerosols. However, more research and improvements in the test methodologies are needed before such methods can be reliably implemented. Until the factors controlling the performance of source control devices are better understood and better testing methodologies are developed, results from test methods such as filtration efficiency testing, airflow resistance testing, and fit factor measurements should be interpreted cautiously when used to evaluate source control devices for respiratory aerosols.

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Declaration of interests statement

The authors declare no competing interests.

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Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols

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Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols

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ABSTRACT

Face masks are recommended to reduce community transmission of SARS-CoV-2. One of the primary benefits of face masks and other coverings is as source control devices to reduce the expulsion of respiratory aerosols during coughing, breathing, and speaking. Face shields and neck gaiters have been proposed as an alternative to face masks, but information about face shields and neck gaiters as source control devices is limited. We used a cough aerosol simulator with a pliable skin headform to propel small aerosol particles (0 to 7 μm) into different face coverings. An N95 respirator blocked 99% (standard deviation (SD) 0.3%) of the cough aerosol, a medical grade procedure mask blocked 59% (SD 6.9%), a 3-ply cotton cloth face mask blocked 51% (SD 7.7%), and a polyester neck gaiter blocked 47% (SD 7.5%) as a single layer and 60% (SD 7.2%) when folded into a double layer. In contrast, the face shield blocked 2% (SD 15.3%) of the cough aerosol. Our results suggest that face masks and neck gaiters are preferable to face shields as source control devices for cough aerosols.

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Yannis Drossinos

Introduction

SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), can be transmitted from person-to-person by large respiratory aerosols (airborne liquid droplets and dried particles greater than about 10 μm in diameter) produced by people who are infectious while they are talking, singing, coughing, breathing or sneezing (CDC 2020a; Hamner et al. 2020). Smaller aerosols also are emitted by people during these activities, suggesting that short-range airborne transmission of SARS-CoV-2 might be possible under some circumstances (Anderson et al. 2020; CDC 2020a; Fennelly 2020; Ma et al. 2020; Morawska and Milton 2020).

To interrupt this potential transmission route, the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and other public health organizations recommend the wearing of face masks or other face coverings by the general public during the ongoing COVID-19 pandemic (CDC 2020b, 2020c; Edelstein and Ramakrishnan 2020; WHO 2020). One of the primary benefits of face coverings is to act as source control devices to reduce the expulsion of aerosols containing the virus from people who are infectious during coughing, breathing, and speaking. Source control devices are intended to protect other people from infectious aerosols emitted by the wearer, as compared with personal protective equipment such as N95 respirators which are primarily intended to protect the wearer. A face covering can provide source control in two ways (Diaz and Smaldone 2010). First, and most importantly, the covering may collect aerosol particles by filtration, impaction, or other mechanisms, and thus prevent infectious aerosols from entering the environment. Second, the face covering may change the direction of travel and the velocity of the aerosol stream and thus possibly divert the aerosol away from a potential recipient. However, deflection is more uncertain as a source control mechanism. For example, if large aerosols are deflected downward, they may settle to the floor or otherwise be unable to reach the breathing zones of other people. However, since exhaled breath is often warmer than the surrounding air, this

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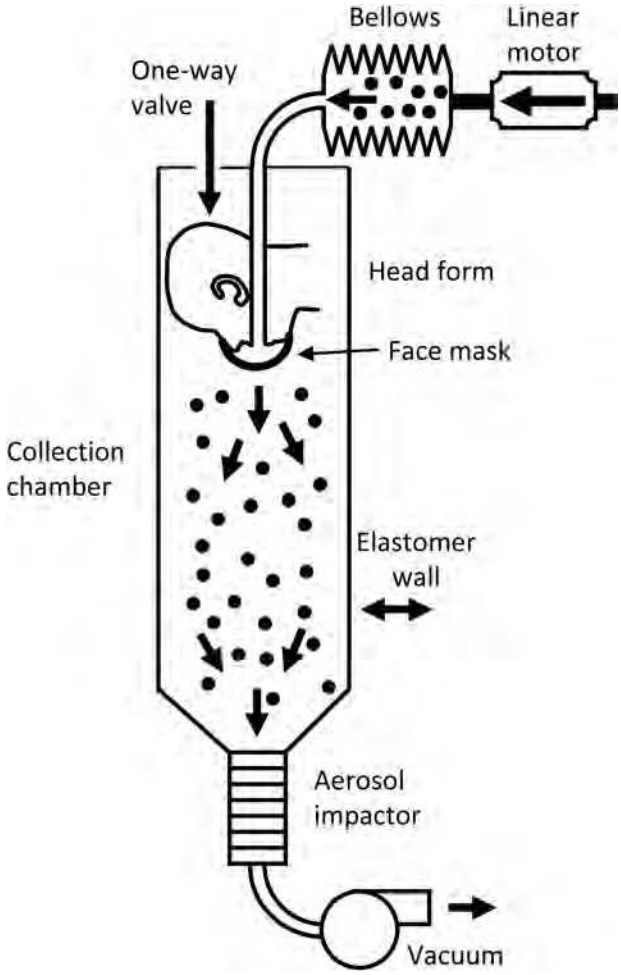

Figure 1. Cough aerosol simulator system for source control measurements. The system consists of an aerosol generation system, a bellows and linear motor to produce the simulated cough, a pliable skin head form on which the face mask, neck gaiter or face shield is placed, a 105 liter collection chamber into which the aerosol is coughed, and an Andersen impactor to separate the aerosol particles by size and collect them. More information about the cough aerosol simulator is provided in the SI.

downward deflection may be counteracted by the buoyancy of the breath for smaller aerosols. In addition, if the respiratory aerosols are deflected sideways, they may be diverted away from a person directly in front of the wearer but toward someone to the side or behind the wearer.

Studies using manikins (Lai, Poon, and Cheung 2012; Patel et al. 2016) and patients with respiratory infections (Leung et al. 2020; Milton et al. 2013) have shown that wearing medical face masks can reduce the dispersion of potentially infectious aerosols from patients. Two studies in which face masks were required for visitors and healthcare workers interacting with patients in bone marrow transplant centers found a reduction in respiratory viral infections among patients (Sokol et al. 2016; Sung et al. 2016). Studies of cloth face masks have suggested that they also can be effective at reducing the release of respiratory aerosols into the environment (Asadi et al. 2020; Davies et al. 2013; Konda et al. 2020). Several computational fluid dynamics studies have examined the generation and expulsion of respiratory aerosols and have provided important insights into the ability of face coverings to reduce the dispersion of large and small aerosols from the wearer (Dbouk and Drikakis 2020; Mittal, Ni, and Seo 2020).

Unfortunately, the use of face masks and other face coverings by the general public can present challenges. People often dislike wearing masks, and compliance can be low and inconsistent (Longtin et al. 2009). Mask wearers may repeatedly don, doff and adjust face masks, which can contaminate the hands and potentially lead to disease transmission, especially when the masks are reused (Brady et al. 2017; Casanova et al. 2008). For cloth masks, the filtration efficiency and air flow resistance of different textiles varies widely (Konda et al. 2020; Teesing et al. 2020; Wilson et al. 2020). Alternative face coverings such as neck gaiters (an elastic fabric tube that fits snugly around the head and neck) are commonly used, but information about their performance as source control devices is limited. Factors such as how well the mask fits the face and the coverage provided by a mask can have a substantial impact on the effectiveness of face masks (Davies et al. 2013; Lawrence et al. 2006). Comparisons of face coverings have found substantial differences in the ability of different types of these devices to reduce the release of respiratory aerosols (Asadi et al. 2020; Davies et al. 2013).

An opinion article in JAMA proposed that face shields would be more effective than face masks at reducing community disease transmission, in large part because the authors felt that face shields were more comfortable and thus that they were more likely to be widely adopted by the public (Perencevich, Diekema, and Edmond 2020). A previous study by our group of face shields used as personal protective devices showed that face shields protect the wearer from large cough aerosols directed at the face but are much less effective against smaller aerosols which were able to flow around the edges of the shield and be inhaled (Lindsley et al. 2014). However, very little work has been done examining face shields as source control devices. Two qualitative flow visualization studies of face shields and masks found that, although face shields deflected the air flow from the mouth, they did not stop aerosol particles from traveling around the face shield and entering the environment

(Verma, Dhanak, and Frankenfield 2020; Viola et al. 2020). Beyond these studies, quantitative data on the efficacy of face shields for source control are lacking.

The objective of our study was to conduct a quantitative comparison of the efficacy of an N95 respirator, a medical procedure mask, a commercial 3-ply cloth face mask, a single and double layer fabric neck gaiter, and a commercial disposable face shield as source control devices to reduce the expulsion of small cough-generated aerosol particles into the environment. Our results provide more information about the effectiveness of different types of source control devices and will help the public health community make recommendations about the best ways to use these devices to help reduce the spread of COVID-19.

Materials and methods

Experimental design

In our experiments, a cough aerosol simulator propelled a test aerosol through a headform into a collection chamber (Figure 1), and the amount of aerosol in the collection chamber was measured in each of six size fractions. The collection efficiency of each face mask, neck gaiter, or face shield was determined by comparing the amount of aerosol that was collected from the chamber with and without the device. Our test method was similar to the modified Greene and Vesley method used to test medical masks (Quesnel 1975), with the human test subject replaced by the cough aerosol simulator.

Cough aerosol simulator

The cough aerosol simulator is a modified version of the NIOSH cough aerosol simulator described previously (Lindsley et al. 2019; Lindsley et al. 2014; Lindsley et al. 2013). The experimental cough aerosol was generated by nebulizing a solution of 14% KCl and 0.4% sodium fluorescein using a single-jet Collison nebulizer (BGI, Butler, NJ, USA) at 103 kPa (15 lbs./in^2), passing the aerosol through a diffusion drier (Model 3062, TSI, Shoreview, MN, USA), and mixing it with 10 L/min of dry filtered air. The test aerosol was loaded into an elastomeric bellows, and the cough airflow was produced by a computer-controlled linear motor that compresses the bellows. The cough aerosol was expelled through the mouth of a headform into a collection chamber. The headform used in the study has pliable skin that mimics the elastic properties of human skin in order to create a realistic simulation of how each face covering or shield would fit a human face (Bergman et al. 2014).

Source control devices

The source control devices tested were an N95 medical respirator (3 M model 1860), a medical grade (ASTM Level 3) procedure mask with ear loops (Kimberly Clark model 47107), a cloth face mask with 3 layers of cotton fabric and ear loops (Hanes Defender), a fabric neck gaiter (FKGIONG Sun UV Protection Neck Gaiter, 95% polyester, 5% Spandex) and a disposable face shield (Fisher Scientific # 19-181-600 A). The neck gaiter was tested both as a single layer of fabric and doubled over to provide two layers of fabric. The masks and respirator were not equipped with exhalation valves. The face shield was 25 cm tall and extended from the forehead of the headform to 3 cm below the chin and around the side to 3 cm before the front of the ear. Photographs of the source control devices on the headform are shown in the online supplementary information (SI).

Mask fit test

For the experiments, either no device, a face mask, a neck gaiter, or a face shield were placed on the head form. Each device was used for two consecutive tests. For face masks and gaiters, a respirator fit test was performed using a PortaCount (TSI). The fit factor is a measure of the protection against airborne particles that is provided by a respiratory protective device. It is defined as the ratio of the aerosol concentration outside the respiratory protective device to the aerosol concentration inside the device (i.e., the aerosol concentration that is inhaled by the wearer). For example, a fit factor of 10 means that the ambient aerosol concentration is 10 times higher than the concentration inside the mask, and that the mask is therefore filtering out 90% of the ambient aerosol.

Aerosol collection and analysis

After placing the device on the headform and performing the fit test, the system was sealed. The test aerosol was then generated and propelled with a simulated cough through the headform and into the collection chamber. The Andersen impactor at the bottom of the collection chamber collected the aerosol particles that traveled through or around the device for 20 min after each cough. The Andersen impactor operates at a flow rate of 28.3 liters/minute and has six collection stages and a filter that separate the aerosol particles into seven size fractions based on the aerodynamic diameter of the particles: <0.6 µm; 0.6–1.1 µm; 1.1–2.1 µm; 2.1–3.3 µm; 3.3–4.7 µm;

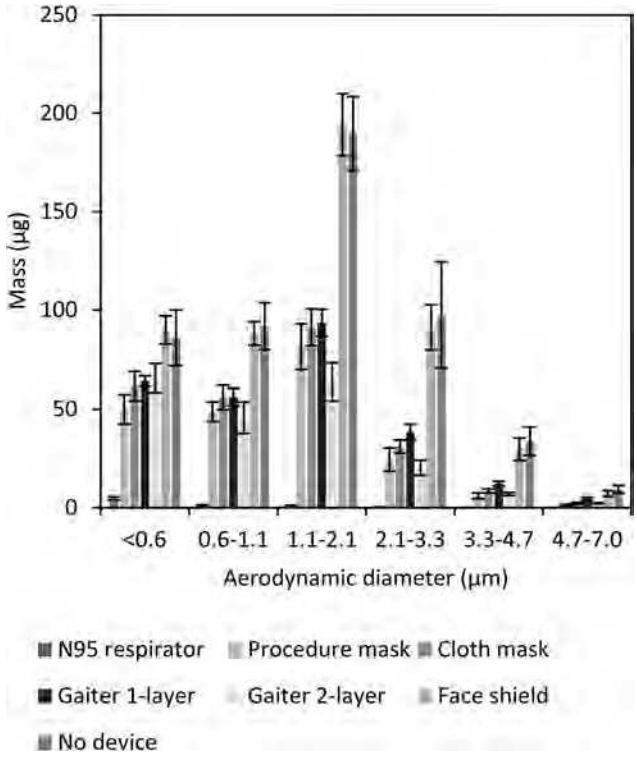

Figure 2. Mass of aerosol collected in each size fraction. The graph shows the amount of simulated respiratory aerosol that was collected from the collection chamber in each aerosol particle size fraction after a single simulated cough. The bars show the mean and standard deviation. A larger color version of this figure is shown in the SI.

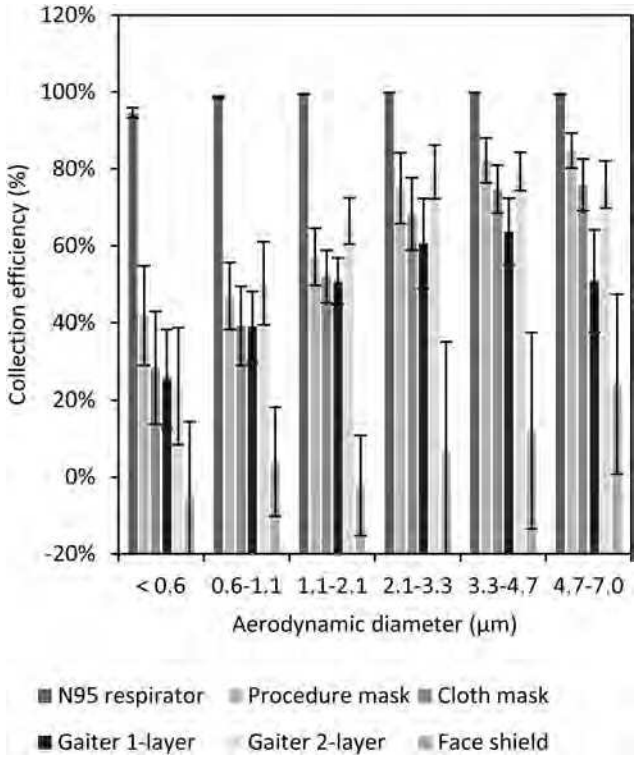

Figure 3. Collection efficiency of face masks, neck gaiter and face shield. The collection efficiency is the percentage of aerosol particles that were blocked by the face mask, neck gaiter or face shield compared with experiments without a device. The plot shows the means and standard deviations of the collection efficiency in each size fraction. A larger version of this figure is shown in color in the SI.

4.7–7.0 µm; and >7 µm. Because the amount of aerosol in the largest size fraction was small and because of possible losses due to settling of the large aerosol particles, data for the largest size fraction was not included in the analysis. The impactor collection plates were coated with a solution of glycerol and Brij 35 to prevent particles from bouncing off the plates during collection (Mitchell 2003). After aerosol collection was completed, the impactor plates were rinsed with 0.1 M Tris solution and the fluorescence of the solution was measured using a fluorometer (SpectraMax M4, Molecular Devices). The complete experimental protocol is given in the SI.

Statistical analysis

The performance of each device was evaluated by comparing the total mass of the aerosol particles from a single cough that passed through or around the device and was collected by the Andersen impactor. The results were evaluated using a one-way ANOVA and multiple comparisons among the different devices and the control experiments without a device were conducted using a Tukey-Kramer test. To control for variations in the amount of aerosol in each cough, a sample of each cough aerosol was collected from the bellows prior to coughing and used to normalize the aerosol mass collection results for each experiment.

Results

The cough aerosol simulator provides a cough with a controlled cough airflow rate containing a test aerosol with a consistent aerosol size distribution. The simulator allows for a direct quantitative comparison of the ability of different types of source control devices to block the expulsion of simulated cough aerosol particles of different sizes into the environment. The flow rate of the simulated cough used in our experiments was based on cough flow profiles recorded from influenza patients and had a volume of 4.2 L with a peak flow rate of 11 L/s (Lindsley et al. 2013). The cough aerosol collected from the control experiments without a face covering had a mass median aerodynamic diameter of 1.3 µm, a geometric standard deviation of 2.3 and a total aerosol mass of 505 µg (standard deviation 69).

For our study, we tested the collection efficiencies (that is, the fraction of the cough aerosol that was

Table 1. Total mass of aerosol expelled into collection chamber and device collection efficiencies.

Device tested	Number of experiments	Fit factor	Aerosol mass (μg)	Collection efficiency
No device	12	n/a	512 (64)	n/a
Procedure mask	6	2.9 (0.5)	212 (23)	58.5% (6.9%)
Cloth mask	6	1.3 (0.1)	251 (23)	50.9% (7.7%)
Neck gaiter (single layer)	6	1.7 (0.5)	270 (18)	47.2% (7.5%)
Neck gaiter (double layer)	6	1.9 (0.4)	206 (26)	59.8% (7.2%)
Face shield	6	n/a	502 (46)	1.8% (15.3%)
N95 respirator	6	198 (3.5)	7.2 (1.2)	98.6% (0.3%)

Note: The fit factor, aerosol mass, and collection efficiency are given as mean (standard deviation).

blocked) of a medical grade procedure mask, a cotton cloth face mask, a polyester neck gaiter, an N95 medical respirator and a disposable face shield. These source control devices were chosen to provide representative samples of the different types of face coverings and face shields that are in common use during the pandemic. Neck gaiters are typically worn either as a single layer of fabric over the mouth and nose or doubled over to provide two layers of fabric; for our experiments, we tested both configurations. The quantity of aerosol particles in six size fractions that were able to travel through or around each source control device are shown in Figure 2. The collection efficiencies of the devices are shown as a function of aerosol size in Figure 3. All the devices showed increased collection efficiencies as the aerosol size increased.

On average, the N95 respirator blocked 99% of the total mass of test aerosol from being released into the environment, while the medical procedure mask blocked 59%, the cloth face mask blocked 51%, the single-layer gaiter blocked 47%, the double-layer gaiter blocked 60%, and the face shield blocked 2% of the total aerosol (Table 1). The N95 respirator, procedure mask, cloth mask, and the single-layer and double-layer gaiters all significantly reduced the aerosol emitted into the environment compared with no device ($P < 0.0001$ for each), but the face shield did not ($P = 0.9993$). The collection efficiencies of the procedure mask, cloth mask, and the single and double-layer gaiters did not differ significantly from each other, but all blocked cough aerosols significantly better than did the face shield ($P < 0.0001$). The N95 respirator outperformed all the other devices ($P < 0.0001$) (Table 2).

Discussion

Humans continuously emit aerosols of respiratory fluids as they breathe, talk, cough, sneeze, sing, or carry out other respiratory activities. These respiratory aerosols can have a very broad size range, from tens of nanometers in diameter to visible droplets of a millimeter or more (Bourouiba, Dehandschoewercker, and Bush 2014; Fennelly 2020; Gralton et al. 2011; Morawska et al. 2009). Airborne particles larger than 100 μm are ballistic; that is, they are affected primarily by gravity and fall quickly to the ground. Respiratory aerosol particles in this size range tend to deposit within a few meters of the source (Prather et al. 2020). As the aerosol particle diameter decreases from 100 μm, a gradual transition occurs where the settling velocity rapidly decreases and the particles remain airborne for longer times. For example, a 100 μm aerosol particle takes 4 s to fall 1 m in still air, while a 10 μm aerosol particle takes 5.4 min and a 1 μm aerosol particle takes 8 h to settle the same distance (Hinds 1999). Air currents such as plumes of warm air rising from the body can lift these particles and extend the time for which they stay in the air. Thus, small aerosol particles can remain airborne for minutes to hours and can accumulate over time in environments with poor ventilation (Bahl et al. 2020). Small aerosol particles also are easier to inhale and can travel more deeply into the lungs (Vincent 2005).

The amount and sizes of aerosol particles containing SARS-CoV-2 that are expelled by people who are infected are not yet known. Two studies of aerosol samples collected in patient rooms found infectious (replication-competent) SARS-CoV-2 in aerosol particles <4 μm in diameter (Santarpia et al. 2020a) and <10 μm in diameter (Lednicky et al. 2020). Other studies have reported SARS-CoV-2 RNA in exhaled breath from infected patients (Ma et al. 2020), aerosol samples from biocontainment and quarantine units housing SARS-CoV-2 infected persons (Santarpia et al. 2020b), and in aerosol samples at multiple locations throughout two hospitals in Wuhan, China during a COVID-19 outbreak (Liu et al. 2020). The presence of small aerosol particles containing

Table 2. Comparison of aerosol mass expelled into the collection chamber while wearing face masks, neck gaiters and face shields.

PPE types compared		95% confidence intervals for mean differences (μg)			P-value
		Lower limit	Mean difference	Upper limit	
N95 respirator	No device	−567	−504	−442	<0.0001
Procedure mask	No device	−361	−299	−237	<0.0001
Cloth mask	No device	−322	−260	−198	<0.0001
Gaiter (single layer)	No device	−304	−241	−179	<0.0001
Gaiter (double layer)	No device	−368	−306	−243	<0.0001
Face shield	No device	−71	−9	53	0.9993
N95 respirator	Face shield	−567	−495	−423	<0.0001
Procedure mask	Face shield	−362	−290	−218	<0.0001
Cloth mask	Face shield	−323	−251	−179	<0.0001
Gaiter (single layer)	Face shield	−304	−232	−160	<0.0001
Gaiter (double layer)	Face shield	−369	−297	−225	<0.0001
N95 respirator	Gaiter (double layer)	−271	−199	−127	<0.0001
Procedure mask	Gaiter (double layer)	−65	7	79	0.9999
Cloth mask	Gaiter (double layer)	−26	46	118	0.4505
Gaiter (single layer)	Gaiter (double layer)	−7	64	136	0.1051
N95 respirator	Gaiter (single layer)	−335	−263	−191	<0.0001
Procedure mask	Gaiter (single layer)	−130	−58	14	0.1900
Cloth mask	Gaiter (single layer)	−91	−19	53	0.9825
N95 respirator	Cloth mask	−316	−244	−172	<0.0001
Procedure mask	Cloth mask	−111	−39	33	0.6336
N95 respirator	Procedure mask	−277	−205	−133	<0.0001

infectious SARS-CoV-2 detected in these studies suggests that in addition to large aerosols, these small aerosols might play a role in SARS-CoV-2 transmission (Anderson et al. 2020; Bahl et al. 2020; Ma et al. 2020; Morawska and Milton 2020).

Source control devices like face coverings and face shields collect respiratory particles larger than 0.3 μm primarily by impaction and interception of the aerosol particles against the fibers or solid surfaces of the device. As noted earlier, source control devices may also deflect aerosols, but this mechanism can be problematic as a means of source control because the infectious aerosol is not prevented from entering the surrounding environment; it is merely sent in a different direction which may or may not be protective depending upon local airflows and the locations of other people. Our experimental system measures particle collection only; any particles that are deflected but not collected by the face covering are still collected by the Andersen impactor. Thus, we are able to measure the particle collection efficiency of the face coverings without the potentially confounding variable of particle deflection. On the other hand, this does means that any potential benefits from, for example, deflecting large aerosol particles toward the ground were not measured by our system.

Small aerosols require much higher air velocities to deposit by impaction than do larger aerosols, and thus are more difficult to block with source control devices (Hinds 1999; Lindsley 2016). Consequently, small aerosols present the most challenging scenario for testing source control devices since devices that block small aerosol particles would be expected to block larger ones as well. Our results show that face masks and neck gaiters can significantly reduce the expulsion of small respiratory aerosol particles during coughing. This suggests that various types of face coverings can make an important contribution to reducing the quantity of aerosol particles containing SARS-CoV-2 released into the environment by people who are infected. N95 respirators, which are worn for personal protection by healthcare workers and others at highest risk of exposure, are also very effective source control devices. In contrast, the face shield blocked very little of the cough aerosol, indicating that face shields are not effective as source control devices for small respiratory aerosols.

The collection efficiencies of all the devices tested increased as the aerosol particle size increased, and this trend would be expected to continue for larger aerosol particles than were tested here. For example, the collection efficiency of the cloth face mask was 28% for the <0.6 μm particles and increased to 76% for the 4.7 to 7 μm particles. Similarly, the double-layer gaiter blocked 24% of the <0.6 μm particles and 76% of the 4.7 to 7 μm particles. These results suggest that cloth face coverings would be effective as source control devices against the large respiratory aerosols that are thought to play an important role in SARS-CoV-2 transmission.

Our study has several limitations. We used a single cough volume, air flow profile, and aerosol size distribution for our studies; these parameters can vary greatly from person to person. We examined the

performance of these devices during simulated coughing but not breathing or speaking, which have different air flow rates and aerosol size distributions. Some internal losses of the test aerosol particles likely occurred due to settling or impaction on the surfaces of the collection chamber, which may affect the estimates of the collection efficiencies. We only used a single representative example of each type of device. The shape and composition of face coverings vary widely, and this would be expected to affect the performance of individual devices. Some face masks have exhalation valves or vents which could reduce their efficacy as source control devices. The fit of a particular mask to an individual wearer and compliance in wearing the mask correctly (i.e., over the nose and mouth) also are important factors in how well the mask performs as a source control device. Because we used a < 0.6 to 7 µm test aerosol, our results do not indicate if face shields would be more effective as source control devices for large droplets. The face shield that we tested has a widely used design, but alternative designs are being marketed that provide greater facial coverage and, in some cases, include fabric skirts between the shield and the face. These alternative face shield designs might perform better as source control devices.

Previous studies have shown that face shields provide eye and facial protection to the wearer from droplets and splashes (Lindsley et al. 2014; Roberge 2016). When a face shield is worn in addition to a face mask, the face shield can also help reduce surface contamination of the mask by large aerosols and reduce the likelihood of hand contamination when the mask is removed or inadvertently touched (Lindsley et al. 2014). Our previous study showed that face shields provide some benefits as personal protective equipment when face masks cannot be worn (Lindsley et al. 2014), but as with all personal protection and source control devices, their limitations must be respected. Our results suggest that face masks and neck gaiters are more effective than face shields as source control devices to reduce the expulsion of respiratory aerosols into the environment as a public health measure to reduce the community transmission of SARS-CoV-2.

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Declaration of interests statement

The authors declare no competing interests.

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From: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>
Sent: Tuesday, January 11, 2022 2:05 PM
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
Cc: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>; McCalla, Haley (CDC/OD/OCS) <LNO3@cdc.gov>; Brunson, Juanita (CDC/DDNID/NCBDDD/DBDID) (CTR) <qrl8@cdc.gov>
Subject: N95 effectiveness as source control

Dear Partners,

We have had a number of questions from you and others about N95 effectiveness as source control and wanted to share some information back with you.

National Institute for Occupational Safety and Health (NIOSH) researchers have evaluated N95s as source control in two different peer reviewed publications. In the first paper (Lindsley et al. 2021a- attached), NIOSH researchers found that a N95 respirator (3M model 1860) was 99% effective at blocking cough aerosols. In a second paper (Lindsley et al. 2021b- attached), NIOSH researchers found that one N95 respirator (3M 1860 N95) was 99% effective at blocking coughed and exhaled aerosols, and a second N95 Respirator (BYD) was 83% effective at blocking cough aerosols and 95% effective at blocking exhaled aerosols.

References (attached)
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Many thanks,
Aliki

Aliki Pappas Weakland, MPH MSW (she/her/hers)
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Coronavirus Disease 2019 (COVID-19) | CDC

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Saturday, January 08, 2022 1:55 PM EST
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
Subject: PARTNER ALERT: CDC Expands Booster Shot Eligibility

Dear Partners –

Yesterday, CDC adjusted our recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months.

Earlier this week CDC made this recommendation for recipients of a Pfizer-BioNTech primary seriesand, after FDA action this morning, we're extending this recommendation to recipients of a Moderna primary series. This means that people 12 and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.

Recently CDC strengthened our COVID-19 vaccination recommendations for children, now recommending that:

- Moderately to severely immunocompromised children ages 5–11 years receive an additional primary dose of Pfizer-BioNTech to ensure optimal protection from the vaccine.
- Children and teens ages 12–17 years should receive a booster shot.

Thank you,

Vaccine Task Force
COVID-19 Response

From: Dobbs, Thomas E
Subject: Fw: Follow up from 11/16 ASTHO IDPC call
Date: Friday, December 10, 2021 2:24:59 PM
Attachments: image001.png
IDPC Meeting Notes_11.22.2021.docx
DRAFT - Public Health Authority Policy Statement.002.docx

From: Kate Heyer <kheyer@astho.org>
Sent: Tuesday, November 23, 2021 3:22 PM
To: McLaughlin, Joseph B (HSS) <joseph.mclaughlin@alaska.gov>; David Lakey, MD <dlakey@utsystem.edu>; Shah, Nirav <nirav.shah@maine.gov>; Dobbs, Thomas E <Thomas.Dobbs@msdh.ms.gov>; ScottHarris <Scott.Harris@adph.state.al.us>; jose.romero@arkansas.gov <jose.romero@arkansas.gov>; kristen.ehresmann@state.mn.us <kristen.ehresmann@state.mn.us>; Randall Mayer <randall.mayer@idph.iowa.gov>; Jeff Stover <jeff.stover@vdh.virginia.gov>; Terry Dwelle <tldwelle1692t@gmail.com>; manisha.juthani@ct.gov <manisha.juthani@ct.gov>
Cc: Griffin, Jenny <Jenny.Griffin@msdh.ms.gov>; Patricia Vinson <Patricia.Vinson@adph.state.al.us>; Grace Lee <glee@astho.org>; Marcus Plescia <mplescia@astho.org>; Meredith Allen <mallen@astho.org>; Andy Baker-White <abaker-white@astho.org>; Ericka McGowan <emcGowan@astho.org>; Carolyn McCoy <cmccoy@astho.org>
Subject: Follow up from 11/16 ASTHO IDPC call

Good afternoon,

Thank you for participation in last week's IDPC call. Attached please see notes from the call and an updated draft of the *Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease* policy statement.

- Since we met last week, we have been fortunate to gain a new IDPC member! **Dr. Manisha Juthani (SHO-CT)** has agreed to serve on the IDPC and plans to join us on our next call. Please join me in welcoming her to our group.
- *Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease* policy statement: Andy incorporated edits from our call in the attached draft. **If you are interested in meeting with Andy as a small group to wordsmith the draft, please let me know and I'll work to propose a few dates and times for that conversation.**
- As I mentioned during the call, Alyssa Boyea from our staff will be also be sending a request for your feedback to the questionnaire to assess public opinion on rebuilding trust and confidence in public health after the Thanksgiving holiday.
- Additionally, CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) will soon be updating its Data Security and Confidentiality Guidelines. The purpose of the document is to recommend standards for all NCHHSTP programs that, when adopted, will facilitate the secure collection, storage, and use of data while maintaining confidentiality. NCHHSTP has requested that ASTHO provide concrete examples and feedback on what needs to be updated in these guidelines. Please share anything you think should be added, removed, or reframed within these guidelines with me by **December 15.**

Lastly, the next IDPC call is scheduled for **February 15, 2022 at 12PM ET**. An agenda and call-in information will be sent closer to the call. Please send any suggested agenda topics to me.

Thank you all for your continued support of the IDPC and have a wonderful Thanksgiving.

Kate

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PUBLIC HEALTH AUTHORITY TO PREVENT AND CONTROL THE SPREAD OF COMMUNICABLE AND INFECTIOUS DISEASE

POSITION

The Association of State and Territorial Health Officials (ASTHO) supports the establishment of robust public health legal authorities to facilitate the timely and adequate response to communicable and infectious disease outbreaks. These legal authorities are often exercised without the need of an emergency declaration and may allow, among other things, the abatement of nuisances, investigation of the causes of disease, institution of quarantine measures, ordering individuals or groups to isolate, conducting contact tracing and case investigations, collecting data, temporarily limiting or canceling public events, temporarily restricting or closing venues, and requiring vaccination verification for certain conduct and activities (e.g., school attendance). Beyond their use in the response to the historic pandemic caused by the novel coronavirus, in the past, these powers have been routinely exercised for more commonly experienced disease outbreaks, such as mumps and measles. Additionally, other societal sectors, such as business, education, cultural, and religion often depend on public health to stop the spread of infectious disease, prevent widespread disruptions, and quell public anxiety and fear. Maintaining these state and territorial legal authorities are key to being prepared for communicable and infectious disease outbreaks both now and in the future.

Summary of Recommendations:

- Ensure public health authority that can respond to future disease outbreaks without undue delay.
- Support public health authority that is guided by data and science.
- Ensure public health authority that protects the public's interest and well-being.

BACKGROUND

Establishing and using legal authority to control the spread of infectious disease dates to before the founding of the country. For example, colonial governments implemented isolation and quarantine precautions for incoming ships to prevent the introduction and spread of smallpox and other contagions.[1] These powers and activities were seen not only as a way of protecting the health of the local communities but also protective of trade and commerce.[2] As the scientific understanding of communicable and infectious disease grew, new tools such as contact tracing, disease investigation, data collection, and vaccines were added to public health's legal authority and practice. During the current pandemic public health authority has been used, with evidenced benefit, to slow the spread of the coronavirus by limiting the size of gatherings, encouraging social distancing, temporarily closing high-risk venues, and requiring the use of face coverings in certain places.[3,4,5,6,7,8,9]

Despite the successes in exercising public health authority, grave questions and negative perceptions about the role and use of public health powers in response to the pandemic and, by implication, future infectious disease outbreaks have arisen. Over the last year, the critical attitude toward the pandemic response has led to the rolling back of public health authority in several jurisdictions.[10] The reductions in public health legal authority will conceivably make it more difficult to respond to future disease outbreaks. As state and territorial policy makers continue to address the many issues related to the current pandemic, they are encouraged to consider these potential impacts and costs.

RECOMMENDATIONS

With regards to state and territorial public health authority to prevent and control the spread of communicable and infectious disease, ASTHO recommends:

- Ensuring public health legal authority that is appropriate and necessary for the prevention and control of future communicable and infectious disease outbreaks. Highly contagious illnesses, like measles, can be effectively contained through the public health measures and activities that are being questioned and criticized during the COVID-19 pandemic. We are unsure how the next major disease outbreak will spread and public health authority must be ready and able to respond to future diseases. Public health authority to implement non-medical and medical interventions swiftly and adeptly must be maintained and the creation of administrative burdens that delay public health action, endangers the public well-being, and leaves communities vulnerable to infectious disease outbreaks, should be avoided.
- Supporting evidence-based laws and policies for the identification, prevention, and control of communicable and infectious diseases. Public health authority should align with present and future diseases that public health agencies are obligated and required to confront and the authority should also be exercised in a manner that addresses the identifiable, known characteristics of the disease outbreak.
- Ensuring that public health legal authority properly and adequately balances a public health agency's obligations and requirements to protect the public's health and well-being with the rights of individuals. Laws and policies that undermine and encumber a public health agency's obligations or arbitrarily limit the agency's authority, impede disease prevention and control. Public health authority that is reasonable and aligned with the preventing and controlling the spread of infectious disease should be established and maintained.

APPROVAL DATES

Prevention Policy Committee Approval:
Board of Directors Approval:
Policy Expires:

ASTHO membership supported the development of this policy, which was subsequently approved by the ASTHO Board of Directors. Be advised that the statements are approved as a general framework on the issue at a point in time. Any given state or territorial health official must interpret the issue within the current context of his/her jurisdiction and therefore may not adhere to all aspects of this Policy Statement.

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[3] Castillo R, Staguhn E, Weston-Farber E. "The effect of state-level stay-at-home orders on COVID-19 infection rates." *Am. Journal of Infection Control*. 2020. 48(8):958-960. Available at https://doi.org/10.1016/j.ajic.2020.05.017. Accessed 9-28-2021.

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[5] Lyu W, Wehby G. “Comparison of Estimated Rates of Coronavirus Disease 2019 (COVID-19) in Border Counties in Iowa Without Stay-at-Home Order and Border Counties in Illinois with a Stay-at-Home Order.” *JAMA Netw. Open.* 2020. 3(5):1-7. Available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766229?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=051820. Accessed 9-28-2021.

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[8] Howard J, Huang A, Li Z, et al. “An evidence review of face masks against COVID-19." *Proc. Natl. Acad. Sci.* 2021. 118 (4):1-12. Available at: https://doi.org/10.1073/pnas.2014564118. Accessed 9-28-2021.

[9] Dasgupta S, Kassem AM, Sunshine G, et al. “Differences in rapid increases in county-level COVID-19 incidence by implementation of statewide closures and mask mandates — United States, June 1–September 30, 2020.” *Ann Epidemiol*. 2021. 57:46-53. Available at https://doi.org/10.1016/j.annepidem.2021.02.006. Accessed 9-28-2021.

[10] Weber L, Barry-Jester AM. “Over Half of States Have Rolled Back Public Health Powers in Pandemic.” *Kaiser Health News*. Sept. 15, 2021. Available at https://khn.org/news/article/over-half-of-states-have-rolled-back-public-health-powers-in-pandemic/. Accessed 11-1-2021.

November 16, 2021 | 12 – 1 p.m. ET

IDPC Meeting

Attending

- Jose Romero
- Scott Harris
- Thomas Dobbs
- Randy Mayer
- Joe McLaughlin
- Kris Ehresmann
- Jeff Stover
- Carolyn McCoy
- Kate Heyer
- Grace Lee
- Andy Baker-White
- Meredith Allen
- Ericka McGown
- Marcus Plescia

Meeting Notes

- Carolyn McCoy (ASTHO) provided an update on her discussion between staff in Rep. Rosa De Lauro's office from the Appropriations Committee with Dr. Dobbs on flexible funding.
    - ASTHO has been tracking three key issues:
        - Bipartisan Infrastructure Bill was signed into law.
        - Build Back Better Act, which is awaiting a score from the Congressional Budget Office (CBO) before being sent to members of Congress who will move on a vote.
            - The House may take it to the floor this week, despite parts of the CBO scoring estimates not coming out until the end of this week.
            - ASTHO is keeping track of this proposal because 7.5 billion is allocated for PH preparedness in the proposal.
        - The Fiscal Year 2022 Fiscal Appropriations process is underway.
            - Dr. Dobbs spoke to Senate Appropriations y staff. There is $1 billion proposed in the House, $600 million proposed in the Senate for flexible funding for PH infrastructure.
    - Federal funding runs out on Dec 3rd, and it is largely acknowledged that there is a need for a short-term continuing resolution. There is a question on how long this funding will last and if it will go into the 2022 election year. Likely fiscal fallout from not raising the debt ceiling would be catastrophic.

Andy Baker-White (ASTHO) shared the draft of the ***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease*** policy statement

- IDPC members discussed some edits that could be made on the list of recommendations.
    - State health officials shared that they have gotten far less resistance on isolation/quarantine mandates directed towards individuals compared to broader

PH-based population-based interventions (mask and vaccine mandates, school closures, etc.)

- Members emphasized the need to make sure that the recommendations section needs to be concise as some may not read the rest of the statement.
- Members expressed appreciation for the statement striking a balance between protecting individual rights and ensuring the public wellbeing. Many people do not recognize their obligation to protecting community health, so making this statement stronger would be a suggestion.
    - Joe McLaughlin said that CSTE has a public health law subcommittee, and it be helpful to reach out to them for some collaboration.
        - ASTHO has a steering committee of attorneys to who can also provide feedback.
    - Dr. Dobbs said many people don't respect the individual liberties of people who want to be safe during the pandemic. The pandemic has allowed those who are reckless to rob freedoms from people who want to live safely.

- The ***Preparing for the Next Pandemic/Public Health Crisis*** white paper was presented to the IDPC to gather feedback and edits.
    - The pandemic has highlighted how the PH sector has received a lot of funding, but that it is not always at the right time or for the right activities. Action-based flexible funding is necessary.
    - Members expressed a need for an all-hazards preparedness and response plan that is more nimble, more useful, less cumbersome, and easy for all those in the workforce to access and execute a pandemic response plan.
        - The white paper should acknowledge the role of misinformation during a pandemic response. Communications have been a challenge, especially for those whose first language was English. It's important to think about non-English speaking populations when planning for and throughout a response.
        - Ensuring judicious use of FEMA funds, proposing requiring a 100% federal match, and increasing surveillance capacity were all discussed as additional recommendations to the white paper.
    - Depoliticization of public health is vital in future pandemic responses. State leaders should be trained to be prepared to navigate political environments early and frequently in their work at a health agency. Legislators must support state health departments and the science.
    - There is a critical need to instill and boost trust in public health.
        - Mandates are challenging to explain when you're trying to increase trust in public health because they further emphasize and exacerbate public health fears of government overreach.
        - Emphasizing that PH is prevalent in everyday life, not just during a pandemic, is crucial for boosting the public's education on the role of PH.
            - State health agencies should emphasize that we train for PH responses through everyday PH initiatives.

- Another white paper is currently being drafted by MIT. It may be useful to reference this document, specifically on using technology for surveillance. Having an IT infrastructure is part of the PH infrastructure.
- Members emphasized that now, during the COVID-19 pandemic, is the most important time to get ahead of PH fear and mistrust.
- Members discussed ways to build back trust in public health. Members discussed whether the IDPC believes that a year from now there is going to be this level of mistrust. He wanted more perspective on trust as an issue going into the future, or if mistrust is just an issue now.
    - Dr. Dobbs said that they are using their roles as leaders to promote other important PH topics, because PH is broader than a pandemic.
    - Jeff Stover said VA is doing some marketing on a "PH Reality Campaign". Using the environment of the COVID-19 pandemic right now serves as platform to educate people on what PH really is.

- Next topics for future IDPC calls:
    - Trust in public health institutions.
    - Negative test reporting, contact tracing (for conditions outside of COVID such as STDs and TB), frequency of case reporting, and what the markers are for COVID becoming endemic.

Action Items

- Andy Baker-White will incorporate the IDPC's suggested edits in the draft of the policy statement. Any members who wish to send proposed edits via e-mail can e-mail kheyer@astho.org or reach out to set up a time for a call with Andy
- ASTHO will incorporate the IDPC's suggestions into the white paper and consider whether to engage public health attorneys to review. The ASTHO team will also solicit feedback from the ASTHO Preparedness Policy Committee and provide a draft back for IDPC review.

astho™

From:	Craig, Jim
To:	Adcox-Green, Ashley; Boxx, Robert; Byers, Paul; Craft, Christy; Darnell, Tim; Hall, David; Horn, Marshall; Jennings, Twyla; Parker, Melissa; Sharlot, Liz; Taylor, Kathryn; William McLeod; Ware, Daphne; Williams, Alisa; Young, Dorthy
Subject:	FW: HHS COVID-19 Update - 3/31
Date:	Friday, April 2, 2021 6:03:48 AM

Good morning!

From: Polk, Jennifer (OS/ASPR/SIIM) <Jennifer.Polk@hhs.gov>
Sent: Thursday, April 1, 2021 7:53 AM
Subject: HHS COVID-19 Update - 3/31

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Wednesday, March 31, 2021 8:26 PM
Subject: HHS COVID-19 Update - 3/31

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 31, 2021:

Highlights from the White House COVID-19 Response Team briefing:

Andy Slavitt:

- **Increasing Vaccination Sites:** The President committed to opening at least 12 more federally run mass vaccination sites, adding to the existing total of 25 sites. Three new sites will open next week in Memphis, Tennessee, Milwaukee, Wisconsin, and Greenbelt, Maryland, in addition to the two we announced on Monday in St. Louis, Missouri, and Gary, Indiana. Each of these sites is the first federally run mass vaccination site in its respective state, and each can administer 3,000 vaccinations a day.
- **Mask Mandates:** We need every governor, mayor, and local leader to maintain or reinstate mask mandates. And we need every American to do their part so that we can win this race and save lives.

Dr. Walensky:

- **Case Update:** CDC's most recent data show that the seven-day average of new cases is slightly less than 62,000 cases per day. We continue to see an increase, and this is almost a 12 percent increase from the seven-day period prior. Hospitalizations also continue to increase. The most recent seven-day average — about 4,900 admissions per day — is up from 4,600 admissions per day in the prior seven-day period. The seven-day average of deaths remains slightly above 900 deaths per day.
- **Inequities in COVID-19 Deaths:** COVID-19 deaths were highest for older adults and males, and were higher, as we previously saw, among American Indian and Alaska Natives, Hispanics, non-Hispanic Blacks, and non-Hispanic Native Hawaiian and Pacific Islander persons compared

to non-Hispanic whites. In fact, among nearly all these ethnic and racial minority groups, the COVID-19-related deaths were more than double the death rate of non-Hispanic white persons. Based on the current state of the pandemic, these impacts have remained in 2021, where we continue to see that communities of color account for an outsize portion of these deaths.

- **Number of People Vaccinated:** This week, we will reach 100 million people who have received at least one dose of the COVID-19 vaccine in the United States — a remarkable feat in such a short period of time. Further, over 70 percent of people over age 65, our most vulnerable group, have received at least one vaccine dose. In addition to increasing the number of mass vaccination sites across the country with FEMA, expanding the Federal Retail Pharmacy Program, and ensuring that all Americans have a vaccine site within five miles of their home, we are also activating mobile vaccination units and clinics. CDC is also excited to partner with the Administration for Community Living to support their efforts to get older, at-risk adults and those with disabilities vaccinated.
- **Guidance for Adult Day Service Centers:** CDC updated COVID-19 guidance for adult day service centers. These populations are at high risk for severe COVID-19 disease, and this guidance will help center administrators and staff protect themselves and adults receiving their services by promoting and engaging in preventive behaviors that reduce COVID-19 spread and help maintain healthy operations and environments of these facilities.
- **B.1.1.7 Variant:** We now have B.1.1.7 (U.K. variant) as 26 percent of the circulating variant across the United states, and it is the predominant strain in at least five regions of the United States. The variant is more transmissible – somewhere between 50 and 70 percent more transmissible than the wild-type strain. Therefore, to the extent that people are not practicing those standard mitigation strategies, we do think that more infections will result because of B.1.1.7. We believe that the current mitigation strategies of masking and distancing would work just as well against the current, the wild-type strain, as they do the B.1.1.7 strain.

Dr. Fauci:

- **Importance of Getting Vaccinated:** We are seeing now immune protection against COVID-19 variants when individuals are vaccinated against the wild-type strain, namely the common virus in society, on two mechanisms: the antibody response that has a spillover effect and the cross-reactivity. Vaccination is not only going to protect us against the common COVID-19 virus in society, but it has the potential, to a greater or lesser degree, to also protect against a range of variants. So, when vaccination becomes available, get vaccinated.

Vaccine Updates

Federal Retail Pharmacy Program: CDC updated their general information on the Federal Retail Pharmacy Program for COVID-19 Vaccination. As the program expands and supply becomes more readily available, the allocation may be adjusted to reflect partner size (number of store locations nationwide), reach (percent of the total US population living within 5 miles of a store location), and ability to vaccinate (throughput). The program, which will scale up to eventually include COVID-19 vaccination at all 40,000+ retail locations, will make it easier for individuals to access free COVID-19 vaccine at a pharmacy in their community, and improve vaccine uptake while decreasing the

logistical and operations burden on state, local, and territorial health departments.

Johnson & Johnson Janssen Vaccine: CDC updated their general information on the Johnson & Johnson Vaccine. The J&J/Janssen vaccine is recommended for people aged 18 years and older. Learn more about how CDC is making COVID-19 vaccine recommendations and CDC's vaccine rollout recommendations.

FEMA Vaccination Sites: FEMA announced that it will open a COVID-19 vaccination site in Greenbelt, Maryland on April 7th. The center's capacity is expected to be up to 3,000 shots per day. President Biden also committed to opening sites in Memphis, TN and Milwaukee, WI. These sites join many new FEMA vaccination sites recently announced, including in Boston, Massachusetts; Essex, New Jersey; Norfolk, Virginia; and Yakima, Washington, all of which open today. In the next week, federal communication vaccination center pilot sites in Gary, Indiana and St. Louis, Missouri are scheduled to open, as well. The agency has provided more than $4.47 billion for expenses related to COVID-19 vaccination at 100% federal cost share.

Peace Corps Assistance in COVID-19 Response: FEMA and the Peace Corps announced a historic partnership to combat the COVID-19 pandemic, marking only the second time in the Peace Corp's history where volunteers will serve a domestic deployment. The Peace Corps will soon begin recruiting for the special domestic deployment through Peace Corps Response, a program that sends in individuals with specialized experienced to short-term service assignment of up to 12 months. Assignments will focus on urgent needs as identified by FEMA and on communities that have been traditionally under-served.

Evaluating Moderna COVID-19 Variant Vaccine: An investigational vaccine designed to protect against the B.1.351 SARS-CoV-2 variant has been administered as part of a new Phase 1 clinical trial evaluating the vaccine candidate's safety and immunogenicity in adult volunteers. The vaccine, known as mRNA-1273.351, was developed by the biotechnology company ModernaTX, Inc., based in Cambridge, Massachusetts. The trial is led and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The trial will enroll approximately 210 healthy adult volunteers at four clinical research sites in the United States that are part of the NIAID-funded Infectious Diseases Clinical Research Consortium (IDCRC).

HHS Podcast: HHS's new podcast, *COVID-19 Immunity in Our Community*, features top medical experts to answer questions on COVID-19 vaccines. Today's episode, "Building Vaccine Trust Within the Black Community," discusses how we can start to rebuild the Black community's trust in the vaccines, in order to achieve herd immunity and, hopefully, regain some sense of normalcy in our everyday lives.

Testing and Treatment

Covid-19 Precautions: CDC updated their COVID-19 page, reiterating that it is critical to keep taking precautions to prevent COVID-19. Learn more about how to protect yourself and others from CDC's recommendations.

COVID-19 Self Testing: CDC and NIH launched an innovative community health initiative called "Say Yes! COVID Test" starting in two locales, Pitt County, North Carolina, and coming soon to Chattanooga/Hamilton County, Tennessee. As many as 160,000 residents across the two communities will have access to free, rapid antigen tests that they can administer themselves to use three times a week for one month. NIH will provide the tests (also called a home-test or at-home test) and evaluate the effectiveness of the initiative, which aims to determine if frequent self-administered COVID-19 testing helps residents reduce community transmission of SARS-CoV-2, the virus that causes COVID-19 disease.

$147 Million to Expand Production of Swabs: DOD and HHS awarded $146.7 million to Puritan Medical Products on March 26 for renovations in the company's Orlinda, Tenn. facility to increase production capacity of foam tip swabs used in COVID-19 diagnostic tests. Funded through HCEA, the award will help the company boost total production capacity of the swabs to 250 million per month by February 2022.

Monoclonal Antibody Treatments: 3 EUAs for monoclonal antibody (mAb) treatments for mild-to-moderate COVID-19 in at-risk patients: bamlanivimab, casirivimab/imdevimab, and bamlanivimab/etesevimab. Learn more about FDA-authorized monoclonal treatments that can help at-risk patients fight the disease.

HHS Innovative Challenge for Masks: The U.S. Department of Health and Human Services launches $500,000 innovation challenge competition today encouraging American inventors to aid the nation's COVID-19 response by designing effective, comfortable face masks for personal use that resolve the common complaints people have about wearing masks. The contest taps into the nation's creativity and entrepreneurial spirit to help curb the spread of SARS-CoV-2, the virus that causes COVID-19.

Information for Specific Populations

Healthcare Workers: CDC updated their guidance for managing patients with COVID-19, including clinical guidance, home and hospital care, care for special populations, disease severity, and more.

Guidance for Adult Day Services Centers: CDC released guidance for administrators and staff to prevent the spread of COVID-19. Adult Day Services Centers (ADSCs) provide social or health services to community-dwelling adults aged 65 and over and adults of any age living with disability. Older adults and persons with disabilities are at highest risk for severe illness from COVID-19 including hospitalization, intensive care, and death. ADSC administrators and staff can help protect themselves and program participants (that is, adults attending ADSCs) from COVID-19 by promoting and engaging in preventive behaviors that reduce spread and maintain healthy operations and environments at ADSC facilities. This guidance is meant to supplement — not replace — any Federal, state, tribal, local, or territorial public health and safety laws, rules, and regulations with which adult day services center programs must comply. CDC has also developed recommendations for participants at ADSCs and their caregivers.

Suggestions for Youth and Summer Camps: CDC offers suggestions for ways in which camp administrators can help protect campers, staff, and communication, and prevent the spread of COVID-19. Camp administrators can determine, in collaboration with state and local health officials, whether and how to implement these considerations, making adjustments to meet the unique needs and circumstances of the local community. Implementation should be guided by what is feasible, practical, acceptable, and tailored to the needs of each community. These suggestions are meant to supplement— not replace —any state, local, territorial, or tribal health and safety laws, rules, and regulations with which camps must comply.

Essential Services for Malaria: CDC updated their key considerations for continuing essential

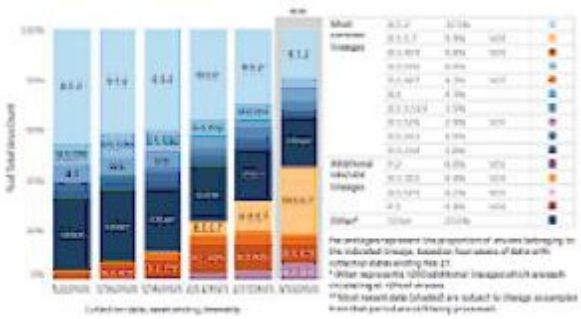
malaria prevention and control activities safely and effectively. These considerations should supplement country Ministry of Health guidance.

CMS Updates

Medicare Fee-for-Service Billing: CMS updated their COVID-19 Frequently Asked Questions on Medicare Fee-for-Service (FFS) Billing. The policies set out in this FAQ are effective for the duration of the public health emergency unless superseded by future legislation. The FAQs in this document supplement the previously released FAQs, 1135 Waiver FAQs.

Research

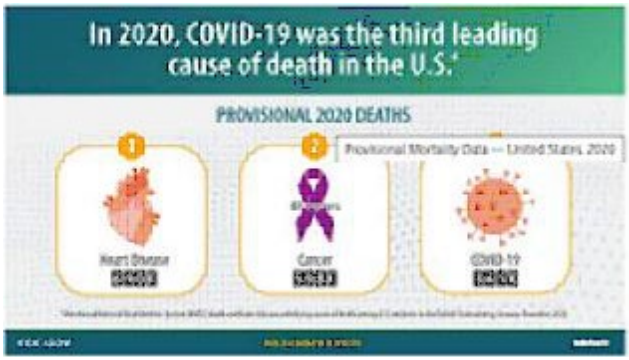
Variant Proportions in the U.S: CDC's national genomic surveillance program identifies new and emerging SARS-CoV-2 variants to determine implications for COVID-19 diagnostics, treatments, or vaccines authorized for use in the United States. Monitoring the spread of emerging variants in the United States relies on widespread, rapid sequencing. To accelerate sequencing in the United States, CDC has contracted with commercial diagnostic laboratories, and, in partnership with the Association of Public Health Laboratories (APHL), has implemented the National SARS-CoV-2 Strain Surveillance (NS3) program to provide a comprehensive and population-based US surveillance system. This data, along with data from many other sources, are used to inform national and state public health actions related to variants.



COVID-19 2020 Mortality Surveillance: The Morbidity and Mortality Weekly Report (*MMWR*) on death certificate-based ICD-10 diagnosis codes for COVID-19 mortality surveillance addresses that among the 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both. These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of death certificate diagnoses is essential for an authoritative public record.

Provisional 2020 Mortality Data: The Morbidity and Mortality Weekly Report (*MMWR*) on provisional mortality data in the United States in 2020 addresses that the age-adjusted death rate increased by 15.9% in 2020. Overall death rates were highest among non-Hispanic Black persons and non-Hispanic American Indian or Alaska Native persons. COVID-19 was the third leading cause of death, and the COVID-19 death rate was highest among Hispanics. Provisional death estimates

provide an early indication of shifts in mortality trends. Timely and actionable data can guide public health policies and interventions for populations experiencing higher numbers of deaths that are directly or indirectly associated with the COVID-19 pandemic.



Case Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 cases will remain stable or have an uncertain trend over the next 4 weeks, with 223,000 to 723,000 new cases likely reported in the week ending April 24, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of new reported cases per week will likely decrease in 4 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported cases are uncertain or predicted to remain stable in the other states and territories. View previous case forecasts.

Hospitalization Forecasts: This week's national ensemble predicts that the number of new daily confirmed COVID-19 hospital admissions will remain stable or have an uncertain trend over the next 4 weeks, with 2,300 to 8,700 new confirmed COVID-19 hospital admissions likely reported on April 26, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of daily confirmed COVID-19 hospital admissions will likely increase in 6 jurisdictions and decrease in 12 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported hospital admissions are uncertain or predicted to remain stable in the other states and territories. View previous hospitalization forecasts.

Death Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 deaths will remain stable or have an uncertain trend over the next 4 weeks, with 3,100 to 10,200 new deaths likely reported in the week ending April 24, 2021. The national ensemble predicts that a total of 565,000 to 585,000 COVID-19 deaths will be reported by this date. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of newly reported deaths per week will likely decrease in 8 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported deaths are uncertain or predicted to remain stable in the other states and territories. View previous death forecasts.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

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From:	Dobbs, Thomas E
To:	Craig, Jim
Subject:	Fw: TFAH"s Ready or Not report releasing this Wednesday - (Sent by Tim Hughes on behalf of Rhea Farberman)
Date:	Monday, March 8, 2021 5:44:47 PM
Attachments:	New Report Measures States" Health Emergency Preparedness[1].pdf TFAH-2021-ReadyOrNot-FnlEmb.pdf

Top Tier

From: Tim Hughes <thughes@tfah.org>
Sent: Monday, March 8, 2021 3:02 PM
To: Tim Hughes <thughes@tfah.org>
Subject: TFAH's Ready or Not report releasing this Wednesday - (Sent by Tim Hughes on behalf of Rhea Farberman)

Dear State Health Official,

TFAH will release its annual report *Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism* measuring states' health emergencies preparedness on Wednesday, March 10. Not surprisingly, this year the report has a special focus on the impact of COVID-19, highlighting the need to increase resources for emergency preparedness. We clarify that our report measures all-hazards preparedness and is not a measure of any state's COVID-19 response.

As we have done in past years, we measure 10 health security indicators in each state and discuss the relationship of each to all-hazard preparedness. We placed states into one of three performance tiers (high, middle and low) based on these indicators. Twenty states and the District of Columbia placed in the high-performance tier, 15 states placed in the middle performance tier and 15 states placed in the low performance tier.

Particularly significant in this year's report is our emphasis on how the pandemic demonstrated the importance of the federal government's role in a health emergency on the scale of a pandemic, the impact of structural racism on a community's resilience during a health emergency, and, the critical need for core public health funding including workforce and infrastructure support.

The report is being shared with news media ahead of the Wednesday morning lift of the embargo. It is likely to be covered in news markets across the country. I recommend you share these materials with your communications staff today so they can prepare for any media requests.

I'd be happy to answer any questions.

Thank you,
Rhea

Rhea K. Farberman, Director
Strategic Communications and Policy Research
Trust for America's Health
rfarberman@tfah.org

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FOR RELEASE: EMBARGOED UNTIL 12:01 AM, March 10, 2021

CONTACT: Brianna Kelley, 202 360-4061 Kelley@teamsubjectmatter.com

Rhea Farberman, 202 494-0860 RFarberman@tfah.org

New Report Finds Gaps in States' Preparedness for Public Health Emergencies

COVID-19 Illuminated critical harm of underinvestment in public health infrastructure

(Washington, DC) --- March 10, 2021 – The COVID-19 pandemic has starkly demonstrated that underinvestment in preparedness to respond to public health emergencies can cost hundreds of thousands of lives and wreak havoc on the economy. A new report released today by Trust for America's Health (TFAH) measured states' performance on 10 key emergency preparedness indicators and found room for improvement in every jurisdiction.

The report, *Ready or Not 2021: Protecting the Public's Health from Diseases, Disasters and Bioterrorism* measured states' readiness for health emergencies of any kind (not just the COVID-19 crisis). It placed 20 states and the District of Columbia in a high level of preparedness category, 15 states in a middle preparation tier and 15 states in a low degree of preparation tier.

State performance, by scoring tier, 2020

Performance Tier	States	Number of States
High Tier	CO, CT, DC, DE, GA, ID, KS, MA, MD, ME, MS, NC, NE, NM, OK, RI, UT, VA, VT, WA, WI	20 states and DC
Middle Tier	AL, CA, FL, IA, IL, KY, LA, MI, MN, MT, ND, NJ, OR, TN, TX	15 states
Low Tier	AK, AR, AZ, HI, IN, MO, NH, NV, NY, OH, PA, SC, SD, WV, WY	15 states

For nearly two decades, TFAH has examined the nation's public health emergency preparedness in this annual report. During that time, all states have made improvements in their emergency preparedness, but all continue to have room for additional strengthening of their public health preparedness and response.

"The importance of this report is that it gives states actionable data to adopt policies that save lives. The COVID-19 crisis shows that we have much more work to do to protect Americans from health threats, particularly in the ways in which structural racism create and exacerbate health risks within communities of color," said John Auerbach, President and CEO of Trust for America's Health. "States need to take aggressive steps to shore up their preparedness for all types of public health emergencies."

While the report's findings are not a measure of any state's COVID-19 response, they demonstrate that while states' readiness is important, national health emergencies on the scale of a pandemic require strong federal leadership and coordination, and long-term investment in public health infrastructure and workforce. States alone, even those that rank high in this report, are not sufficiently equipped to respond to a pandemic without federal help, say the report's authors.

The report found:

A majority of states have made preparations to expand healthcare and public health capabilities in an emergency, often through collaboration. Thirty-four states participated in the Nurse Licensure Compact, up from 26 in 2017. The compact allows registered nurses and licensed practical or vocational nurses to practice in multiple jurisdictions with a single license. In an emergency, this enables health officials to quickly increase their staffing levels. In addition, **hospitals in most states have a high degree of participation in healthcare coalitions**. On average, 89 percent of hospitals were in a coalition and 17 states and the District of Columbia had universal participation, meaning every hospital in the jurisdiction was part of a coalition. Such coalitions bring hospitals and other healthcare facilities together with emergency management and public health officials to plan for and respond to incidents. **Every state and the District of Columbia had public health laboratories that had plans for a large influx of testing needs.** This ability to surge laboratory testing capacity during the COVID-19 crisis was extremely critical.

Most states are accredited in the areas of public health, emergency management, or both. As of December 2020, the Public Health Accreditation Board (PHAB) or the Emergency Management Accreditation Program (EMAP) accredited 42 states and the District of Columbia; 29 states and the District of Columbia were accredited by both groups, a net increase of one since November 2019. Both programs help ensure that necessary emergency preparation and response systems are in place and staffed by qualified personnel.

Seasonal flu vaccination rates, while still too low, have risen significantly. The seasonal flu vaccination rate among Americans ages 6 months or older rose from 42 percent during the 2017–2018 season to 52 percent during the 2019–2020 season but is still below the 70 percent target vaccination rate set by *Healthy People 2030.*

In 2019, only 55 percent of employed state residents, on average, used paid time off, the same percentage as in 2018. Those without paid leave are more likely to work when they are sick and risk spreading infection. This became particularly relevant during the COVID-19 pandemic, as isolation and quarantine are important tools for controlling the outbreak.

Most residents who got their household water through a community water system had access to safe water. On average, just 5 percent of state residents used a community water system in 2019 that did not meet all applicable health-based standards.

The report includes recommendations for actions by federal and state policymakers to improve the nation's public health emergency preparedness in seven priority areas:

- Provide stable, sufficient funding for domestic and global public health security.
- Strengthen policies and systems to prevent and respond to outbreaks and pandemics.
- Build resilient communities and promote health equity generally and in preparedness.
- Ensure effective public health leadership, coordination, and workforce.
- Accelerate development and distribution, including last mile distribution, of medical countermeasures.
- Strengthen the healthcare system's ability to respond and recover during and from health emergencies.
- Prepare for environmental threats and extreme weather.

The *Ready or Not* report series is funded by the Robert Wood Johnson Foundation with additional support from The California Endowment, W.K. Kellogg Foundation and The Kresge Foundation.

###

Trust for America's Health is a nonprofit, nonpartisan organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority. www.tfah.org. Twitter: @healthyamerica1

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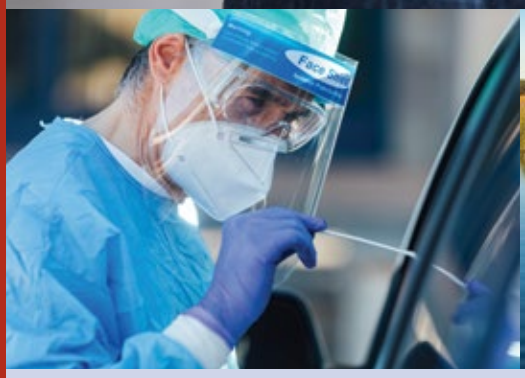
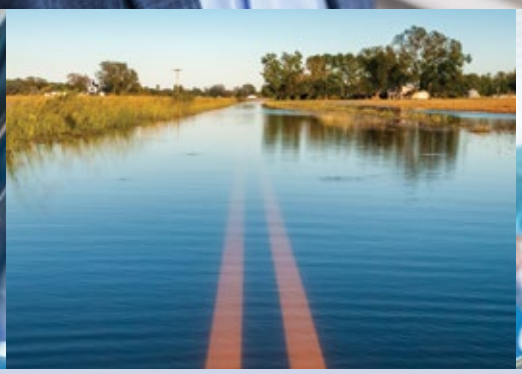
ISSUE REPORT

Ready or Not:

PROTECTING THE PUBLIC'S HEALTH FROM DISEASES, DISASTERS, AND BIOTERRORISM 2021





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MARCH 2021

Acknowledgements

Trust for America's Health (TFAH) is a nonprofit, nonpartisan public health policy, research, and advocacy organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority.

The Ready or Not report series is supported by generous grants from the **Robert Wood Johnson Foundation**, with additional support from **The California Endowment, W.K. Kellogg Foundation** and **The Kresge Foundation.** Opinions in this report are TFAH's and do not necessarily reflect the views of its funders.

The National Health Security Preparedness Index (NHSPI) is a joint initiative of the Robert Wood Johnson Foundation, the University of Kentucky, and the University of Colorado. TFAH wishes to recognize and thank Glen Mays and Michael Childress of the NHSPI for their collaboration and expertise as well as the Robert Wood Johnson Foundation for its continued funding support.

Ready or Not and the NHSPI are complementary projects that work together to measure and improve the country's health security and emergency preparedness. TFAH looks forward to a continued partnership.

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This report benefited from the insights and expertise of the following external reviewers. Although they have reviewed the report, neither they nor their organizations necessarily endorse its findings or recommendations. TFAH is extremely grateful to these reviewers for their time and expertise.

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Editor's note: This report was being prepared during a presidential transition. We have included comments in the report where we have noted action on TFAH policy recommendations by the Biden administration.

View this report online at www.tfah.org/report-details/readyornot2021

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EXECUTIVE SUMMARY

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Executive Summary

The past year, 2020, will long be remembered as the year more than 2 million people lost their lives due to a global pandemic. Not since the 1918 influenza pandemic has a single event so urgently demonstrated the criticality of a strong public health system. This *Ready or Not* report has tracked the country's level of public health emergency preparedness since 2003. For nearly two decades, it has asked the fundamental question: "are we ready?" Unfortunately, the COVID-19 crisis has provided a clear answer: an emphatic "no."

The COVID-19 crisis has illuminated the urgent need for federal, state, local, tribal, and territorial leaders to take aggressive steps to shore up the nation's preparedness for all types of emergency events. The pandemic put a spotlight on a public health system hollowed-out by years of insufficient funding. Health departments were overstretched, responding to the pandemic with archaic technologies[1] and with overworked staff who faced threats and retribution.[2] These gaps were all the more critical in 2020 because the federal government failed to take an evidence based, leadership role in the pandemic response, with many decisions being left to states that would ordinarily be federally coordinated. It also demonstrated the harm that can be done when science and public health expertise are stifled by political interference and misinformation.

In addition, the pandemic has once again demonstrated and exacerbated the impact of structural racism, both historic and current, on the health and well-being of communities of color and Tribal Nations. Acknowledging the lingering health impacts of slavery and the treatment of native peoples and addressing current day racist policies, systems, and attitudes must be part of building the nation's resilience. In short, equity is not separate from preparedness. Ensuring an equitable opportunity for the health and well-being of all residents before a disaster creates more resilient communities during an emergency. Equity must be an explicit and foundational principle in all emergency planning. Achieving equity in all facets of emergency response requires including equity accountability metrics in emergency preparation and management.

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Foundational capabilities are necessary throughout the public health system, from the Centers for Disease Control and Prevention (CDC) to state, local, tribal, and territorial health departments, including:[3]

- Health monitoring and assessment, comprising surveillance, epidemiology, and laboratory capacity;
- All-hazards preparedness and response;
- Policy development and support;
- Public communications;
- Community outreach and partnership development;
- Organizational and administrative competencies (i.e., leadership, governance, and health equity); and
- Accountability and performance management.[4]

Today, only half of Americans are protected by a comprehensive local public health system.[5] The Public Health Leadership Forum estimates a $4.5 billion annual shortfall in the spending necessary to meet the infrastructure needs of public health agencies nationwide.[6] This shortfall was on display throughout the COVID-19 pandemic, as decades of chronic underfunding hindered communications, disease surveillance, contact tracing, vaccine delivery, and other key health department activities.

"A powerful aspect of this report is its long history objectively measuring states' preparedness. This year's recommendations are almost identical to past years. Had the nation paid more attention to pandemic threats and TFAH's commonsense and consistent recommendations, this country would be in a very different place today."

Shelley A. Hearne, DrPH
Johns Hopkins University Bloomberg School of Public Health

It is also important to note that the infusion of COVID-19 emergency funding was onetime funding—critical to the pandemic response but not a solution to the system's longtime underinvestment.

This report is designed to give policymakers at all levels of government actionable data and recommendations with which they can target policies and spending to strengthen their jurisdiction's emergency preparedness. The report's 10 key public health preparedness indicators give state officials benchmarks for progress, point out gaps within their states all-hazards preparedness, and provide data to compare states' performance against like jurisdictions. These data points, or ones similar to them, have been the focus of this report for over a decade and are meant to measure readiness for a broad set of health security threats. They are not tailored to an assessment of a given state's response to the COVID-19 pandemic, as widescale political, funding, economic, and social factors all influenced the virus impact and local responses. A state may do well in terms of its ranking in this report but poorly in its response to the COVID-19 pandemic—and vice versa. While no state has been spared, what seems to have mattered most in the pandemic response is a state's socioeconomic and racial profile, as well as the adherence of elected leaders and residents to evidence-based public health guidelines. The pandemic has illustrated that robust and sustained funding, elected officials' leadership, and federal-state coordination and planning are key to protecting Americans' health security. Moreover, there is no substitute at the state or local level for a strong federal response.

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COVID-19 AND EMERGENCY PREPAREDNESS: TRAGIC LESSONS

TFAH's *Ready or Not: Protecting the Public's Health from Diseases, Disasters and Bioterrorism* report has tracked the nation's readiness to respond to a public health emergency for nearly two decades. During that time, no event highlighted the critical importance of this report's purpose—measuring and promoting readiness to safeguard Americans' health during an emergency—to the degree the COVID-19 crisis has.

The COVID-19 pandemic is an on-the-ground, real-time measure of the nation's public health emergency response system—a test the federal government failed according to most public health experts. An October 2020 report by Columbia University Earth Institute's National Center for Disaster Preparedness estimated that the federal government's inadequate pandemic response led to between 130,000 and 210,00 avoidable deaths. The report submits that if the United States had implemented sufficient testing, earlier lockdowns, a national mask-wearing mandate, and provided federal guidance on social distancing, over 200,000 lives could have been saved.[7]

With a possible single exception (water system safety), all of the readiness indicators measured annually by this *Ready or Not* report played a role in jurisdictions' COVID-19 response. Seven were relevant to the effort to control the pandemic and save lives: (1) nurse licensure compact (allowing jurisdictions to borrow medical personnel when they need to surge capacity), (2) hospital participation in healthcare coalitions, (3) public health and emergency management accreditation, (4) public health funding, (5) access to paid time off, (6) flu vaccination rates (as a proxy for a community's vaccination infrastructure and receptivity), and (7) laboratory surge capacity. TFAH will continue to measure states on these indicators, as they play a central role in the standing-ready, public health protection capacity that every state needs.

The pandemic has also spotlighted a number of issues not currently measured by the report but critical and dramatically apparent if absent during a health emergency: federal and state political leadership, interagency coordination, consistent and well-executed public communications, and health equity.

Importance of Federal Leadership

Government at multiple levels shares responsibility for emergency planning and response. Under this tiered structure, when an event requires a larger response than a local entity can provide, government from the tier above it—typically a tribal, territorial or state agency—provides assistance. When a state's response resources are not enough to meet demands during an emergency, the federal government provides support. For a public health emergency as significant and contagious as COVID-19, clear communication and strong leadership and coordination by the federal government are essential, elements

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that were lacking during the initial months of the pandemic response. Instead, inconsistent messages between federal agencies and the White House; lack of centralized coordination, such as for procurement of personal protective equipment (PPE); and political interference with guidance from scientific agencies—all led to confusion and contradictory policies among states and weakened the emergency response.

TFAH has made a number of policy recommendations designed to ensure robust and nonpartisan federal leadership during future public health emergencies, including:

- Create a White House Health Security Directorate, including senior advisors to the president with public health expertise on health security issues. This directorate would oversee the national biodefense strategy and all interagency emergency responses.
- Ensure full transparency and consistency in federal messaging from the White House, CDC, ASPR, FDA, and National Institutes of Health (NIH) concerning public health issues to ensure message clarity, avoid confusion, and build trust.
- Ensure that federal public health officials are fully empowered to make decisions based on science and without undue political influence. Efforts to infuse politics into public health decision-making puts the public's health at risk.
- HHS should strengthen leadership by working with states and suppliers to ensure adequate stockpiling and distribution of medical countermeasures and ancillary emergency response products, such as personnel protective equipment.

Overcoming the Legacy of Racism

The legacy of slavery, genocide, and centuries of racism, combined with current day interpersonal and structural racism, is at the root of the disproportionate impact COVID-19 has had on communities of color and Tribal Nations. These systemic inequities, in access to healthcare, housing, education, transportation, and employment, existed before the pandemic and have been exacerbated by it. Health inequities due to disadvantages experienced by racial, ethnic, or other population groups are preventable differences in the burden of disease, injury, and health emergencies and to opportunities to achieve good health.[8] Addressing issues at the root of health inequity is imperative to ensuring all people, regardless of their race or ethnicity or where they live, have the opportunity for good health and are protected during a health emergency.

TFAH has called on the administration and Congress to make advancing health equity and eliminating health disparities a national priority by:

- Ensuring that all COVID-19 response actions prioritize advancing health equity, including access to COVID-19 testing and vaccinations.
- Creating a Truth, Racial Healing, and Transformation Commission, and provide funding to communities to begin the process of acknowledging a history of racism and working to dismantle the myth of hierarchy based on race.
- Expanding funding for initiatives serving communities that have been marginalized by disinvestment, and ensure that federal funding supports processes that meaningfully engage the most affected communities in the planning and implementation of such initiatives.
- Developing a White House led strategy focused on addressing the root causes of disease and on promoting health equity.
- Creating a *social determinants of health* line item at the Centers for Disease Control and Prevention (CDC), authorized and fully funded by Congress, with sufficient funding to guarantee grant-funded efforts throughout the nation.
- Requiring all agencies to collect, disaggregate, and report health data in such a way that the impact of health conditions, policies, or interventions on specific population groups are known, including health status data by race, ethnicity, sexual orientation, gender identity, primary language, and disability status.

The tragedy of the COVID-19 pandemic, including over 500,000 deaths in the United States (as this publication was being prepared) and unprecedented harm to the economic security of millions of American families, will forever be a painful reminder of the critical importance of pre-event public health emergency preparations, investments in public health infrastructure, and evidence-based policy and communications. The pandemic has undeniably demonstrated that historical discrimination coupled with current-day racism impacts a community's health status and ability to weather a disaster. The COVID-19 crisis has also painfully reinforced that national leadership must be grounded in science and committed to addressing structural racism, both of which are imperative to saving lives during an emergency.

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This edition of the *Ready or Not series* finds that states have made progress in most of the report's measured areas, especially rates of seasonal flu vaccination. However, improvement in other areas—such as paid time off for workers and hospital patient safety—has stalled. In this 2021 report, Trust for America's Health (TFAH) found that three states improved their standing compared with last year, while eight fell behind. Three states improved by one tier, six states dropped one tier, and two dropped two tiers.

TABLE 1: Top-Priority Indicators of State Public Health Preparedness

INDICATORS			
1	**Incident Management:** Adoption of the Nurse Licensure Compact.	6	**Water Security:** Percentage of the population that used a community water system that failed to meet all applicable health-based standards.
2	**Cross-Sector Community Collaboration:** Percentage of hospitals participating in healthcare coalitions.	7	**Workforce Resiliency and Infection Control:** Percentage of employed population that used paid time off.
3	**Institutional Quality:** Accreditation by the Public Health Accreditation Board.	8	**Countermeasure Utilization:** Percentage of people ages 6 months or older who received a seasonal flu vaccination.
4	**Institutional Quality:** Accreditation by the Emergency Management Accreditation Program.	9	**Patient Safety:** Percentage of hospitals with a top-quality ranking ("A" grade) on the Leapfrog Hospital Safety Grade.
5	**Institutional Quality:** Size of the state public health budget compared with the past year.	10	**Health Security Surveillance:** The public health laboratory has a plan for a six- to eight-week surge in testing capacity.

Notes: The National Council of State Boards of Nursing organizes the Nurse Licensure Compact. The federal Hospital Preparedness Program of the U.S. Office of the Assistant Secretary for Preparedness and Response supports healthcare coalitions. The U.S. Environmental Protection Agency assesses community water systems. Paid time off includes sick leave, vacation time, or holidays, among other types of leave. The Leapfrog Group is an independent nonprofit organization. TFAH drew every indicator, and some categorical descriptions, from the National Health Security Preparedness Index, with one exception: public health funding. See "Appendix A: Methodology" for a description of TFAH's funding data-collection process, including its definition.

Source: National Health Security Preparedness Index [9]

The *Ready or Not* report groups states and the District of Columbia into one of three tiers (high, middle, low) based on their performances across the 10 indicators. This year, 20 states and the District of Columbia scored in the high-performance tier, 15 placed in the middle-performance tier, and 15 were in the low-performance tier (see Table 2). (See "Appendix A: Methodology" for more information on the scoring process.)

Three states showed notable improvement, moving up a tier: Georgia, Montana, and Rhode Island. Georgia, which rose from the middle tier to the high tier, improved its standing by achieving accreditation by the Emergency Management Accreditation Program and by having a greater share of its hospitals receive high marks on patient safety. Montana, which elevated from the low tier to the middle tier, increased its public health funding level in fiscal year 2020. And Rhode Island, which rose from the middle tier to the high tier, did so by dramatically increasing its community drinking-water security.

Two states fell from the high tier to the low tier: Missouri and Pennsylvania. Missouri cut its public health funding in FY 2020 and saw an increase in the share of its residents that used a community water system with one or more health-based violations. Its flu vaccination rate ticked up marginally, but by less than the nation as a whole. Likewise, Pennsylvania also cut its public health funding level, and its share of hospitals that received an "A" rating—one of the highest in the nation—rose by slightly less than the national average. Other steps it could take to improve its standing include joining the Nurse Licensure Compact or increasing its below-average share of residents who take paid time off from work.

Five states fell from the high tier to the middle tier: Alabama, Illinois, Iowa, New Jersey, and Tennessee. These states did not experience significant backsliding overall, but they lost ground, as a number of other states took greater steps that increased their standing.

One state fell from the middle tier to the low tier: Arizona. Arizona's below-average flu vaccination rate rose, but by less than the nation overall, so its overall standing fell back.

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TABLE 2: State Public Health Emergency Preparedness State performance, by scoring tier, 2020		
Performance Tier	**States**	**Number of States**
High Tier	CO, CT, DC, DE, GA, ID, KS, MA, MD, ME, MS, NC, NE, NM, OK, RI, UT, VA, VT, WA, WI	20 states and DC
Middle Tier	AL, CA, FL, IA, IL, KY, LA, MI, MN, MT, ND, NJ, OR, TN, TX	15 states
Low Tier	AK, AR, AZ, HI, IN, MO, NH, NV, NY, OH, PA, SC, SD, WV, WY	15 states

Note: See "Appendix A: Methodology" for scoring details. Complete data were not available for U.S. territories.

TFAH's Analysis Found:

A majority of states have made preparations to expand healthcare and public health capabilities in an emergency, often through collaboration. Thirty-four states participated in the Nurse Licensure Compact, up from 26 in 2017,[10] with Indiana and New Jersey being the most recent adopters.[11] The compact allows registered nurses and licensed practical or vocational nurses to practice in multiple jurisdictions with a single license. In an emergency, this enables health officials to quickly increase their staffing levels. For example, nurses may cross state lines to work at evacuation sites or other healthcare facilities. In addition, **hospitals in most states have a high degree of participation in healthcare coalitions.** On average, 89 percent of hospitals were in a coalition, and 17 states and the District of Columbia had universal participation, meaning every hospital in the jurisdiction was part of a coalition. Such coalitions bring hospitals and other healthcare facilities together with emergency management and public health officials to plan for and respond to incidents or events requiring extraordinary action. This increases the likelihood that providers serve patients in a coordinated and efficient manner during an emergency. What's more, **every state had public health laboratories that had plans for how to manage a large influx of testing needs.** States had a plan to surge public health laboratory capacity for six to eight weeks as necessary during overlapping emergencies or large outbreaks, an increase of six states since 2017.

Most states are accredited in the areas of public health, emergency management, or both. As of December 2020, the Public Health Accreditation Board (PHAB) or the Emergency Management Accreditation Program (EMAP) accredited 42 states and the District of Columbia; 29 states and the District of Columbia were accredited by both groups, a net increase of one since November 2019. (EMAP has now accredited Delaware and Georgia; Maryland transitioned from being accredited by both bodies to the PHAB only, with the EMAP providing conditional accreditation.) Eight states (Alaska, Hawaii, Indiana, New Hampshire, South Dakota, Texas, West Virginia, and Wyoming) were not accredited by either group. Both programs help ensure that necessary emergency prevention and response systems are in place and staffed by qualified personnel.

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Seasonal flu vaccination rates, while still too low, have risen significantly. The seasonal flu vaccination rate among Americans ages 6 months or older rose from 42 percent during the 2017–2018 season to 52 percent during the 2019–2020 season.[12] However, *Healthy People 2030*, a set of federal 10-year objectives and benchmarks for improving the health of all Americans by 2030, set a seasonal influenza vaccination-rate target of 70 percent annually.[13]

In 2019, only 55 percent of employed state residents, on average, used paid time off, the same percentage as in 2018. Those without paid leave are more likely to work when they are sick and risk spreading infection. In the past, the absence of dedicated paid sick leave has been linked to or has exacerbated some infectious disease outbreaks.[14] This became particularly relevant during the COVID-19 pandemic, as isolation and quarantine were important tools for controlling the outbreak. The Families First Coronavirus Response Act helped address this issue during the early stages of the pandemic for employers with fewer than 500 employees and certain public employers, temporarily requiring employees to be paid up to 80 hours of sick leave benefits under certain conditions.[15] In January 2021, the Biden administration economic stimulus package proposal included extending paid sick leave to over 100 million U.S. workers.

Only 31 percent of hospitals, on average, earned a top-quality patient safety grade, up slightly from 30 percent in 2019. Hospital safety scores measure performance on such issues as healthcare-associated infection rates, intensive-care capacity, and an overall culture of error prevention. In January 2021, the Biden administration's economic aid package included extending paid sick leave to over 100 million U.S. workers.

Most residents who received their household water through a community water system had access to safe water. On average, just 5 percent of state residents used a community water system in 2019 (latest available data) that did not meet all applicable health-based standards, down slightly from 7 percent in 2018. Water systems with such violations increase the chances of water-based emergencies in which contaminated water supplies place the public at risk.

Based on its policy research and analysis, consultation with experts, and review of progress and gaps in federal and state preparedness—with a particular focus on the preparation gaps and shortfalls identified by the COVID-19 pandemic—**TFAH is recommending policy action in seven priority areas:**

1. **Provide stable, sufficient funding for domestic and global public health security.**
2. **Strengthen policies and systems to prevent and respond to outbreaks and pandemics.**
3. **Build resilient communities and promote health equity generally and in preparedness.**
4. **Ensure effective public health leadership, coordination, and workforce.**
5. **Accelerate development and distribution, including last-mile distribution, of medical countermeasures.**
6. **Strengthen the healthcare system's ability to respond to and recovery from health emergencies.**
7. **Prepare for environmental threats and extreme weather.**

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Report Purpose and Methodology

TFAH's annual *Ready or Not* report series tracks states' readiness for public health emergencies based on 10 key indicators that collectively provide a checklist of top-priority issues and action items for states and localities to continuously address. By gathering together timely data on all 50 states and the District of Columbia, the report assists states in benchmarking their performance against comparable jurisdictions. TFAH completed this research after consultation with a diverse group of subject-matter experts and practitioners.

Ready or Not and the National Health Security Preparedness Index

The indicators included in this report were drawn from, and identified in partnership with, the National Health Security Preparedness Index (NHSPI),[16] with one exception: a measure of state public health funding-level trends, which reflects how well-resourced key agencies are to prepare and respond to emergencies. The NHSPI is a joint initiative of the Robert Wood Johnson Foundation, the University of Kentucky, and the University of Colorado. (See "Appendix A: Methodology" for a detailed description of how TFAH selected and scored the indicators.)

While state placements in *Ready or Not* and the NHSPI largely align, there are some important differences. The two projects have somewhat different purposes and are meant to be complementary, rather than duplicative. With more than 100 indicators, the Index paints a broad picture of national health security, allowing users to zoom out and holistically understand the extent of both individual states' and the entire nation's preparedness for large-scale public health threats. In slight contrast, *Ready or Not,* with its focus on 10 select indicators, focuses attention on state performances on a subset of the Index and spotlights important areas for stakeholders to prioritize. TFAH and the NHSPI work together to help federal, state, and local officials use data and findings from each project to make Americans safer and healthier.

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Earning Vaccine Confidence in Communities of Color

Interview with Claude A. Jacob, Dr.PH(c), MPH, the chief public health officer at the Cambridge, Massachusetts, Public Health Department, and **Maria Lemus,** the executive director of Visión y Compromiso, about barriers—both historic and contemporary—to COVID-19 vaccinations within communities of color. This interview was conducted in December 2020.

TFAH: As this report is being finalized, the United States is nearing a time when many Americans, particularly those at the highest risk of infection or the most serious impact if infected, can be vaccinated. What are the barriers to high rates of vaccination in communities of color and among Tribal nations?

Dr. Jacob: We are fortunate in Cambridge. Flu vaccine participation is strong and childhood vaccine compliance is also very high, which we view as rough proxies for COVID-19 vaccine acceptance. That being said, there is a long and sordid history of abuse and mistreatment of these communities by the U.S. government and healthcare system. That many Black and Brown people continue to feel deep mistrust of the healthcare system is understandable. All of us in healthcare and public health must understand that this mistrust goes back to slavery for Black Americans and the genocide perpetuated against indigenous people that lasted for centuries.

We have strong relationships with community organizations, leaders in the faith community, and others who are well known and trusted among communities of color, and we will partner with them to overcome these barriers to vaccine uptake. Recent national and state surveys have told us that Americans view their personal physician as the most trusted voice on COVID-19. Given this finding, we plan to work closely with our hospitals, ambulatory sites, and healthcare providers to help spread the message.

Ms. Lemus: There are many barriers. The ones I'm most concerned about are myths and misinformation, including crazy social media propaganda, fear of adverse reactions, and problems with vaccine accessibility. High rates of the uninsured among some populations groups and misconceptions about who is at risk are additional concerns.

TFAH: The pace of COVID-19 vaccines development has been quicker than many people expected. In some communities this may mean that the vaccine will be available before communications programs about the vaccine's safety and availability have fully taken root. What do those responsible for vaccine distribution need to do when distributing the vaccine under these circumstances?

Dr. Jacob: First of all, we need to celebrate the news that, so far, two vaccines have received FDA emergency use authorization. That two vaccines were developed, tested, and manufactured in less than 12 months is a breathtaking achievement. While we can't let down our guard on physical distancing, wearing masks,

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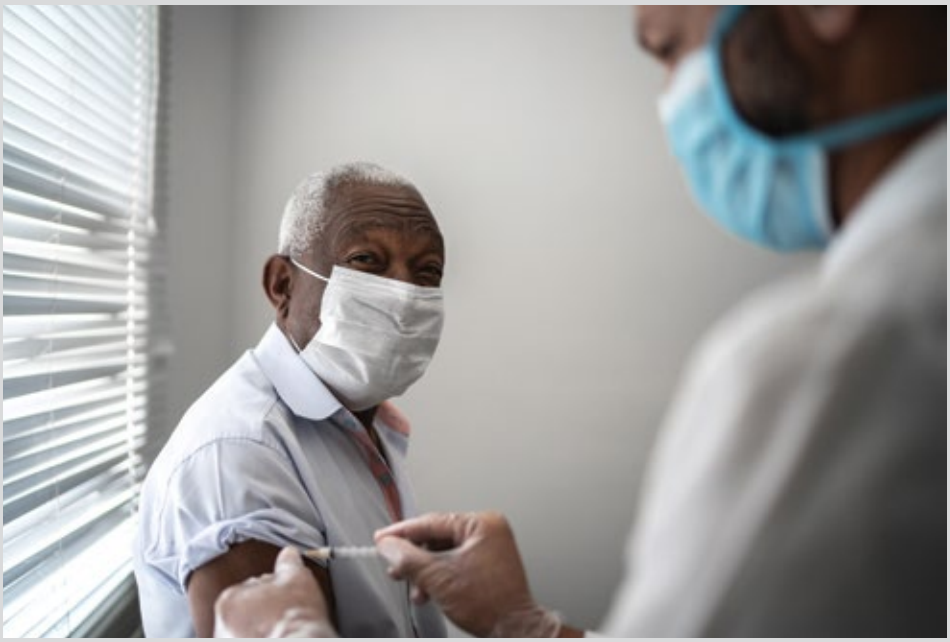
and continuing to practice good hand hygiene, the COVID-19 vaccine marks a watershed moment in the pandemic. We now see the light at the end of the tunnel. At the same time, it's understandable that people have many questions and deep concerns given how quickly the vaccine was developed and approved. For communities of color, the concern over safety comes with a long-standing, entrenched, and well-placed mistrust of the healthcare system.

Communication will be pivotal in educating everyone, especially communities of color, about the safety and importance of this vaccine. To start, we need to have communities of color and physicians of color at the decision-making table to inform and ensure a vaccine rollout that is equitable for all members of our community. Messaging around the vaccine also needs to be informed by, and tested with, communities of color to make sure that these communication efforts resonate. We have a superb opportunity to work with those on the front line of this pandemic, especially doctors, nurses, and physicians' assistants, to help amplify the message in core communities. By all accounts, frontline medical workers are the most trusted source of health information and they are the first to be vaccinated, starting this past December. We should use their voices of trust and reason to speak to communities of color about the safety and critical importance of getting this vaccine.

Ms. Lemus: It will be imperative to share data about the vaccine without jargon and to have trusted messengers deliver the information. I heard a quote recently in response to the question, "Do you know what's in Tylenol?": "No, but I trust it will help me."



TFAH: A woeful history of mistreatment of people of color by government and the healthcare system is at the root of much of the lack of trust in the COVID-19 vaccine within those communities but there are other barriers to vaccine access. What are they and how can they be overcome?

Ms. Lemus: The understandable distrust of government is going to be a huge barrier to the vaccine. A specific example for my community is the Bracero Program, which between 1942 and 1964, based on a series of bilateral agreements between the U.S. and Mexican governments, brought nearly 4.6 million Mexican citizens to work on U.S. farms, railroads, and factories. Those workers experienced racial and wage discrimination and were forced to live and work in substandard conditions. More recently, there have been allegations of unnecessary hysterectomies being performed in ICE detention centers.

The only way to overcome these histories will be to first acknowledge them. Leaders must acknowledge and speak to these injustices; they must denounce them and support remedies. They need to give real-time examples of the efforts being made to engage with and empower communities and to correct past wrongs. Only then will government be able to be heard and only by using trusted messengers and community navigators.

It's also important to remember that the reasons for distrust of government within underrepresented communities is not only about historical legacies; it is based on current-day events and climates. However, it can be corrected. My organization, Visión y Compromiso, has as its mission providing leadership-development and capacity-building opportunities for *promotores* and community health workers in over 4,000 communities. These community-based *promotores* will have a critical role to play in reducing vaccine hesitancy in communities of color. Messaging to convince people to be vaccinated has to feature their heroes, their community leaders, their voices.

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Dr. Jacob: Communities of color have historically had difficulty accessing healthcare. Lack of transportation, work schedules, childcare needs, and competing financial interests—such as paying rent and bills—pose significant barriers to healthcare, as do other social determinants of health, such as poverty and lack of education. Even with the Affordable Care Act—which greatly expanded access to health insurance for everyone—Hispanic, Black, and some Asian communities have lower insurance coverage rates than any other population. Many of them remain uninsured altogether.

The cost of the vaccine is being covered by the federal government through tax dollars, but providers can charge to administer the vaccine, if they choose. We need to do everything we can and work with providers to eliminate fees they may charge in the interest of overcoming this public health emergency. When it is available, we need to bring the vaccine to the public rather than making people come to the vaccine. In Cambridge, the public health department, through its partnership with the city's first-responders and others, have made free COVID-19 testing available to all residents (regardless of symptoms) since July 2020. Starting in November 2020, this "no-barrier," city-funded testing program expanded to seven days a week (from two days/week) and from two neighborhood sites to four. These testing sites are geographically dispersed, and all but one are located in neighborhoods with disproportionately high rates of new COVID-19 infections.

TFAH: What is the importance of where the COVID-19 vaccine is available in your community?

Ms. Lemus: Where the vaccine will be available is another critical issue. The credibility, location, hours, accessibility, relationship to community, their staff, and emissaries are important to individual and families' decision to be vaccinated. *Promotores* are important also in gathering information to contribute to the vaccine distribution and administration, planning implementation, and communications. Community-based organizations must be included in all planning and execution; they are a big part of the solution. Partnering with community-based organizations allows local officials to scale means and resources.

Dr. Jacob: As I have already mentioned, the Cambridge Public Health Department has had enormous success with COVID-19 testing and flu vaccinations by bringing these services to people in the communities where they live and work. We have taken a traditional grassroots approach—going door to door in harder-hit neighborhoods and providing information in eight languages—to build trust and understanding. We need to use this same approach with the COVID-19 vaccine and build on these robust community linkages, which are anchored to the long-standing relationships that we have with partners on the ground.

TFAH: As the chief public health officer for the city of Cambridge, Massachusetts, what is your department's role in increasing vaccine uptake in your community? What resources do you need to be successful?

Dr. Jacob: Local public health has an important role and responsibility in educating communities about the safety and importance of the COVID-19 vaccine, as it does with all vaccinations. Once the vaccine is made available to the general public, the Cambridge Public Health Department, through its partnership with city agencies and the private sector, will be ready to provide vaccines to residents. Throughout the pandemic, our department has worked hand in hand with city partners, especially first-responders, to provide testing and flu shots, and we will rely on this strong, successful relationship to provide the COVID vaccine. It is critically important to note that we could not do our work without strong financial support. Our city manager, Louis A. DePasquale, and the Cambridge City Council have provided financial resources to fight this pandemic and keep our residents and those who work in Cambridge safe. They have long been committed to the important work of the public health department, which is enhanced by the Cambridge Health Alliance led by Dr. Assaad Sayah, who is the commissioner of public health for the city of Cambridge.

Dr. Claude A. Jacob is the chief public health officer for the City of Cambridge, Massachusetts. He served as the president of the National Association of City and County Health Officials in 2016–2017.

Maria Lemus is the executive director of Visión y Compromiso, headquartered in San Francisco, California. Visión y Compromiso provides leadership, advocacy, and capacity-development training to community health workers.

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Assessing State Preparedness

Every state needs to be prepared to respond to a variety of potential public health emergencies; such readiness requires understanding an individual state's preparedness strengths, risks, and vulnerabilities. To help states assess their readiness, and to highlight a checklist of top-priority concerns and action areas, this report examines a set of 10 select indicators. The indicators, used consistently year to year, draw heavily from the National Health Security Preparedness Index (NHSPI), a joint initiative of the Robert Wood Johnson Foundation, the University of Kentucky, and the University of Colorado. They capture core elements of emergency preparedness.

Based on states' standing across the 10 indicators (see "Appendix A: Methodology" for scoring details), TFAH placed states into three performance tiers: high, middle, and low. (See Table 3.)

TABLE 3: State Public Health Emergency Preparedness
State performance, by scoring tier, 2020

Performance Tier	States	Number of States
High Tier	CO, CT, DC, DE, GA, ID, KS, MA, MD, ME, MS, NC, NE, NM, OK, RI, UT, VA, VT, WA, WI	20 states and DC
Middle Tier	AL, CA, FL, IA, IL, KY, LA, MI, MN, MT, ND, NJ, OR, TN, TX	15 states
Low Tier	AK, AR, AZ, HI, IN, MO, NH, NV, NY, OH, PA, SC, SD, WV, WY	15 states

Note: See "Appendix A: Methodology" for scoring details. Complete data were not available for U.S. territories.

Importantly, the implications of this assessment, and responsibility for continuously improving, extend beyond any one state or local agency. Such improvement typically requires sustained engagement and coordination by a broad range of policymakers and administrators. Moreover, some indicators are under the direct control of federal and state lawmakers, whereas improvement in other indicators requires multisector, statewide efforts, including by residents.

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INDICATOR 1: ADOPTION OF NURSE LICENSURE COMPACT

KEY FINDING: 34 states participate in the Nurse Licensure Compact.

Workforce shortages can impair a state's ability to effectively manage disasters or disease outbreaks, potentially resulting in poorer health outcomes for those affected. This reality was starkly illuminated by the COVID-19 pandemic as healthcare capacity in some parts of the country was overwhelmed by the number of people needing care. In an event like a pandemic, the ability to quickly surge qualified medical personnel by bringing healthcare workers from out of state is a key component of healthcare readiness.

This indicator examines whether states have adopted legislation to participate in the Nurse Licensure Compact (NLC). Launched in 2000 by the National Council of State Boards of Nursing, the NLC permits registered nurses and licensed practical nurses to practice with a single multistate license—physically or remotely—in any state that has joined the compact. The NLC provides standing reciprocity, with no requirement that an emergency be formally declared.

Throughout much of 2020, the COVID-19 pandemic placed extraordinary pressure on hospitals across the country as surging infections sent admissions soaring. States that were members of the NLC were well positioned to bring in nurses from other member states, without harmful delays, or to send nurses to other member states that were experiencing acute shortages. For example, New Jersey, which experienced one of the most severe outbreaks in spring 2020, began implementing the NLC, immediately qualifying out-of-state nurses with a multistate license to practice.[17] "I think the COVID-19 outbreak is going to cause the states that are not in the compact now to really take a second look at it," says NLC Director Jim Puente. "If the NLC was expanded to all 50 states, none of the guesswork with emergency orders would be necessary because nurses could travel to other states where they are needed. No applications, fees, or background checks would be necessary."

As of December 2020, 34 states had adopted the NLC, with Indiana and New Jersey being the most recent adopters.[18] This was a net increase of two since 2019 and eight since 2017. Toni Herron, the education compliance officer of the Indiana State Board of Nursing, which joined the compact on July 1, 2020, said that the NLC "presents innovative ways for our Indiana nurses to improve both access to care for patients, while simultaneously reducing the regulatory burden on licensees." [19]

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TABLE 4: 34 States Participate in the Nurse Licensure Compact

Participants and nonparticipants, 2020

Participants			Nonparticipants	
Alabama	Louisiana	North Dakota	Alaska	Nevada
Arizona	Maine	Oklahoma	California	New York
Arkansas	Maryland	South Carolina	Connecticut	Ohio
Colorado	Mississippi	South Dakota	District of Columbia	Oregon
Delaware	Missouri	Tennessee	Hawaii	Pennsylvania
Florida	Montana	Texas	Illinois	Rhode Island
Georgia	Nebraska	Utah	Massachusetts	Vermont
Idaho	New Hampshire	Virginia	Michigan	Washington
Indiana	New Jersey	West Virginia	Minnesota	
Iowa	New Mexico	Wisconsin		
Kansas	North Carolina	Wyoming		
Kentucky				

Note: Indiana and New Jersey joined the NLC in 2020.

Source: National Council of State Boards of Nursing.[20]

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INDICATOR 2: HOSPITAL PARTICIPATION IN HEALTHCARE COALITIONS

KEY FINDING: Widespread hospital participation in healthcare coalitions was common in 2017*; only four states (California, New Hampshire, Ohio, and South Carolina) reported 70 percent or less of their hospitals participated in coalitions supported by the HHS Hospital Preparedness Program.

The federal Hospital Preparedness Program (HPP), which is managed by the HHS Office of the Assistant Secretary for Preparedness and Response, provides cooperative agreements to states, localities, and territories to develop regional coalitions of healthcare organizations that collaborate to prepare for, and in many cases respond to, medical surge events.[21] Coalitions prepare members with critical tools, including medical equipment and supplies, real-time information, enhanced communication systems, and exercises and training for healthcare personnel.[22] A healthcare coalition must contain a minimum of two acute-care hospitals, emergency medical services, emergency management, and public health agencies.[23] Healthcare coalitions invest in local capacity to prepare for and respond to events, reducing jurisdictions' reliance on federal medical assets during disasters.

Broad and meaningful participation by hospitals in healthcare coalitions means that when disaster strikes, systems are in place to coordinate the response, freeing hospitals to focus on clinical care. In the past, healthcare coalitions have assisted in patient transfer, evacuations, and information sharing in events such as Hurricane Harvey in 2017.[24] More recently, the COVID-19 pandemic presented the most intense, widespread, and prolonged test of U.S. hospital systems in a century, threatening at several points to overwhelm facilities' capacities. Healthcare coalitions performed roles such as facilitating the transport of equipment and supplies, sharing information about available beds and ICU capacity, and training healthcare workers on PPE use, treatments, and testing guidelines.[25] During a pandemic, coordination across a region is essential to alleviate pressure on any single facility, to promote cooperation and information sharing for supplies and bed availability, and to facilitate training of healthcare personnel.[26] The extent to which healthcare systems leveraged the resources of their coalitions during the pandemic is a subject that requires further research.

On average, 89 percent of hospitals in states belonged to a healthcare coalition in 2017, with universal participation, meaning every hospital in the state was part of a coalition, in 17 states (Alaska, Colorado, Connecticut, Delaware, Hawaii, Louisiana, Minnesota, Mississippi, Nevada, North Dakota, Oregon, Rhode Island, South Dakota, Utah, Vermont, Virginia, and Washington) and the District of Columbia. (See Table 5.) However, some states, such as Ohio (25 percent) and New Hampshire (47 percent) lagged behind.

The pandemic exposed major gaps in healthcare preparedness, mentioned in TFAH's 2020 report, including coordinating surge capacity across the healthcare system;[27] building and maintaining preparedness for high-consequence infectious diseases;[28] preparedness of facilities that serve people at higher risk, such as long-term care facilities; and lack of training and preparedness for events in healthcare.[29] Experts have also identified additional gaps, such as pediatric surge capacity,[30] burn capacity and other specialty

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care needed for emerging threats, and ongoing stress on the healthcare system's ability to provide emergency care. While healthcare coalitions can help address some of these vulnerabilities, systemwide approaches to preparedness are needed.

**This summary reflects the latest available data (2017). Because these data are no longer being updated, TFAH will consider replacing this measure in future assessments.*

TABLE 5: Widespread Participation of Hospitals in Healthcare Coalitions

Percent of hospitals participating in healthcare coalitions, 2017

States	Percent of Participating Hospitals
AK, CO, CT, DC, DE, HI, LA, MN, MS, NV, ND, OR, RI, SD, UT, VT, VA, WA	100%
ID, WI	98%
GA, WV	97%
KS	96%
AL, NE, NC, OK	95%
ME	94%
KY	93%
WY	92%
TN	91%
MI	90%
MD	89%
IL	88%
MO	87%
NY, PA	86%
MT	83%
MA, NJ	82%
AR	81%
IA, TX	80%
IN	75%
FL	73%
AZ	72%
NM	71%
CA	70%
SC	56%
NH	47%
OH	25%

Note: This indicator measures participation by hospitals in healthcare coalitions supported through the federal Hospital Preparedness Program of the Office of the Assistant Secretary for Preparedness and Response. The latest available data is from 2017.

Source: NHSPI analysis of data from the Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.[31]

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INDICATORS 3 AND 4: ACCREDITATION

KEY FINDING: Most states are accredited by one or both of two well-regarded bodies—the Public Health Accreditation Board and the Emergency Management Accreditation Program—but eight are not accredited by either.

The Public Health Accreditation Board (PHAB), a nonprofit organization that administers the national public health accreditation program, advances quality within public health departments by providing a framework and a set of evidence-based standards against which they can measure their performance. Among standards with direct relevance to emergency preparedness are assurances of laboratory, epidemiologic, and environmental expertise to investigate and contain serious public health problems, policies, and procedures for urgent communications and maintenance of an all-hazards emergency operations plan.[32] Through the process of accreditation, health departments identify their strengths and weaknesses, increase their accountability and transparency, and improve their management processes, which all promote continuous quality improvement.[33]

Emergency management, as defined by the Emergency Management Accreditation Program (EMAP), encompasses all organizations in a given jurisdiction with emergency or disaster functions, which may include prevention, mitigation, preparedness, response, and recovery. The EMAP helps applicants ensure—through self-assessment, documentation, and peer review—that they meet national standards for emergency response capabilities.[34]

The PHAB and the EMAP each provide important mechanisms for improving evaluation and accountability. Accreditation by these entities demonstrates that a state's public health and emergency management systems are capable of effectively responding to a range of health threats. The priority capabilities that the PHAB and the EMAP test include identification, investigation, and mitigation of health hazards; a robust and competent workforce; incident, resource, and logistics management; and communications and community-engagement plans.[35,36] States sometimes aim to meet applicable standards but do not pursue accreditation.

As of December 2020, 29 states and the District of Columbia were accredited by both the PHAB and the EMAP—a net increase of one (Delaware and Georgia are now accredited by the EMAP; Maryland transitioned from being accredited by both bodies to the PHAB only, with the EMAP providing conditional accreditation) since November 2019. Nevada is once again accredited by the EMAP, alongside an additional 12 states that have received accreditation from one or the other. (See Table 6.) "Over the last eighteen months we have worked diligently to review our processes, plans, and relationships," said the director of Delaware's Emergency Management Agency, A.J. Schall. "Over that time, we learned a tremendous amount and modernized procedures."[37]

Just eight states (Alaska, Hawaii, Indiana, New Hampshire, South Dakota, Texas, West Virginia, and Wyoming) received no accreditation from either body. A state without an accreditation has not necessarily been denied accreditation; the state may not have pursued accreditation. This analysis includes state-level accreditations only, it does not include accredited local or tribal health departments. In some instances, local public health departments have an accreditation in states that do not.

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TABLE 6: 42 States and the District of Columbia Accredited by the PHAB and/or EMAP

Accreditation status by state, December 2020

PHAB and EMAP			PHAB only	EMAP only	No Accreditation
Alabama	Idaho	New Mexico	Maine	Kentucky	Alaska
Arizona	Illinois	New York	Maryland	Michigan	Hawaii
Arkansas	Iowa	North Dakota	Minnesota	Nevada	Indiana
California	Kansas	Ohio	Montana	North Carolina	New Hampshire
Colorado	Louisiana	Oklahoma	Oregon	South Carolina	South Dakota
Connecticut	Massachusetts	Pennsylvania	Washington	Tennessee	Texas
Delaware	Mississippi	Rhode Island		Virginia	West Virginia
District of Columbia	Missouri	Utah			Wyoming
Florida	Nebraska	Vermont			
Georgia	New Jersey	Wisconsin			
29 states + DC			**6 states**	**7 states**	**8 states**

Note: These indicators track accreditation by the PHAB and the EMAP. TFAH classified states with conditional or pending accreditation at the time of data collection as having no accreditation. States sometimes aim to meet applicable standards but do not pursue accreditation.

Sources: NHSPI analysis of data from the PHAB and the EMAP.[38]

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INDICATOR 5: STATE PUBLIC HEALTH FUNDING TRENDS

Key Finding: Most states held their public health funding steady or increased it in FY 2020, but seven reduced funding.

The COVID-19 pandemic showed how sufficient and sustained funding for a comprehensive public health system is integral to preparedness and response, including the ability to detect, prevent, and control disease outbreaks and mitigate the health consequences of disasters. General public health capabilities—such as those pertaining to epidemiology, environmental hazard detection and control, infectious disease prevention and control, and risk communications—and targeted emergency response resources are necessary to ensure that officials maintain routine capabilities and that surge capacity is readily available for emergencies. A trained and standing public health workforce, and one that knows its community, is critical to the surge capacity that is so often necessary during an emergency.

According to the Public Health Activities and Services Tracking project at the University of Washington, state public health programming and services span six core areas:[39]

1. **Communicable disease control.** Public health services related to communicable disease epidemiology, hepatitis, HIV/AIDS, immunization, sexually transmitted diseases, tuberculosis, etc.
2. **Chronic disease prevention.** Public health services related to asthma, cancer, cardiovascular disease, diabetes, obesity, tobacco, etc.
3. **Injury prevention.** Public health services related to firearms, motor vehicles, occupational injuries, senior fall prevention, substance-use disorder, other intentional and unintentional injuries, etc.
4. **Environmental public health.** Public health services related to air and water quality, fish and shellfish, food safety, hazardous substances and sites, lead, onsite wastewater, solid and hazardous waste, zoonotic diseases, etc.
5. **Maternal, child, and family health.** Public health services related to the coordination of services; direct service; family planning; newborn screening; population-based maternal, child, and family health; supplemental nutrition; etc.
6. **Access to and linkage with clinical care.** Public health services related to beneficiary eligibility determination, provider or facility licensing, etc.

The overall infrastructure of public health supports states' ability to promote health equity, build resilience in the population, and carry out emergency response activities. But public health funding is typically discretionary, making it vulnerable to neglect or retrenchment, especially when times are tight. This can undermine emergency preparedness activities and weaken response and recovery efforts. State investment in public health is important for the operations of health agencies: about 28 percent of state and territorial health department revenues are from state sources,[40] while 21 percent of local health department revenue is from state sources, on average.[41]

Fortunately, 43 states and the District of Columbia maintained or increased public health funding in FY 2020. (See Table 7.) But seven states reduced the money they directed to these vital activities, increasing the likelihood that they will be less prepared and less responsive in the moments that matter most. (This indicator does not assess the adequacy of states' public health funding. It should also be noted that due to inflation and population growth, stable funding is in some cases a funding reduction.) The COVID-19 economic recession has already had a severe impact on state revenue,[42] which could constrain state public health funding levels over the coming years.

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TABLE 7: State Public Health Funding Held Stable or Increased in 43 states and DC

Public Health Funding, by state FY 2019 – 2020

State	Percentage Change
Alabama	-4%
Alaska	118%
Arizona	52%
Arkansas	-2%
California	40%
Colorado	9%
Connecticut	8%
Delaware	8%
District of Columbia	2%
Florida	8%
Georgia	3%
Hawaii	-2%
Idaho	2%
Illinois	7%
Indiana	0%
Iowa	-3%
Kansas	13%
Kentucky	1%
Louisiana	3%
Maine	24%
Maryland	4%
Massachusetts	4%
Michigan	14%
Minnesota	78%
Mississippi	2%
Missouri	-1%
Montana	2%
Nebraska	7%
Nevada	15%
New Hampshire	11%
New Jersey	2%
New Mexico	8%
New York	0.3%
North Carolina	2%
North Dakota	31%
Ohio	13%
Oklahoma	29%
Oregon	0.5%
Pennsylvania	-0.4%
Rhode Island	3%
South Carolina	3%
South Dakota	2%
Tennessee	9%
Texas	28%
Utah	9%
Vermont	7%
Virginia	-6%
Washington	6%
West Virginia	6%
Wisconsin	2%
Wyoming	8%

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Note: While states received federal one-time COVID response funding, those funds are not included in these tallies, as all federal funds are excluded from this measure. However, in some cases, state funding for pandemic response may have been included in the data reported to TFAH. For some states, COVID response funding may have resulted in an increase in the state's overall public health expenditure for the year. Other states may have reallocated money from one line to another with little impact on the overall funding level.

Owing to differences in organizational responsibilities and budgeting, funding data are not necessarily comparable across states. See "Appendix A: Methodology" for a description of TFAH's data-collection process, including its definition of public health funding.

Source: TFAH analysis of states' publicly available funding data.

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INDICATOR 6: COMMUNITY WATER SYSTEM SAFETY

KEY FINDING: Few Americans drink from community water systems that are in violation of applicable health-based standards required by the Safe Drinking Water Act. But room for improvement remains.

Access to safe water is essential for consumption, sanitation, and the efficient operation of the healthcare system. In the United States, the vast majority of the population gets water from a public water system,[43] and the U.S. Environmental Protection Agency (EPA) sets legal limits on contaminants in drinking water, including microorganisms, disinfectants, and their byproducts, chemicals, and radionuclides;[44] the EPA also requires states to periodically report drinking-water quality information.[45] Water systems must report any violations, such as failing to follow established monitoring and reporting schedules, failing to comply with mandated treatment techniques, violating any maximum contaminant levels, and failing to meet customer-notification requirements.[46]

The United States has one of the safest public drinking-water supplies in the world, but some communities, particularly low-income communities, struggle to maintain constant access to safe water. When water safety issues occur, it can require a multisector emergency response, as well as a long-term public health response. The most prominent water-contamination crisis in recent years occurred in Flint, Michigan, where a 2014 change in water supply caused distribution pipes to corrode and to leach lead and other contaminants into the drinking water. Tens of thousands of residents, including young children, were exposed to high levels of lead and other toxins.[47] In 2019, residents of Newark, New Jersey, had to rely on bottled water due to high levels of lead in their tap water.[48] In children, even low levels of lead exposure can damage the nervous system and contribute to developmental delays, learning disabilities, weight and hearing loss.[49] These incidents could have long-term consequences on the health and brain development of children, as well as the mental health and trust of the community.

As climate change contributes to more frequent wildfires, a residual danger is the release of toxic chemicals into community water systems. For example, months after the deadly Camp Fire in Paradise, California, in 2018, experts still advised residents not to drink or cook with the water due to concerns about benzene contamination.[50,51] Among the health effects of long-term exposure to unsafe levels of benzene is a decrease in red blood cells, which can lead to anemia. It can also cause excessive bleeding and can affect the immune system, increasing the chance for infection.[52]

Other water-related emergencies and concerns in the United States include harmful algal blooms,[53] which can impact human and animal health, the safety of seafood, damage the economies of affected communities, increase the presence of toxic chemicals like per- and polyfluoroalkyl substances (PFAS), and reduce the availability of clean water during power outages,[54] a particular concern in rural areas where smaller utilities may not have enough backup power to meet the demands of the water and sewage services. Water shortages can have a particularly dire impact on healthcare systems, which rely on clean water for many procedures and hygiene practices.

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New CDC data indicate waterborne pathogens cause nearly 7,000 deaths, seven million illnesses and more than $3 billion in healthcare costs each year. The risks around drinking water disproportionately threaten communities of color, highlighting the impact historical structural racism and continued institutional bias can have on a critical resource most Americans take for granted. In some areas, redlining has kept peri-urban communities of color, tribal lands and rural agricultural areas out of municipal water systems, thereby increasing their potential exposure to waterborne illness. In addition, older buildings are more vulnerable to waterborne pathogens in their pipes.[55]

According to the EPA, across the nation, 5 percent of state residents on average used a community water system in 2019 that failed to meet all applicable health-based standards, down from 7 percent in 2018. That share was 0 to 1 percent in Hawaii, Maryland, Minnesota, Nevada, North Dakota, Vermont, and Washington. (See Table 8.) But in four states (New Jersey, New York, Oregon, and West Virginia), more than 15 percent of residents used a community water system with health-based violations.

TABLE 8: Few Americans Used Contaminated Community Water Systems
Percent of state populations who used a community water system in violation of health-based standards, 2019

States	Percent of Population
HI, MD, MN, ND, NV, VT, WA	0%
CA, ID, IL, IN, ME, OH	1%
AL, CO, DE, MI, NC, NE, NH, WY	2%
CT, FL, SC, VA	3%
AK, IA, KY, RI, SD, TN, TX,	4%
AZ, DC, KS, UT, WI	5%
NM	6%
GA, MA	7%
AR, MS, MT	8%
MO, PA	9%
LA	13%
OK	15%
NJ, OR, WV	16%
NY	45%

Note: The EPA estimates that more than 13 million American households get their drinking water from private wells.[56] The data reported by this indicator do not reflect the water quality of those households. Only regulated contaminants are measured. These data do not include water safety on Indian reservations.

According to health officials in New York, a drinking water system in New York City is in violation because of an uncovered reservoir, but it has no current violations with respect to contaminants.

Source: NHSPI analysis of data from the EPA.[57]

INDICATOR 7: USE OF PAID TIME OFF

KEY FINDING: Just over half of workers in states, on average, used some type of paid time off—sick leave, vacation, holidays—in 2019. Most states were closely clustered to that midpoint, with few outliers.

Note: The specification of this indicator has been adjusted slightly from a measure of those who received paid time off to a measure of those who used it.

The need for paid time off was obvious during the pandemic, when frontline and essential workers—people who could not work from home during the outbreak—were often compelled to work when sick themselves or caring for a sick family member. Black and Hispanic workers typically have less access to paid sick leave and are overrepresented in groups of frontline workers.[58]

When workers without paid leave get sick, they face the choice of going to work and potentially infecting others or staying home and losing pay—or even their jobs. They encounter similarly impossible decisions when a child or another dependent family member gets sick. Therefore, access and the ability to use job-protected paid time off, especially dedicated paid sick leave, can strengthen infection control and resilience in communities by reducing the spread of contagious diseases and bolstering workers' financial security. This is particularly important for industries and occupations that require frequent contact with the public. For example, people working in food service, older adults and nursing care facilities and childcare commonly have no paid sick leave.[59] Low-wage workers[60] and workers of color are also less likely to have access to paid leave compared with white and higher-earning workers.[61] This often leads employees to work throughout an illness or return to work before their symptoms have fully subsided, when time off could have dramatically reduced the potential of workplace infections.[62,63]

The public health benefit is clear: at a societal level, flu rates have been shown to be lower in cities and states that mandate paid sick leave.[64,65] When employees who previously did not have access are granted paid or unpaid sick leave, rates of flu infections decrease.[66]

During the COVID-19 pandemic, studies consistently showed that access to paid sick leave helped slow the spread of the virus.[67] The Families First Coronavirus Response Act helped temporarily address this issue for employers with fewer than 500 employees and certain public employers, temporarily requiring employees to be paid sick leave benefits under certain conditions. This helped reduce the spread of the virus in workplaces and communities by removing a barrier to employees staying home when necessary. However, these protections expired on December 31, 2020, despite the ongoing need for the use of paid leave to control the pandemic; instead, Congress provided a tax credit for employers to offer paid sick leave.[68]

But many workers, particularly low-wage workers, did not have access to paid sick leave during the pandemic and were therefore left to make impossible choices between protecting their health and that of their family or protecting their financial security. State paid leave laws helped in a few jurisdictions. Beginning in March 2020, two states with existing state paid sick leave policies, California and Rhode Island, experienced large increases in temporary disability and family caregiving leave claims. California claims rose by 43 percent between February and March 2020.[69] Rhode Island claims nearly tripled between February and March 2020.[70] A January Biden administration proposal, if adopted by Congress, would provide paid leave to people who are: sick with

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Covid-19 symptoms; quarantining because of Covid-19 exposure; needing time off to get the vaccine; caring for family members who are sick with Covid-19 symptoms; caring for children whose school or day care center is closed because of the pandemic; caring for older relatives or adult dependents whose long-term care facility is closed because of the pandemic.[71]

Paid time off also increases access to preventive care among workers and their families, including routine checkups, screenings, and immunizations. Delaying or skipping such care can result in poor health outcomes and can ultimately lead to costlier treatments. Workers without paid sick days are less likely to get a flu shot, and their children are less likely to receive routine checkups, dental care, and flu shots.[72]

In 2019, 55 percent of workers in states, on average, took some type of paid time off—the same percentage as in 2018—according to the Current Population Survey, which is sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics.[73] Connecticut (64 percent), the District of Columbia (65 percent), Mississippi and Oregon (63 percent), and Texas (68 percent) stood out as states where relatively high percentages of workers used such benefits, whereas fewer workers used them in Arkansas (45 percent), South Carolina (45 percent), South Dakota (44 percent), Utah (45 percent), and Wyoming (47 percent).[74] (See Table 9.)

TABLE 9: 55 Percent of Workers, On Average, Used Paid Time Off
Percent of employed population that took paid time off, 2019

States	Percent of Workers
TX	68%
DC	65%
CT	64%
MS, OR	63%
MD, NM, NY	61%
AK, IA, WA	60%
GA, HI, MA	59%
MT, VA	58%
NE	57%
CA, CO, KS, RI, VT, WI	56%
AL, IL, NV, OK, WV	55%
FL, NH	54%
LA, MO, TN	53%
MN, NJ	52%
ID, IN, ME, NC, ND, PA	51%
MI, OH	49%
AZ, DE, KY	48%
WY	47%
AR, SC, UT	45%
SD	44%

Note: Paid time off includes sick leave, vacations, and holidays. The data are measured based on a survey of a sample of the general population. The specification of this indicator has been adjusted slightly from a measure of those who received paid time off to a measure of those who used it.

Source: NHSPI analysis of data from the Annual Social and Economic Supplement of the Current Population Survey.[75]

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INDICATOR 8: FLU VACCINATION RATE

KEY FINDING: Flu vaccination coverage rose for the second consecutive year during the 2019–2020 season, with a greater share of every age group analyzed receiving a vaccine. Overall, 52 percent of U.S. residents ages 6 months or older received vaccinations—still well below the overall target level of 70 percent of the population vaccinated annually.

The CDC recommends that, with few exceptions, everyone ages 6 months or older get vaccinated for seasonal influenza annually; yet, year after year, even with a steady increase among adults over the past three decades, coverage estimates indicate that just over half of Americans do.[76] *Healthy People 2030* set federal 10-year benchmarks for improving the health of all Americans, including an overall seasonal influenza vaccination-rate target of 70 percent annually.[77]

Vaccination is the long-standing best prevention against the seasonal flu, particularly for people at high risk of severe flu-related outcomes, including people with certain chronic health conditions and older adults, groups that are also at higher risk from COVID-19. In addition to protecting Americans from the seasonal flu, establishing a cultural norm of vaccination, building vaccination infrastructure, and establishing policies that support vaccinations can help prepare the country to vaccinate all Americans quickly during the pandemic. A major concern as the 2020–2021 flu season opened was that a high incidence of seasonal flu coupled with the amount of illness caused by the pandemic would overwhelm health systems. During 2021, as the country works to deliver the COVID-19 vaccine, seasonal flu vaccination programs provide important process lessons, networks, communications strategies, and goals for the COVID-19 vaccination effort.

Under the Affordable Care Act, all routine vaccines recommended by the Advisory Committee on Immunization Practices, including flu vaccines, are fully covered when provided by in-network providers, except in states that have not expanded their Medicaid programs in accordance with the act. Some barriers to flu vaccination may

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include a belief that the vaccine does not work very well; misconceptions about the safety of the vaccine;[78] or a belief that the flu does not carry serious risks.[79] State laws may also make it more difficult for parents to get their children vaccinated by a pharmacist, as some states do not allow children to get flu vaccines at a pharmacy and even more have age restrictions and/or require a physician's prescription.

During the 2019–2020 flu season, 52 percent of residents ages 6 months or older were vaccinated, according to the CDC, the highest rate in at least a decade. This was a notable uptick from 42 percent during the 2017–2018 flu season. One possible explanation is the increased awareness of the public, clinicians, and public health officials about the importance of vaccination, owing to the high number of illnesses and deaths two years prior. The major role that vaccination will play in the country's—and the world's—recovery from the extraordinarily deadly COVID-19 pandemic will, hopefully, make an indelible impression on all Americans about the value of vaccination.

Across the country, states have taken noteworthy actions to vaccinate residents against seasonal flu. For example, during the 2018–2019 flu season, the Tennessee Department of Health organized statewide Fight Flu TN events with vaccination clinics, and last year, it launched a statewide media campaign.[80] The state's flu vaccine rate (ages 6 months or older) increased from 36 percent during the 2017–2018 flu season to 49 percent during the 2019–2020 season. Indiana's Department of Health has also engaged in focused efforts to increase vaccination rates, particularly among people who are uninsured or underinsured. One way it has done this is by partnering with local health departments and pharmacies to provide vaccinations, and by working with the Indiana Immunization Coalition to create education and outreach materials and social media messaging.[81] Indiana's flu vaccination rate (ages 6 months or older) improved from 37 percent for the 2017–2018 flu season to 51 percent for the 2019–2020 season.

Rhode Island (61 percent), Connecticut (61 percent), and Massachusetts (61 percent) had the highest coverage, while vaccination rates were lowest in Nevada (44 percent), Florida (45 percent), and Idaho (45 percent). (See Table 10.)

Children, particularly young children, were more likely to receive vaccinations than were adults. Nearly 64 percent of those ages 6 months to 17 years received vaccinations in 2019–2020, compared with 48 percent of adults.[82]

TABLE 10: Just Over Half of Americans Received a Seasonal Flu Vaccination
States' seasonal flu vaccination rates for people ages 6 months or older, 2019–2020

State	Vaccination Rate, Ages 6 Months or Older
Rhode Island	60.9
Connecticut	60.7
Massachusetts	60.6
Virginia	58.8
South Dakota	58.7
Nebraska	58.3
Wisconsin	58.3
Maryland	57.8
District of Columbia	57.6
New Hampshire	57.6
Vermont	57
Iowa	56.6
North Dakota	56.5
Minnesota	56.3
Washington	56.3
Pennsylvania	56.1
North Carolina	55.8
Colorado	55.6
Maine	55.6
Delaware	55
Arkansas	54.9
Kansas	54.5
New Jersey	54
Oklahoma	54
New Mexico	53.2
New York	52.9
Illinois	52.2
West Virginia	52.2
Utah	51.9
Oregon	51.4
California	51.3
Hawaii	51
Ohio	51
Kentucky	50.9
Indiana	50.8
South Carolina	50.7
Missouri	50.2
Michigan	49.7
Montana	49.6
Tennessee	49.1
Alabama	48.4
Louisiana	47.5
Texas	47.3
Wyoming	47.3
Arizona	46.5
Georgia	45.9
Mississippi	45.9
Alaska	45.8
Idaho	44.9
Florida	44.5
Nevada	44.4

Note: Data are calculated from a survey sample, with a corresponding sampling error.

Source: Centers for Disease Control and Prevention.[83,84]

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INDICATOR 9: PATIENT SAFETY IN HOSPITALS

KEY FINDING: On average, 31 percent of hospitals received an "A" grade in the fall 2020 hospital safety assessment administered by the Leapfrog Group, a nonprofit advocate for safety, quality, and transparency in hospitals.

Every year, hundreds of thousands of people die from hospital errors, injuries, accidents, and infections, collectively making such incidents a leading cause of death in the United States.[85,86] Keeping hospital patients safe from preventable harm is an important element of preparedness; those hospitals that excel in safety are less likely to cause or contribute to a public health emergency and are better positioned to handle any emergencies that put routine quality standards to the test.

During the COVID-19 pandemic, hospitals were an active setting for viral transmission, threatening the safety of patients, staff and visitors, and also discouraging people in need of urgent or emergency care from going to the ER, likely contributing to overall excess mortality.[87] But universal masking and availability and proper use of PPE, in addition to other steps, such as adequate ventilation, limiting the sharing of patient rooms, and universal hand hygiene, proved to be critical in preventing outbreaks in hospitals.

The Leapfrog Group calculates its hospital safety score by using 28 evidence-based metrics that measure the success of healthcare processes and outcomes. The measures track such issues as healthcare-associated infection rates, the number of available beds and qualified staff in intensive-care units, patients' assessments of staff communications and responsiveness, and a hospital's overall culture of error prevention.[88] These measures are especially critical for health systems' readiness for emergencies and outbreak prevention and control, which include workforce training and availability, surge capacity, and infection-control practices.

In the Leapfrog Group's fall 2020 assessment, 31 percent of general acute-care hospitals across the United States, on average, met the requirements for an "A" grade—a slight increase from fall 2018, when the share was 28 percent. But results varied widely state to state, from no hospitals in Alaska, North Dakota, or South Dakota receiving the top score, to a majority of hospitals doing so in Maine (63 percent), Idaho (58 percent), Delaware (57 percent), Massachusetts (57 percent), Oregon (55 percent), Virginia (53 percent), and North Carolina (52 percent). (See Table 11.)

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TABLE 11: Hospital Patient Safety Scores Vary Significantly by State

States percentage of hospitals with "A" grade, fall 2020

State	Percent of Hospitals
Maine	63%
Idaho	58%
Delaware	57%
Massachusetts	57%
Oregon	55%
Virginia	53%
North Carolina	52%
Vermont	50%
Colorado	48%
Pennsylvania	47%
Utah	46%
Hawaii	45%
Texas	43%
Michigan	43%
Washington	40%
Maryland	38%
New Jersey	37%
Ohio	37%
Florida	36%
California	36%
Kentucky	36%
South Carolina	34%
Illinois	34%
Tennessee	33%
Wyoming	33%
Georgia	32%
Kansas	32%
Connecticut	32%
Mississippi	30%
Louisiana	29%
Rhode Island	29%
Arizona	26%
Wisconsin	24%
Missouri	24%
Minnesota	23%
Oklahoma	23%
Montana	22%
Nevada	21%
District of Columbia	20%
Alabama	20%
Indiana	19%
New Mexico	17%
Iowa	16%
New Hampshire	15%
New York	10%
Arkansas	7%
Nebraska	6%
West Virginia	5%
Alaska	0%
North Dakota	0%
South Dakota	0%

Note: This measure captures only general acute-care hospitals.

Source: The Leapfrog Group.[89]

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INDICATOR 10: STATE SURGE CAPACITY

KEY FINDING: Every state reported having a plan in 2020 for a six- to eight-week surge in laboratory-testing capacity to respond to an outbreak or other public health event.

Public health laboratories have been essential to emergency response and effective disease surveillance systems throughout the pandemic. They help detect and diagnose health threats as they emerge, and they track and monitor the spread of those threats, which can help public health officials learn how to control them. Public health labs exist in every state and territory and are the backbone of the Laboratory Response Network (LRN), a national network of laboratories that provide the infrastructure and capacity to respond to public health emergencies.[90]

When a disaster or disease outbreak strikes, public health laboratories must be able to surge to meet increased demand, just like hospitals and other responders. The Association of Public Health Laboratories defines internal surge capacity as a "sudden and sustained increase in the volume of testing that a LRN reference laboratory can perform in an emergency situation, implementing substantial operational changes as defined in laboratory emergency response plans and using all resources available within the laboratory."[91] Surging capacity can require staff movement or reassignment, extra shifts, and hiring. Labs also have to plan for infrastructure factors, such as sufficient biological safety cabinets and chemical fume hoods; amount and type of supplies; space for intake, processing, and storage of samples; versatility and capacity of analytical equipment and instruments; availability of PPE; and power supply.[92] It should also be noted that while the existence of surge plans are important, these plans have to be funded, tested, and regularly updated.

State public health laboratories have been critical assets throughout the COVID-19 pandemic, especially in early 2020, when they were the only laboratories outside the CDC authorized to conduct testing.[93] Despite early challenges in the tests rolled out to states, at least one public health laboratory in every state, DC, Puerto Rico, and Guam was able to test for COVID-19 as of June 2020.[94] Testing capacity increased over time, as private labs received authorization and ramped up capacity, and as a variety of rapid molecular tests were manufactured and approved for use at home; but the processing of the CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel assisted officials throughout with monitoring the course of the pandemic. Still, the country's testing capacity never reached what most experts argued was necessary to allow for comprehensive, timely surveillance of the virus's spread during the height of the pandemic. This problem was most acute in spring 2020, when an estimated one in 10 infections were confirmed, improving somewhat to roughly one in three in late 2020.[95,96]

In addition, public health laboratories are studying the genetic sequencing of the COVID-19 virus to identify variants. Such genomic surveillance is critical to understanding and preventing the spread of the virus but more federal funding is needed to support the work.[97]

Going forward, some challenges to the effectiveness of public health laboratory preparedness include funding gaps to invest in infrastructure and modernization, workforce shortages, a lack of standardized platforms to exchange data electronically, and a limited ability to detect radiological, nuclear, and chemical threats.[98]

In 2020, the District of Columbia and all states reported to the Association of Public Health Laboratories that they had a plan for a six- to eight-week surge in testing capacity, a net increase of six since 2017 and 2018. (See Table 12.)

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TABLE 12: Every State Planned for a Laboratory Surge.

State public health laboratories with a plan for a six- to eight-week surge in testing capacity, 2020

Had a Plan			
Alabama	Illinois	Montana	Rhode Island
Alaska	Indiana	Nebraska	South Carolina
Arkansas	Iowa	Nevada	South Dakota
Arizona	Kansas	New Hampshire	Tennessee
California	Kentucky	New Jersey	Texas
Colorado	Louisiana	New Mexico	Utah
Connecticut	Maine	New York	Vermont
Delaware	Maryland	North Carolina	Virginia
District of Columbia	Massachusetts	North Dakota	Washington
Florida	Michigan	Ohio	West Virginia
Georgia	Minnesota	Oklahoma	Wisconsin
Hawaii	Mississippi	Oregon	Wyoming
Idaho	Missouri	Pennsylvania	Vermont

Note: This indicator tracks only the existence of a plan, not its quality or comprehensiveness, or the frequency with which it is used or tested.

Source: Association of Public Health Laboratories.[99]

TABLE 13: INDICATORS OF PUBLIC HEALTH EMERGENCY PREPAREDNESS

	Nurse Licensure Compact (NLC)	Hospital Preparedness Program	Public Health Accreditation Board (PHAB)	Emergency Management Accreditation Program (EMAP)	Public Health Funding	Water Security	
	State participates in NLC, 2020	Percent of hospitals participating in health care coalitions, 2017	Accredited by PHAB, 2020	Accredited by EMAP, 2020	Percentage change, FY 2019-20	Percent of population who used a community water system in violation of health-based standards, 2019	
Alabama	✓	95%	✓	✓	-4%	2%	
Alaska		100%			118%	4%	
Arizona	✓	72%	✓	✓	52%	5%	
Arkansas	✓	81%	✓	✓	-2%	8%	
California		70%	✓	✓	40%	1%	
Colorado	✓	100%	✓	✓	9%	2%	
Connecticut		100%	✓	✓	8%	3%	
Delaware	✓	100%	✓	✓	8%	2%	
D.C.		100%	✓	✓	2%	5%	
Florida	✓	73%	✓	✓	8%	3%	
Georgia	✓	97%	✓	✓	3%	7%	
Hawaii		100%			-2%	0%	
Idaho	✓	98%	✓	✓	2%	1%	
Illinois		88%	✓	✓	7%	1%	
Indiana	✓	75%			0%	1%	
Iowa	✓	80%	✓	✓	-3%	4%	
Kansas	✓	96%	✓	✓	13%	5%	
Kentucky	✓	93%		✓	1%	4%	
Louisiana	✓	100%	✓	✓	3%	13%	
Maine	✓	94%	✓		24%	1%	
Maryland	✓	89%	✓		4%	0%	
Massachusetts		82%	✓	✓	4%	7%	
Michigan		90%		✓	14%	2%	
Minnesota		100%	✓		78%	0%	
Mississippi	✓	100%	✓	✓	2%	8%	
Missouri	✓	87%	✓	✓	-1%	9%	
Montana	✓	83%	✓		2%	8%	
Nebraska	✓	95%	✓	✓	7%	2%	
Nevada		100%		✓	15%	0%	
New Hampshire	✓	47%			11%	2%	
New Jersey	✓	82%	✓	✓	2%	16%	
New Mexico	✓	71%	✓	✓	8%	6%	
New York		86%	✓	✓	0%	45%	
North Carolina	✓	95%		✓	2%	2%	
North Dakota	✓	100%	✓	✓	31%	0%	
Ohio		25%	✓	✓	13%	1%	
Oklahoma	✓	95%	✓	✓	29%	15%	
Oregon		100%	✓		0%	16%	
Pennsylvania		86%	✓	✓	0%	9%	
Rhode Island		100%	✓	✓	3%	4%	
South Carolina	✓	56%		✓	3%	3%	
South Dakota	✓	100%			2%	4%	
Tennessee	✓	91%		✓	9%	4%	
Texas	✓	80%			28%	4%	
Utah	✓	100%	✓	✓	9%	5%	
Vermont		100%	✓	✓	7%	0%	
Virginia	✓	100%		✓	-6%	3%	
Washington		100%	✓		6%	0%	
West Virginia	✓	97%			6%	16%	
Wisconsin	✓	98%	✓	✓	2%	5%	
Wyoming	✓	92%			8%	2%	
51-state average	**N/A**	**89%**	**N/A**	**N/A**	**12%**	**5%**	

Note: See "Appendix A: Methodology" for a description of TFAH's data-collection process and scoring details. States with conditional or pending accreditation at the time of data collection were classified as having no accreditation. Some state residents use private drinking-water sources, rather than community water systems. Private sources are not captured by these data. Only regulated contaminants are measured. Paid time off includes sick leave, vacations, and holidays. The patient safety measure captures only general acute-care hospitals.

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TABLE 13: INDICATORS OF PUBLIC HEALTH EMERGENCY PREPAREDNESS

		Paid Time Off	Seasonal Flu Vaccination	Patient Safety	Public Health Lab Capacity	State Performance
		Percent of employed population who used paid time off, 2019	Seasonal flu vaccination rate for people ages 6 months or older, 2019–20	Percentage of hospitals with "A" grade, fall 2020	Public health laboratories had a plan for a six- to eight-week surge in testing capacity, 2020	Scoring tier, 2020
	Alabama	55%	48.4	20%	✓	Middle
	Alaska	60%	45.8	0%	✓	Low
	Arizona	48%	46.5	26%	✓	Low
	Arkansas	45%	54.9	7%	✓	Low
	California	56%	51.3	36%	✓	Middle
	Colorado	56%	55.6	48%	✓	High
	Connecticut	64%	60.7	32%	✓	High
	Delaware	48%	55	57%	✓	High
	D.C.	65%	57.6	20%	✓	High
	Florida	54%	44.5	36%	✓	Middle
	Georgia	59%	45.9	32%	✓	High
	Hawaii	59%	51	45%	✓	Low
	Idaho	51%	44.9	58%	✓	High
	Illinois	55%	52.2	34%	✓	Middle
	Indiana	51%	50.8	19%	✓	Low
	Iowa	60%	56.6	16%	✓	Middle
	Kansas	56%	54.5	32%	✓	High
	Kentucky	48%	50.9	36%	✓	Middle
	Louisiana	53%	47.5	29%	✓	Middle
	Maine	51%	55.6	63%	✓	High
	Maryland	61%	57.8	38%	✓	High
	Massachusetts	59%	60.6	57%	✓	High
	Michigan	49%	49.7	43%	✓	Middle
	Minnesota	52%	56.3	23%	✓	Middle
	Mississippi	63%	45.9	30%	✓	High
	Missouri	53%	50.2	24%	✓	Low
	Montana	58%	49.6	22%	✓	Middle
	Nebraska	57%	58.3	6%	✓	High
	Nevada	55%	44.4	21%	✓	Low
	New Hampshire	54%	57.6	15%	✓	Low
	New Jersey	52%	54	37%	✓	Middle
	New Mexico	61%	53.2	17%	✓	High
	New York	61%	52.9	10%	✓	Low
	North Carolina	51%	55.8	52%	✓	High
	North Dakota	51%	56.5	0%	✓	Middle
	Ohio	49%	51	37%	✓	Low
	Oklahoma	55%	54	23%	✓	High
	Oregon	63%	51.4	55%	✓	Middle
	Pennsylvania	51%	56.1	47%	✓	Low
	Rhode Island	56%	60.9	29%	✓	High
	South Carolina	45%	50.7	34%	✓	Low
	South Dakota	44%	58.7	0%	✓	Low
	Tennessee	53%	49.1	33%	✓	Middle
	Texas	68%	47.3	43%	✓	Middle
	Utah	45%	51.9	46%	✓	High
	Vermont	56%	57	50%	✓	High
	Virginia	58%	58.8	53%	✓	High
	Washington	60%	56.3	40%	✓	High
	West Virginia	55%	52.2	5%	✓	Low
	Wisconsin	56%	58.3	24%	✓	High
	Wyoming	47%	47.3	33%	✓	Low
	51-state average	**55%**	**52.8**	**31%**	**N/A**	**N/A**

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Recommendations for Policy Actions

As 2020 has shown, saving lives and protecting the country's economic stability during a pandemic requires pre-event investment and planning, a strong public health system, federal leadership, and a coordinated response. The same is true for all types of public health emergencies. Effective preparedness and response require sufficient funding, a trained workforce, and multisector teamwork. Authentic engagement with community-based leaders and organizations are also necessary.

TFAH based the following policy recommendations on research and analysis, consultation with experts, and a review of gaps in federal and state preparedness. TFAH offers the following recommendations for federal, state, local, tribal, and territorial policymakers and other stakeholders to improve public health emergency readiness.

Priority Area 1: Provide Stable, Sufficient Funding for Domestic and Global Public Health Security

The COVID-19 pandemic has uncovered the tragic consequences of the nation's long-term neglect of public health capacity at the global, federal, state, local, tribal, and territorial levels. Understaffed health departments are in some cases using 20th-century tools, such as telephones and fax machines,[100,101] to respond to a 21st-century pandemic.[102] At the same time, funding for the Public Health Emergency Preparedness cooperative agreement, a critical source of funding for health departments to build capabilities to effectively respond to a range of public health threats, has been cut by just over one-quarter since FY 2003, or about half, after adjusting for inflation.[103] The HPP, the only federal source of funding to help the healthcare delivery system prepare for and respond to disasters, has been cut by nearly half over the same time period, or by nearly two-thirds, after adjusting for inflation.[104] Therefore, health departments were already working from a deficit when the pandemic emerged. Federal policymakers need to rapidly improve the COVID-19 response and build back a system currently unprepared to address future emergencies. Short-term investments made through COVID response funding legislation cannot fill the gap left by ongoing public health funding shortfalls, nor can they address underlying health inequities that are making the nation less resilient.

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RECOMMENDATIONS FOR FEDERAL GOVERNMENT:

- **Rebuild and modernize the public health system, including by creating a mandatory $4.5 billion per year Public Health Infrastructure Fund to support foundational public health capabilities at the state, local, territorial, and tribal levels (STLT).** Strong foundational capabilities would improve the protection of all communities across a range of threats. However, a nationwide funding shortage, exacerbated by the pandemic, has prevented health departments across the country from developing and maintaining these capabilities. An additional funding limitation is that health departments receive very little funding that is not tied to specific diseases or categories. Congress should invest in cross-cutting public health capabilities, such as proposed in the Public Health Infrastructure Saves Lives Act.[105] Congress must also increase funding for specific programs that support health security, including the Public Health Emergency Preparedness and the HPP cooperative agreements. These state and local preparedness programs have demonstrated their value by saving lives, improving the speed and quality of response during emergencies, and ensuring that local authorities can adequately respond to most local health emergencies and outbreaks without federal assistance. Congress should provide additional funding to modernize public health and response functions at the CDC and ensure the agency has the capacity to respond to any event.

- **Invest in sustained public health data modernization.** Sustained investment in health data systems at the federal, state, and local levels is imperative. The CDC is the world's premier public health agency, yet years of inadequate funding has meant that the agency and its partners are reliant on archaic data systems. Americans felt the pain of delayed and disjointed disease surveillance throughout the pandemic, as the public health surveillance infrastructure relied on antiquated, disconnected systems and methods for tracking and responding to diseases. Congress wisely invested $500 million in the Coronavirus Aid, Relief, and Economic Security Act (P.L.116-136) and $50 million in the FY 2020 and FY 2021 appropriations bills as a down-payment on the CDC's data modernization initiative. These investments will help build the foundations for data sharing across public health, modernize the CDC's services and systems, leverage new data sources, and ensure public health can act on innovative data analytics. However, these advancements must be augmented and sustained, making up for decades of neglect. Congress should build on these initial investments with at least $450 million in immediate funding and at least $100 million per year to the CDC's data modernization initiative to modernize and sustain these systems. New data systems should be interoperable and cloud-based.

- **Ensure complete, disaggregated demographic data collection and reporting during public health emergencies.** The gaps in COVID-19 data reporting by race, ethnicity, sexual identity, gender identity, primary language, disability status, the intersections of these demographics, and other factors hindered the response and masked the true breadth of inequities during the pandemic. These gaps exposed long-standing shortcomings in demographic data collection and reporting in public health. Congress should invest in data modernization for STLT public health to enable accurate and comprehensive data collection. In addition, HHS should stand up a task force—including the Office of the Assistant Secretary for Planning and Evaluation, CDC, Office of the National Coordinator on Health Information Technology, Office of Minority Health,

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and CMS, in consultation with state, local, territorial and tribal agencies and private-sector stakeholders—to identify and address barriers to the collection and regular reporting of disaggregated, detailed demographic data during the pandemic and beyond. If needed, Congress should provide HHS agencies the authority to require jurisdictions to report race and ethnicity during public health emergencies.[106]

- **Accelerate crisis responses through a standing public health emergency response fund and faster supplemental funding.** In addition to stable core funding, the federal government needs readily available funds on hand to enable a rapid response while Congress assesses the necessity for supplemental funding. Congress should continue a no-year infusion of funds into the Public Health Emergency Rapid Response Fund and/or the Infectious Disease Rapid Response Fund to serve as available funding that would provide a temporary bridge between preparedness and supplemental emergency funds. Congress should replenish such funding on an annual basis, and funding should not come from existing preparedness resources, as response capacity cannot substitute for adequate readiness. The HHS secretary should only use such funding for acute emergencies that require a rapid response to save lives and protect the public.

- **Demonstrate a long-term commitment to global health security.** The United States should recommit to partnerships with international bodies such as the WHO, and Congress should solidify America's role as a global health leader, commit to implementing the Global Health Security Strategy,[107] and provide sustained annual funding for global health security programs at the CDC and the U.S. Agency for International Development. Congress should fund and the CDC should implement the modernization of the U.S. quarantine system, including IT systems, quarantine stations, regulatory framework, and traveler engagement and information.

Editor's note: on January 21, 2021, the Biden administration restored U.S. membership in the WHO.

RECOMMENDATION FOR FEDERAL AND STATE GOVERNMENT:

- **Enable efficient use of emergency funding.** During an emergency, responding agencies at all levels of government must be able to adapt spending policies. States should review their administrative preparedness to ensure they can efficiently use emergency monies, including speeding up contracting and hiring procedures. In addition, Congress may allocate emergency funding to multiple federal agencies. However, differing agency policies and practices can impede speed and coordination of funding across agencies. This can lead to disconnected and less effective emergency responses on the ground. The Office of Management and Budget, HHS, and FEMA should allow waivers of regulatory or administrative requirements to awardees of emergency response funding to allow funding braiding, to encourage coordination between programs and funding streams with similar goals, to provide flexibility to best meet the needs of the affected populations, and to increase efficiencies and reduce administrative duplication, such as in grant reporting.

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Priority Area 2: Prevent Outbreaks and Pandemics

Infectious diseases represent a threat to the health, safety, and economic and social stability of the country. The COVID-19 pandemic has cost the nation hundreds of thousands of lives and at least $16 trillion in losses to the U.S. gross domestic product as of October 2020.[108] The toll in lost educational achievement and long-term mental health impacts have yet to be fully understood. As TFAH, scientists, and public health experts have warned for many years, the nation was not prepared for a severe pandemic. At the same time as the nation battles the worst pandemic in a century, public health and medical providers continue to respond to "everyday" outbreaks: seasonal influenza, vaccine-preventable diseases, healthcare-associated infections, and antibiotic resistance continue to pose threats to health and safety. The United States must be able to prevent and respond to both major pandemics and localized outbreaks.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT, HEALTHCARE, AND AGRICULTURE:

- **Support the vaccine infrastructure.** The CDC's immunization program, sometimes called the "317 program," supports state and local immunization systems to increase vaccination rates among uninsured and underinsured adults and children, to respond to outbreaks, to educate the public, to target hard-to-reach populations, to improve vaccine confidence, to establish partnerships, and to improve information systems. Yet, funding has not kept up with needs, as states have to spend immunization dollars to respond to outbreaks,[109] deal with increases in the numbers of residents who lack health insurance,[110] and attempt to manage the impact of vaccine underutilization. State, local, and tribal health departments are depending on this underfunded infrastructure to distribute and dispense the COVID-19 vaccine, yet COVID funding was not distributed until January 2021. Congress should monitor the COVID-19 vaccination progress and provide additional funding, if needed. Congress should also increase annual funding for the CDC's immunization program as well as the seasonal influenza program and post-licensure vaccine safety monitoring. Congress should also provide needed resources to HHS to study the causes of vaccine resistance and to educate clinical providers on methods for improving vaccine acceptance, such as those proposed in the VACCINES Act.[111]

- **Ensure first-dollar coverage for recommended vaccines under Medicaid, Medicare, and commercial insurance.** Public and private payers should ensure that all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are fully covered, as cost sharing, such as co-pays, can be a significant barrier to vaccination.[112] Congress should require zero cost sharing in Medicare Part D and B plans, and CMS should incentivize Part D plans to eliminate cost sharing and increase receipt of vaccines.[113] An example of legislation that takes steps to improve senior vaccination rates is the Protecting Seniors Through Immunization Act. CMS should encourage state Medicaid plans in states that have not expanded Medicaid to cover all ACIP-recommended vaccines without cost sharing.[114]

- **Significantly increase investments in public health initiatives to combat antibiotic resistance.** Congress should increase funding for innovative prevention methods of detecting and containing outbreaks supported by the Antibiotic Resistance Solutions Initiative at the CDC. The CDC is investing in prevention measures in every state to strengthen lab capacity, track infections across healthcare systems, detect new threats, disrupt pathogens, coordinate prevention strategies, educate healthcare providers on appropriate antibiotic use, and advocate for other innovations. To fully address the scope of AR spread, particularly in healthcare settings, Congress should increase funding for healthcare associated infection/antibiotic resistance programs and activities at state and local health departments. In addition, increases in funding are necessary to build global capacity to prevent and detect resistant infections and to combat the threat to national security.

- **Create incentives for new-product discovery to fight resistant infections.** It is extremely challenging for companies to earn a return on their investments for the development of new antibiotics: (1) antibiotics are typically given for a short duration; (2) the most highly resistant infections are still relatively rare; and (3) new antibiotics must be used judiciously to preserve their effectiveness. These

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factors have resulted in nearly all major pharmaceutical companies exiting the antibiotics market, leaving the critical innovation domain of discovering and developing new antibiotics to small biotech companies with limited budgets and limited research and development capacity. Legislation, such as the DISARM Act, would strengthen the market for antibiotic developers, improving patient access for those who need it most.

- **Eliminate overuse of antibiotics in agriculture.** The FDA should enforce rules regarding veterinary oversight and the judicious use of antibiotics in food animals, ensure data collection and publication, promote antibiotic stewardship programs, and track the impact of these policies on resistance patterns. Farmers and the food industry should stop using medically important antibiotics to promote growth and prevent disease in healthy animals, as recommended by the WHO,[115] and they should invest in research to develop and adopt husbandry practices that reduce the need for routine antibiotics.
- **Decrease over-prescription of antibiotics through implementation of antibiotic stewardship and antibiotic-use reporting.** The CDC estimates that improving prescribing practices and preventing infections could save 37,000 lives over five years.[116] CMS should finalize, implement, and enforce requirements for all CMS-enrolled facilities to have effective antibiotic stewardship programs that align with the CDC's Core Elements guidance and to work with public health stakeholders to track progress in prescribing rates and resistance patterns.[117] All relevant facilities must drastically improve their reporting of antibiotic use and resistance through the National Healthcare Safety Network and should adopt stewardship programs that meet the CDC's Core Elements.[118]
- **Fund the CDC to support state and local public health laboratories.** The CDC should be sufficiently funded to strengthen the Laboratory Response Network and to support state and local public health laboratories; currently, the Epidemiology and Laboratory Capacity grant is only funding approximately half of what laboratories and health department epidemiologists nationwide have requested.

RECOMMENDATIONS FOR FEDERAL AND STATE GOVERNMENT:

- **Provide job-protected paid leave.** The pandemic has called attention to the fact that paid family and medical leave are important infection-control measures, protecting both workers and customers, in addition to creating economic security. Workers are unable to adhere to public health guidance to isolate if they risk losing their jobs or paychecks. While Congress temporarily expanded access to paid leave during the pandemic, a permanent fix is needed. Congress should enact a permanent federal paid family and medical leave policy and dedicated paid sick days protections, and states should ensure effective implementation by passing paid leave laws and/or removing preemption exemptions.
- **Minimize state vaccine exemptions for schoolchildren and increase vaccination of healthcare workers.** States should enact policies that enable universal childhood vaccinations to ensure children, their classmates, educators, and the general public are protected from vaccine-preventable diseases. This includes eliminating nonmedical exemptions and opposing legislation to expand exemptions.[119] States should ensure medical vaccine exemptions are only given when appropriate and are not used as a de facto personal-belief exemption in states where those exemptions have been eliminated. States should require healthcare personnel to receive all ACIP-recommended vaccinations to protect staff and patients, assure continuity of operations in the event of an outbreak, and achieve necessary healthcare infection control. As this report was being prepared for publication, the COVID-19 vaccine was not an ACIP-required vaccine. Healthcare facilities should ensure access to vaccines for all staff and contractors, and they should remove any barriers to staff receiving vaccines. Healthcare facilities should also report healthcare worker vaccination status, such as for seasonal flu and COVID-19, to the CDC's National Healthcare Safety Network.

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Priority Area 3: Build Resilient Communities and Promote Health Equity in Preparedness

Social, economic, and health disparities impact how people within specific communities' experience disasters and how quickly they can recover. Unfortunately, the disproportionate impact of COVID-19 on communities of color and Tribal Nations was foreseeable: underlying health conditions driven by years of structural racism; uneven access to prevention and care during the pandemic; increased risk of exposure due to being frontline workers, such as in food processing, food service, or healthcare;[120] increased risk of exposure due to living in crowded or inadequate housing;[121] and more severe economic impacts for lower-income workers has meant that people of color and Tribal Nations are bearing a disproportionate burden from the pandemic. When intersectional issues, such as homelessness, incarceration, disability, age, lack of access to paid leave, LGBTQ+ status, and immigration status are also at play, the inequities are more pronounced. Addressing underlying inequities and intentionally and meaningfully engaging with the people and communities most likely to be impacted throughout the emergency planning and response process are critical to reducing vulnerability and ensuring that all receive appropriate services, regardless of circumstance. Equity must be an explicit and foundational principle in all emergency planning. Some communities have taken steps to integrate principles of equity throughout public health emergency activities,[122] but more needs to be done.

RECOMMENDATIONS FOR FEDERAL, STATE, AND LOCAL GOVERNMENT:

- **Examine and address gaps in equity in response capabilities.** An external body (such as the GAO or the National Academy of Sciences, Engineering and Medicine) should conduct an assessment of the pandemic specifically focused on gaps in equitable response, including inequities in allocation of scarce resources, healthcare capacity, data collection and reporting, and planning for communities at higher risk, underserved communities, and communities of color.
- **Invest in policies and capacity to address the social determinants of health (SDOH):** People at highest risk during disasters and those who have the hardest time recovering are often those with unstable or unhealthy housing, those with limited access to transportation, and those who live in low-socioeconomic-status communities,[123] all of which bore out during the COVID-19 pandemic. Addressing SDOH can improve resilience, but it must be a cross-sector effort to increase healthy, affordable housing; improve transportation access; fight poverty; and implement other policies proven to advance health. Congress should fund a public health approach to address SDOH, such as the approach proposed in the Improving Social Determinants of Health Act. The legislation would strengthen SDOH capacity at the CDC and enable grants to public health agencies to build cross-sector partnerships and develop community solutions to SDOH. For further discussion on policy options to address SDOH, see TFAH's Blueprint and PHACCS reports.[124,125]
- **Provide resources and technical assistance to communities to enhance equity and resilience before, during, and after an event.** Rather than a top-down approach to promote equity and resilience, policymakers should support an asset-based approach that relies on communities identifying and leveraging their assets. Congress should direct targeted resources to community-based organizations and existing community health networks that focus on the health of communities of color and other groups that bear a disproportionate burden during disasters. Evacuation plans should be inclusive of the community as a whole by meeting and enforcing the requirements of the Americans with Disabilities Act. Grants should support culturally and linguistically appropriate public health campaigns that address prevention and treatment, providing community leaders the opportunity to fully participate in planning activities, allowing organizations to hire and engage community members so emergency plans better reflect the community, and improving data collection and sharing. Federal and other grant makers and states should ensure that existing grants and sub-awards reach the grassroots level and communities most in need.
- **Public health agencies should strengthen their health equity leadership and adopt strategies and accountability metrics to incorporate equity into preparedness.** Equity must not be considered separate from preparedness activities but must serve as the foundation for a more resilient

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community. Ensuring equity is central to all preparedness activities and requires integrating equity accountability measures into all elements of emergency response. Congress should provide the CDC funding to extend its COVID-19 Health Equity Strategy[126] to ongoing preparedness and response work at the agency and with partners. All state and local governments, including health departments, should build up internal infrastructure to drive equity, including by identifying a chief health equity officer who has a leadership role in the emergency operations center and/or incident command structure for all-hazards events and is engaged in every emergency operation center activation. Health equity and emergency preparedness officials should work across programs to incorporate equity issues and goals into preparedness policies and plans;[127] to improve staff capacity to understand how the legacies of discrimination, current-day racial trauma, and other structural inequities affect disaster resilience and recovery; develop and disseminate communications materials that are culturally and linguistically tailored; and to collect and leverage data to identify unique community assets and advance equity before and during events.

RECOMMENDATIONS FOR STATE AND LOCAL GOVERNMENT AND COMMUNITY LEADERS:

- **Plan *with* communities, not for them, and empower their involvement with resources.** Emergency planners must conduct meaningful engagement, partnerships, and listening efforts as well as ongoing inclusion and local hiring (especially from communities typically at higher risk in disasters) in emergency planning and response. Officials should establish relationships with services and organizations that serve these populations before emergencies take place, and government should fund community leaders and community-based organizations to participate in preparedness efforts. Health departments and emergency management agencies should rely on the expertise, community trust, and networks of those who may bear a disproportionate risk, such as older adults, people with disabilities, and individuals with chronic health conditions to ensure emergency plans, procedures, and evacuation shelters meet the needs of all in the community.
- **Address mental health and substance use gaps, bolster crisis resources, and incorporate mental health first-aid and long-term treatment into disaster response and recovery strategies.** Emergencies can exacerbate existing mental health and substance use concerns and disrupt access to care. During the COVID-19 pandemic, there have been reports of increases in a number of mental health concerns,[128] including suicide ideation[129] and drug overdoses.[130] Short-term regulatory relief, like take-home medication for opioid use disorder[131] and waivers for telehealth,[132] have helped, but coordination among state, local, and federal agencies remains vital to delivering resources to affected communities. Policymakers should also incorporate behavioral health needs into disaster planning, as required by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act.

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Priority Area 4: Ensure Effective Leadership, Coordination, and Workforce

The political polarization and contradictory messaging exhibited throughout the pandemic contributed to a wide variation in how individuals and communities responded. Issues such as face coverings, business- and school-closure decisions, and even the mortality numbers became matters for debate by a vocal minority of Americans.[133] Clear national leadership and communication, following the advice of public health and scientific experts, is needed to ensure consistent policies and messaging during a situation as complicated and dangerous as a public health emergency. Perhaps more important than any technology or invention is the presence of trained, experienced people, from the frontline responder to the top of government. The nation's local public health departments responded to the pandemic with an estimated 26,000 fewer public health workers compared with before the 2008 recession.[134] The state budget cuts likely to continue in the years following the pandemic threaten to intensify this workforce shortage. Effective crisis response requires coordination, cooperation, and leadership—elements that governments must build and sustain over time.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT:

- **Strengthen federal leadership, guidance and regulatory authorities for public health emergencies.** During the COVID-19 pandemic, authority and decision-making over the response was ceded to states to an unprecedented degree. This diffusion of responsibility meant wide variation in policy and response decisions regarding business closures, mask mandates, testing strategies, and other tactics. The CDC must be empowered to lead the public health response during a pandemic and issue clear, feasible guidance and regulations for state, local, tribal, and territorial officials and to the public to minimize variation across jurisdictions. The optimal approach is a federal-state partnership rooted in shared decision-making and a clear division of labor.
- **Rebuild trust in federal public health agencies.** The COVID-19 pandemic has damaged faith in federal agencies, including public health agencies such as the CDC and the FDA. Policy decisions from the federal to the local level should be based on the best available science, led by public health experts, and free from any perception of political interference. The president, the HHS secretary, and the leadership of federal public health and emergency response agencies, including the CDC, ASPR, DHS, FEMA and the FDA, must conduct a thorough review on the independence and performance of these agencies. Leaders should establish procedures and policies to ensure the scientific integrity and independence of the agencies, without political interference, and they must correct any errors made during the COVID-19 response. At the same time, elected leaders must publicly support public health to rebuild confidence in those agencies and officials. All federal messages and messengers about public health issues must be consistent and based in science.

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Sundry Photography

- **Invest in public health communications.** Congress must make a significant investment in effective public health communications, including research into best practices for different audiences. The CDC and other federal, state, and local public health agencies should engage with a diverse group of stakeholders to research and test effective public health messaging. From vaccines to mask-wearing, there are subgroups of Americans who are skeptical, hesitant, or confused about COVID-19 public health guidance for various reasons. While some will be recalcitrant, many Americans are simply hesitant or have not been properly engaged. While the substance of communications should be consistent, messages must acknowledge the historical context of distrust and be linguistically and culturally tailored for different populations, and trusted, nongovernmental messengers should receive funding to help deliver messages.

- **The White House should reestablish a health security directorate with public health expertise.** The White House should ensure senior advisors to the president have a strong background in public health and/or biodefense, and the White House should ensure that senior-level interagency cooperation is progressing before, during, and after public health emergencies.

Editor's note: on January 20, 2021, the Biden administration reestablished a National Security Council Directorate for Global Health Security and Biodefense.

- **Clarify and restore roles and responsibilities for government's emergency support functions.** The White House, HHS, CDC, ASPR, U.S. Department of Homeland Security, FEMA, and FDA should work together to clarify roles and responsibilities to improve the nation's emergency preparedness and response capacity.

- **Fund the recruitment and training of public health personnel.** The health security enterprise requires trained, experienced personnel. Federal, state, and local governments must prioritize stable, long-term funding for recruitment and retention of a diverse workforce, including one with experience in public health informatics, laboratory science, health equity, and epidemiology. Congress should also invest in public health workforce development and retention programs, such as student loan repayment and other incentives, especially in underserved areas. Public health schools should incorporate health equity and cultural competency into their preparedness curricula.

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Priority Area 5: Accelerate Development and Distribution of Medical Countermeasures

A robust Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)[135] could negate a range of health threats, but a drug or vaccine is only effective if it reaches the right person at the right time. Medical countermeasures (MCM) are FDA-regulated products that could be used in the event of a public health emergency; they include biologics, drugs, and devices.[136] The challenges faced in distributing scarce medical resources during the pandemic as well as the deployment of COVID-19 vaccine demonstrate the urgency of the right-product/right-time equation. During the first ten months of the pandemic, there was a notable gap in federal coordination, with many federal responsibilities being left to states or to the private sector. The federal government circumnavigated or significantly modified established MCM and medical supply-chain coordination and distribution channels at various points in the pandemic, contributing to confusion and chaos. For example, the lack of federal coordination and transparency left individual hospitals and states to compete with each other for scarce resources,[137] and FEMA and the U.S. Department of Defense were brought in to manage some supply-chain operations despite long-standing systems in place at HHS. Clear federal coordination is necessary during the pandemic, with an eye toward preventing future shortages and shortfalls.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT:

- **Provide significant, long-term funding for the entire MCM enterprise.** The MCM enterprise involves research, manufacturing, surveillance, delivery, training, and monitoring. Long-term coordinated and transparent funding to the Biomedical Advance Research and Development Authority, Strategic National Stockpile, CDC, FDA, NIH, and other components of the PHEMCE would offer more certainty to the biotechnology industry and researchers, would strengthen public-private partnerships, and would enable the purchase of ancillary medical supplies, such as PPE. The United States should grow its investment in innovative, flexible technologies and platforms that will enable faster production of products for a range of biothreats, rather than focusing on products for a single pathogen.[138]

- **Prioritize the distribution and dispensing of MCMs.** It is important that MCMs reach the right person at the right time during emergencies; the challenges in mass vaccination were predicted by the CDC's MCM Operational Readiness Review.[139,140] HHS along with state, local, tribal, and territorial health departments should be properly resourced and require integration of private-sector healthcare supply distributors and supply-chain partners into planning, exercises, and emergency responses to better leverage existing systems and resources. Once

the COVID-19 vaccination campaign is complete, HHS should access and address gaps in vaccine development, procurement, maintenance, deployment and administration; and improve the training of state and local personnel to ensure vaccine administration is well-coordinated.

- **Clarify and strengthen MCM and supply-chain management for emergencies.** HHS must maintain primary authority over public health emergency response, including deployment of the Strategic National Stockpile and emergency medical supply-chain management, in coordination with other federal agencies and in consultation with private-sector and public health partners. Federal agencies should also explore all available authorities, such as through the Defense Production Act, and communicate strategies with stakeholders to bolster the supply chain during emergencies. The HHS secretary should clarify roles and responsibilities for supply-chain management throughout the pandemic and, moving forward, should develop and disseminate best practices for supply management.[141] HHS should strengthen the PHEMCE's work, including regular interagency meetings; engagement with private-sector, supply-chain partners; and improved transparency and communication with state, local, tribal, and territorial partners.

RECOMMENDATIONS FOR FEDERAL, STATE, AND LOCAL GOVERNMENTS AND PARTNERS:

- **Improve MCM guidance and communications for groups at higher risk during an event.** HHS, including the CDC, should consult with experts and work with healthcare professionals and state, local, and tribal partners to develop standardized guidance for dispensing MCMs to groups such as children, older adults, people with disabilities, and people who are homebound. And HHS and state, local, and tribal agencies should work with organizations that reach the public, especially communities at disproportionate risk—such as groups representing older Americans, people with disabilities, and limited English-proficient communities—to improve communications around MCM issues before an event. Communities need to be engaged before an outbreak or event to ensure their understanding of the risks, benefits, and distribution challenges of introducing a medical product to a large portion of the population and ultimately improving acceptance and access to MCMs. It is important to provide clear and accurate guidance to the public in multiple formats and languages, via trusted sources and multiple communications channels, including formats that are accessible to people with hearing or vision loss.

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Priority Area 6: Ready the Healthcare System to Respond and Recover

In the 2019 and 2020 *Ready or Not* reports, TFAH warned that medical surge capacity for a pandemic remained a major gap in the nation's preparedness. The COVID-19 pandemic has placed tremendous strain on the healthcare system, from acute-care facilities[142] to long-term care facilities[143] to small outpatient clinics.[144] Overcrowded facilities, exhausted workforces, disruptions in the supply chain, shortages of PPE and other supplies, interruptions in primary and preventive care, lack of situational awareness, and loss of revenue have been among the significant challenges to the nation's healthcare system. The toll in lives lost due to these compounding issues has yet to be calculated. The NHSPI has consistently found that healthcare delivery readiness scores are in the lowest levels among preparedness domains, with little progress in the past five years.[145] Policymakers need to strengthen existing systems and consider long-term mechanisms to create sustainable healthcare readiness across systems and across geographic borders.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT AND HEALTHCARE:

- **Strengthen the Hospital Preparedness Program and fund regional coordination.** HPP can help build strong healthcare coalitions capable of engaging and supporting members during disaster responses, but the program has been severely underfunded. Congress must provide more robust annual funding—which it has cut in half over the past decade. HHS and the awardees should ensure healthcare leaders takes the lead on HPP planning and implementation to the extent possible, with support and coordination from public health, emergency management, and others, and awardees should ensure as much funding as possible is reaching healthcare coalitions. Healthcare administrators should ensure their facilities have tools and support for meaningful participation in healthcare coalitions, including the ability to share information and resources across the coalition and with public health agencies. Congress should provide additional funding for a tiered regional disaster system to coordinate across coalitions and states,[146] to map specialized disaster care (such as burn or pediatric care) across the country, and to leverage those assets in a coordinated way.[147] Congress should also provide increased funding for healthcare surveillance through CDC's National Healthcare Safety Network—which is the nation's domestic tracking and response system to identify emerging and enduring threat across 37,000 healthcare facilities, including COVID-19, healthcare-associated infections (HAIs), and antibiotic-resistant (AR) infections. These data drive improvements in patient safety and monitor the surge capacity of healthcare facilities to confront new threats.
- **Create incentives and ramifications to build sustainable preparedness and surge capacity across healthcare systems.** The shortages of beds, healthcare personnel, and equipment during the pandemic underscores the need for cooperation among healthcare entities, across systems, and across geographic borders. Although there has been progress in developing healthcare coalitions in many regions and progress in meeting CMS and other accreditation preparedness standards by individual healthcare facilities, these existing mechanisms have not provided enough incentive for many healthcare facilities to create meaningful surge capacity and cooperation across competing entities. Similarly, the Joint Commission's preparedness standards apply to individual facilities and not to the readiness of the healthcare system as a whole.[148] In addition to strengthening existing systems, Congress and HHS should consider long-term sustainability for building healthcare readiness across the system, including meaningful incentives and disincentives, including:
  - An external self-regulatory body, in alignment with federal policy goals, could set, validate, and enforce standards for healthcare facility readiness, stratified by facility type, with authority for financial ramifications.[149]
  - Payment incentives could sustain preparedness, surge capacity, regional disaster partnerships, and reward facilities that maintain specialized disaster care.

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- **Expand access to healthcare.** Access to healthcare is always important and particularly so during a pandemic or disaster. Federal and state governments must ensure every person has access to healthcare, including robust insurance coverage. Millions of Americans still lack insurance coverage, and disparities by race, ethnicity, sexual or gender identity, and other factors have been exacerbated by the pandemic-induced recession.[150] Congress and the administration should strengthen incentives for states to expand Medicaid, make marketplace coverage more affordable, and improve outreach and marketing for enrollment.[151]

- **Assess impact of CMS Preparedness Standards and improve transparency.** An external review by the GAO or a similar entity should assess how CMS preparedness standards have affected overall healthcare readiness, and HHS should begin tracking progress on preparedness measures over time. CMS should also strengthen preparedness standards by adding medical surge capacity and other capabilities, including infection prevention and control, stratified by facility type, as a necessary requirement within the next iteration of the rule.[152]

RECOMMENDATIONS FOR STATE GOVERNMENT AND HEALTHCARE:

- **Integrate healthcare delivery into emergency preparedness and response.** Jurisdictions should engage and integrate the healthcare sector into emergency planning and responses, including plugging healthcare coalitions and other entities representing private healthcare and the healthcare supply chain into emergency planning and response and incident command. Health systems, healthcare coalitions, and public health should develop memoranda of understanding ahead of disasters to improve situational awareness across healthcare and to enable movement of patients, personnel, and supplies. Private-sector healthcare leadership should prioritize preparedness moving forward, including training and workforce protections, surveillance for emerging threats, stockpiling of supplies ahead of disasters, and full engagement in regional collaborations and coalitions.

- **Strengthen state policies regarding disaster healthcare delivery.** States should review credentialing standards to ensure healthcare facilities can call on providers from outside their states, and health systems should ensure they can receive outside providers quickly during a surge response. States should also adopt policies that promote healthcare readiness and ease the ability to surge care and services, such as the NLC, the Interstate Medical License Compact, the Recognition of EMS Personnel Licensure Interstate CompAct,[153] the Uniform Emergency Volunteer Health Practitioners Act,[154] emergency prescription refill laws and protocols, and implementation and education of providers regarding crisis standards of care guidelines.[155,156]

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Priority Area 7: Prepare for Environmental Threats and Extreme Weather

Climate change, environmental hazards, and extreme weather pose serious threats to human health. According to a December 2020 report by TFAH and the Johns Hopkins Bloomberg School of Public Health, many of the states most at risk from climate change are also the least ready to deal with it (see sidebar on page 60). Environmental health involves detecting and protecting communities from hazardous conditions in air, water, food, and other settings, and it is therefore a critical component of the nation's health security. Environmental hazards impact communities differently and exacerbate disparities among people living in poverty, people of color, people with underlying health conditions, and children and older people—all of whom are at particular risk.[157]

RECOMMENDATIONS FOR FEDERAL AND STATE GOVERNMENT:

- **Enact legislation requiring a national strategic plan.** The United States urgently needs a strategic action plan to address the health impacts of climate change. Policymakers should enact legislation requiring HHS to develop such a plan and to fund development and ongoing maintenance of health system capacity specifically for this purpose.
- **Support public health climate-adaptation efforts.** Funding for the CDC's Climate and Health program stands at $10 million per year, while the annual health costs of climate change events were estimated to be more than $14 billion in 2008.[158] Climate-informed health interventions include identifying likely climate impacts, potential health effects associated with these impacts, and the most at-risk populations and locations.[159] Congress should increase funding for environmental health programs, including the CDC's Climate and Health program and environmental health tracking to conduct surveillance and target interventions.
- **Develop sustainable state and local vector-control programs.** As the threat and geographic distribution of mosquitos, ticks, and other vectors changes, Congress should expand funding for the vector-borne disease program at the CDC to support state and local capacity to prevent and detect vector-borne diseases, such as Zika, West Nile Virus, and Lyme disease.
- **Guarantee clean water for all U.S. residents, including after disasters.** The administration and Congress should restore the Clean Water Rule, which includes measures to protect a safe water supply, such as addressing the ongoing problem of lead, per- and polyfluoroalkyl substances, and other toxins in drinking water; taking steps to reduce the potential for waterborne illnesses; and increasing protection against potential acts of terrorism on America's drinking and agricultural water. All states should include water security and sewage removal in their preparedness plans, and they should build relationships among health departments and local environmental and water agencies. The CDC should include national guidance and metrics for planning for a range of water-related crises.

RECOMMENDATIONS FOR STATE GOVERNMENT:

- **Every state should have a comprehensive climate vulnerability assessment and adaptation plan that incorporates public health.** Public health and environmental agencies should work together to track concerns, coordinate risk-management and communications, and prioritize necessary capabilities to reduce and address threats. States and localities should investigate what additional capacities are necessary and identify vulnerable populations and communities. State and local public health officials should incorporate environmental health into emergency operations planning and incident command.
- **Complete all steps of the CDC's Building Resilience Against Climate Effects, or "BRACE," framework, and continuously work to enhance and refine preparations for climate change.** State agencies must conduct and facilitate rigorous vulnerability assessments at the state and local levels. The assessments should focus especially on populations at highest risk and the health threats most pertinent to them. States must also push ahead to complete all steps of the framework, including identifying and implementing evidence-based interventions to protect residents. Finally, as agencies implement interventions, they should continually evaluate effectiveness and strive for quality improvement.

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Year in Review – 2020 Health Threats Incidents and Actions

This section reviews 2020's major events, research, and policy actions related to global and domestic health security.

Disease Outbreaks

Notable Incidents

- **COVID-19**
  - The novel coronavirus SARS-CoV-2, the virus that causes COVID-19, emerged internationally in late 2019. As of late February 2021, as this report was being prepared for publication, over 28 million cases; and over 500,000 deaths have been reported in the U.S. alone.[160] Globally, there have been over 109 million confirmed cases of COVID-19, and over two million deaths, reported to the World Health Organization (WHO).[161] The number of cases and the number of deaths from COVID-19 is higher in the United States than in any other country.[162] In the United States, slightly more women than men have been infected, but deaths in men are disproportionate (54 percent to 46 percent).[163] Black people account for nearly 16 percent of COVID-19 deaths, where race is known, despite representing 13 percent of the U.S. population.[164] Hispanic or Latino people account for 18 percent of reported COVID-19 cases in the U.S. as of late January 2021, a proportion approximately equal to their percentage of the U.S. population.[165] In addition, research indicates a significant level of asymptomatic cases, so true infection counts are likely higher than confirmed cases.[166] Deaths may also be underreported due to inadequate testing and given that the pandemic response itself may have indirectly caused mortality due to limited access to healthcare during pandemic surges and due to those who avoided seeking care in hospitals.[167,168] The Centers for Disease Control and Prevention (CDC) found that in the 10 weeks following declaration of the COVID-19 national emergency, emergency department visits declined 23 percent for heart attack, 20 percent for stroke, and 10 percent for hyperglycemic crisis.[169]
  - Those at highest risk for severe disease and death are the elderly and people with underlying medical conditions, but COVID-19 has severely sickened and killed many young and otherwise healthy individuals, as well. Researchers are trying to determine if certain genetic characteristics are responsible for severe versus mild disease.[170] The disease in young children is usually mild, but in rare cases it is associated with multisystem inflammatory syndrome in children, in which different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs.[171] National data reported between March and July 2020 showed that MIS-C disproportionately impacted Black and Latino children.[172] The long-term effects of COVID-19 infection aren't fully known, but findings show heart

and lung damage in some patients, and many patients report lingering fatigue, shortness of breath, and confusion.[173]

- In June 2020, the U.S. Department of Health and Human Services (HHS) Office of Minority Health announced Morehouse School of Medicine as the awardee for a new $40 million initiative to fight COVID-19 in racial- and ethnic-minority, rural, and socially vulnerable communities. The initiative—the National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities (NIMIC)—is a three-year project designed to work with community-based organizations nationwide to deliver education and information on resources to help fight the pandemic. Its aim is to strengthen efforts to link communities to COVID-19 testing, healthcare, and social services and to share and implement effective response, recovery, and resilience strategies.[174]
- The United States has undertaken unprecedented efforts to accelerate the development, manufacturing, and distribution of COVID-19 vaccines and therapeutics through significant federal investments and scientific cooperation, while maintaining standards for safety and efficacy.[175] Usually, vaccines take years of research and testing before they are available to the public. As of December 2020, two vaccines, one developed and manufactured by Pfizer-BioNTech, the other by Moderna, received emergency-use authorization (EUA) from the U.S. Food and Drug Administration (FDA).[176] Initial administration of the vaccine to priority groups, including healthcare workers and residents of nursing homes, also began in December 2020.

nycshooter

- The Trump Administration created a centralized system to order, distribute, and track COVID-19 vaccines.[177] States can order vaccine quantities (as supply allows) from the CDC. Airlines worldwide are providing transportation for billions of doses of vaccine that must be stored in frigid temperatures. FedEx and UPS are installing ultracold freezers near their air-cargo hubs, and dry-ice producers are increasing production to support vaccine distribution.[178] The U.S. Department of Defense and HHS coordinated the shipment of the initial doses to states.[179] The CDC released a playbook for state, tribal, territorial, and local jurisdictions on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions.[180] The Advisory Committee on Immunization Practices recommended priority groups to receive the initial doses of the vaccines,[181] but the final decisions on population prioritization and logistics

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are up to the states to determine, with most states prioritizing healthcare providers and long-term care facility residents in the initial phase.[182]

- While shipping of the vaccine began shortly after the FDA issued emergency-use authorizations, the initial administration of the newly approved vaccines fell far short of projected goals. As of December 30, 2020, 12.4 million vaccine doses had been distributed to states, but only 2.6 million had been administered. Experts called on the federal government to provide more coordination and resources to the states to increase their capacity to quickly administer the vaccine to more people.[183] The challenges in initial administration of the vaccine likely occurred for many reasons, including: funding for states to administer the vaccine was not signed into law until December 27, 2020, which hindered planning, communications, hiring, and training; the lack of a centralized planning effort; the lack of federal leadership; the lack of communication between federal, state, and local planners on the number of initial doses available and when; slow engagement with local partners; and the sheer immensity and complexity of the project.[184,185] HHS is partnering with pharmacies, including CVS and Walgreens, to deliver vaccines on-site at nursing homes and assisted-living facilities. Following distribution to the initial critical populations, states are planning for COVID-19 vaccines to be available in a phased approach to the priority groups in the broader population at locations such as retail pharmacies, healthcare facilities, and vaccination sites, but as this report was being finalized, a specific time frame for availability of the vaccine to the general population was unclear and may be different from state to state.[186]

Editor's note: In January 2021, the Biden administration set a goal and put in place a plan to administer 100 million vaccine doses during its first 100 days in office.[187] That goal was later increased to 150 million doses. FEMA and National Guard troops went to work in many states to assist in the vaccination effort. As of March 1, 2021, 96,402,490 vaccine doses had been distributed nationwide and 76,899,987 had been administered.[188] However, based on preliminary data from 17 states, during the first two months of vaccine distribution, Blacks and Hispanics were being vaccinated at a much lower rate than were whites.[189]

- **Seasonal flu.** As TFAH was preparing this report, flu rates for the 2020–2021 flu season were lower than usual for major regions of the country.[190] The 2019–2020 flu season was of "moderate severity"; however, the severity of the season in some age groups was higher: hospitalization rates among children ages 0 to 4 years old and adults ages 18 to 49 years old were higher than observed during the 2009 H1N1 pandemic.[191] The CDC estimates found that the 2019–2020 flu accounted for approximately 38 million illnesses, 405,000 hospitalizations, and 22,000 flu deaths.[192] Seasonal flu vaccine coverage rates increased modestly across all age groups in 2019–2020, with vaccine rates among adults increasing 3.1 percentage points over the previous season and up 1.2 percentage points among children—but that was still far below Healthy People 2020 and 2030 goals.[193] The CDC estimates that influenza vaccination prevented 7.5 million illnesses, 3.7 million medical visits, 105,000 hospitalizations, and 6,300

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deaths due to influenza during the 2019–2020 season.[194] The low 2020–2021 seasonal flu activity was likely a result of the mitigation measures to reduce the spread of COVID-19.[195]

- **Hepatitis A.** In 2020, 27 states experienced outbreaks of the Hepatitis A virus, driven in part by increases among those who reported drug use and homelessness.[196] Hepatitis A is a highly transmissible infection.[197] The Hepatitis A vaccine is recommended for certain populations; in 2019, the Advisory Committee on Immunization Practice updated its recommendations to include people experiencing homelessness in the populations who should receive the vaccine.[198] Hepatitis A infections had been going down between 2000 and 2012 but increased in 2013, 2016, and 2018.[199] As of December 4, 2020, there have been 36,848 reported cases that lead to 22,546 hospitalizations and 348 deaths since the ongoing outbreak began in 2016.[200]

- **Measles outbreaks, United States.** In 2020, U.S. measles cases were low—only 13 confirmed cases in eight jurisdictions, as of November 30, 2020.[201] Conversely, 31 states confirmed 1,282 individual cases of measles in 2019.[202] Measles is a highly contagious disease that predominantly affects young children and can cause hospitalization, and death and serious complications, such as pneumonia, encephalitis.[203] It can cause up to a 90 percent chance of disease contraction in unimmunized individuals.[204] Outbreaks have been linked to the sustained spread of measles among unvaccinated communities.[205]

- **Measles outbreaks, global.** The WHO reported that during 2019, there were more measles cases reported worldwide than in any year since 1996—869,770 confirmed cases and an estimated 207,500 deaths.[206] Fortunately, as of September 2020, the number of confirmed cases worldwide was much lower, though the Democratic Republic of the Congo, Brazil, and Nigeria reported high numbers and there were ongoing outbreaks in other nations.[207] However, COVID-19 is increasing the risk of measles outbreaks, following the suspension of measles vaccination campaigns in 26 countries. On the current trajectory, experts predict more child deaths from measles than from COVID-19 in Africa.[208]

- **The Democratic Republic of Congo Ebola outbreak.** On June 1, 2020, the Democratic Republic of the Congo declared its 11th outbreak of Ebola virus disease.[209] In November 2020, it was declared over, following a total of 130 cases and 55 deaths.[210]

- **Candida auris.** C. auris is an emerging drug-resistant fungus that has led to severe illnesses in hospitalized patients. A majority of reported cases in 2020 were in New Jersey, New York, and Illinois. Infection by this multi-drug-resistant fungus has a mortality rate close to 60 percent and presents a serious global health threat.[211] As of November 30, 2020, in the United States, there were 1,595 reported clinical cases of C. auris and an additional 3,056 patients identified with C. auris. There is transmission in multiple countries, as well.[212] With the increase of patient transfers from long term care facilities to ICUs due to COVID-19, the CDC said that it expects C. auris and other fungal infections to remain an infection control challenge for healthcare facilities in the U.S. and around the world.[213]

- **Cholera.** Cholera, an acute intestinal infection, is rare in the United States, but cases have increased steadily since 2005 globally,[214] and it is a major cause of epidemic diarrhea in the developing world. Regions with humanitarian crises, high rates of poverty, and a lack of water and sanitation infrastructure are at higher risk. In 2020, Yemen and Somalia faced serious outbreaks.[215] Researchers estimate that every year, there are 1.3 to 4.0 million cases and 21,000 to 143,000 deaths worldwide due to cholera.[216]

- **Polio.** In August 2020, the African Continent was certified wild poliovirus free by the World Health Organization, making the world poliovirus free except for Pakistan and Afghanistan.[217] After months of severe disruptions from the COVID-19 pandemic, polio vaccination campaigns have resumed in both countries as of August 2020. UNICEF estimates up to 50 million children missed their vaccinations when efforts were halted in March 2020 to minimize transmission of COVID-19.[218]

- **Foodborne illnesses.** In 2020, multistate foodborne illness outbreaks resulted from mushrooms, peaches, onions, clover sprouts, deli meats, and bagged salads. The pathogens involved include several strains of Salmonella and E. coli, as well as Listeria and Cyclospora.[219] The CDC estimates that 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne illness each year in the United States.[220] The five most common pathogens that cause foodborne illness are: (1) Norovirus, (2) Salmonella, (3) Clostridium perfringens, (4) Campylobacter, and (5) Staphylococcus aureus.[221]

Notable Events and Policy Actions:

COVID RESPONSE

- **Public Health Emergency Declaration and early COVID-19 response.** On January 31, 2020, U.S. Health and Human Services Secretary Alex Azar declared a public health emergency for the United States for the 2019 novel coronavirus.[222] Since then, HHS has renewed the declaration several times. The declaration allowed some flexibilities for states, such as temporary reassignment of personnel to the response. Before the declaration and before the Trump administration requested emergency funding, Secretary Azar tapped $105 million from the Infectious Disease Rapid Response Reserve Fund for the initial response.[223] The WHO issued a public health emergency declaration of international concern in January and labeled the outbreak as a pandemic in March, 2020.[224 225]

- **COVID Response Legislation.** Congress has enacted several public laws providing funding and authorities to assist in the response to the pandemic:[226,227]

  - **Coronavirus Preparedness and Response Supplemental Appropriations Act (P.L. 116-123).** The President signed the act into law on March 6, 2020, providing $8.3 billion in emergency funding for public health measures, including the development of medical countermeasures and grants for public health agencies.

  - **The Families First Coronavirus Response Act (P.L. 116-127).** The President signed the act into law on March 18, 2020; it included the Second Coronavirus Preparedness and Response Supplemental Appropriations Act. The legislation expanded food and nutrition programs, unemployment benefits, and emergency family and medical leave; it also required certain employers to provide paid sick leave for workers unable to work due to COVID-19, and it provided access to COVID-19 testing with no cost to the individual.

  - **The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136).** The President signed the act into law on March 27, 2020, providing over $2.2 trillion in relief to individuals; businesses; state, local, and federal agencies; and industry sectors affected by the COVID-19 pandemic and the government-led effort to limit its public health impact. It also included a variety of oversight provisions designed to increase the information available to Congress regarding the federal government's implementation of the CARES Act and response to the COVID-19 pandemic.[228]

  - **The Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139).** The President signed the act into law on April 24, 2020; it included Additional Emergency Appropriations for Coronavirus Response. The bill extended the Paycheck Protection Program and small-business loans and allocated funding for healthcare providers and COVID-19 testing.

  - **The Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (P.L. 116-26).** Congress passed and the President signed the act with the fiscal year (FY) 2021 appropriations bills and signed it into law on December 27, 2021. The bill provided $900 billion in emergency appropriations, including $73 billion for HHS, of which $8.75 billion will support the vaccination campaign.

- **Payments to healthcare providers.** The CARES Act, Paycheck Protection Program and Health Care Enhancement Act, and the Coronavirus Response and Relief Supplemental Appropriations Act allocated $178 billion for a provider relief fund for hospitals, clinics, and other healthcare providers to recover some revenue lost due to the pandemic.[229] In addition, changes in HHS telehealth policies were put in place to expand access to telehealth services during the pandemic.[230]

COVID-19 Vaccine

- **COVID-19 Vaccine.** As of December 2020, two vaccines—one developed and manufactured by Pfizer-BioNTech, the other by Moderna—received emergency-use authorization from the FDA (see COVID sidebar, on page 55).

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COVID RESPONSE

Additional COVID-19 Response Actions:

- **Medical supply shortages.** The quantities of medical supplies in the Strategic National Stockpile and through the private-sector supply chain were not sufficient for a pandemic as widespread as COVID-19. Shortages of PPE,[231] ventilators,[232] testing supplies,[233] and other medical supplies and products reached critical levels at different phases of the pandemic. President Trump invoked the Defense Production Act in April 2020 to try to spur private-sector production of these supplies.[234]
- **National Special Pathogen System.** In March 2020, ASPR expanded the Regional Ebola Treatment Network to become the National Special Pathogen System (NSPS) through COVID-19 emergency supplemental funding. The NSPS builds on the Regional Ebola Treatment Network and was originally created to support the urgent preparedness and response needs of hospitals, health systems, and healthcare providers on the front lines of the COVID-19 outbreak. The system is designed to to help prepare hospitals and health systems to identify, isolate, assess, transport, and treat patients with COVID-19 or other special pathogens or persons under investigation for such illnesses. The long-term vision of the NSPS is to create a nationwide systems-based network approach, similar to other national systems (e.g., the national trauma system) for all special pathogens.
- **Crisis standards of care.** Major surges in COVID-19 patients caused hospitals and intensive-care units to exceed capacity. Hospitals canceled admissions and nonemergency procedures and established alternate care sites. In December 2020, 10 national organizations issued a statement outlining urgent action for states, healthcare systems, and health departments to implement crisis standards of care, including legal protections for healthcare workers, statewide information sharing, distribution of patients and resources, and care coordination across jurisdictions.[235]

Vaccines: Earning Trust and Access in Communities of Color and Tribal Nations

The reported hesitance among some populations of color and Tribal Nations toward COVID-19 vaccines[236] has a basis in historic mistreatment and the effect of current-day structural racism. These experiences could have long-term impacts on vaccine confidence and vaccination rates in these groups. In October 2020, TFAH, the National Medical Association, and UnidosUS partnered to host an expert convening on how to earn vaccine trust and increase vaccine access within communities of color and Tribal Nations. The experts concluded that earning such trust will require working with leaders in those communities to use their agency as trusted messengers. Leaders from these communities must have a place at the planning table and be provided the resources needed to engage with and share information with their stakeholders. All vaccine education messaging must be culturally and linguistically appropriate. Messaging campaigns must feature trusted messengers, and education programs should take advantage of existing health communications networks. Read the full policy brief, *Building Trust in and Access to a COVID-19 Vaccine Within Communities of Color and Tribal Nations*, or find it on the TFAH website.[237]

- **Ending the HIV epidemic.** In FY 2020, the Trump administration awarded funding to its *Ending the HIV Epidemic: A Plan for America Initiative,* which aims to reduce the number of new HIV infections in the United States by 90 percent by 2030. In December 2019, Congress approved the largest increase to domestic HIV/AIDS-prevention programs from multiple federal sources, including the CDC, in decades, bringing federal funding in FY 2020 for HIV/AIDS (across multiple programs) to just over $28 billion.[238,239] In addition, HHS, through the Health Resources and Services Administration (HRSA), awarded more than $2 billion in Ryan White HIV/AIDS Program grants to cities, counties, states, and local community-based organizations. This funding supports a comprehensive program of HIV primary medical care, medication, and essential support services with the goal of improving the health quality of more than half a million people with HIV in the United States.[240]

- **Emerging infectious diseases.** The National Institute of Allergy and Infectious Diseases (NIAID), within NIH, awarded 11 grants totaling approximately $17 million to establish the Centers for Research in Emerging Infectious Diseases. The new global network will involve multidisciplinary investigations into how and where viruses and other pathogens emerge from wildlife and spillover to cause disease in people. NIAID intends to provide approximately $82 million over five years to support the network.[241]

- **Viral hepatitis strategic plan.** HHS released the Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination 2021–2025, which serves as a roadmap to hepatitis elimination. HHS sought input from a broad mix of stakeholders on whether the plan's goals, objectives, and strategies appropriately address the viral hepatitis epidemic and whether there are any critical gaps.[242]

- **National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB).** Antimicrobial resistance, the rise of superbugs that are resistant to existing medicines, is a major threat to health. Originally released in 2015, the 2020–2025 CARB builds on the original by expanding evidence-based activities that have been shown to stop the spread of antibiotic resistance, such as increasing infection prevention and control and improving the way antibiotics are used. Developed by the HHS Office of the Assistant Secretary for Planning and Evaluation and authored by agencies within the CARB Task Force, which is co-chaired by HHS, the U.S. Department of Agriculture, and the U.S. Department of Defense, the plan's purpose is to guide U.S. government activities, as well as action by public health, healthcare, and veterinary partners to address urgent and serious antibiotic-resistant threats that affect people in the United States and globally.[243]

- **United States officially withdraws from the World Health Organization.** In July 2020, President Trump formally announced his intention to withdraw the United States from the WHO, effective July 6, 2021.[244]

Editor's note: on January 21, 2021, the Biden administration restored U.S. membership in the WHO.

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- **Food safety.** In July 2020, the FDA released its *New Era of Smarter Food Safety Blueprint*, which reflects input from a variety of stakeholders and outlines a path forward building on the implementation of the FDA Food Safety Modernization Act.[245] Its four core elements are: (1) tech-enabled traceability and foodborne outbreak response—using technologies, data streams, and approaches that will greatly reduce the time it takes to trace the origin of a contaminated food; (2) smarter tools and approaches for prevention—identifying new tools, processes, and communications to inform prevention efforts; (3) new business models and retail modernization—advancing the safety of both new business models, such as e-commerce and home delivery of food, and traditional business models, such as retail food establishments; and (4) food safety culture—supporting and strengthening cultures that embrace food safety within the FDA, on farms, and in facilities.[246]

Notable Research Findings, Meetings, and Federal Hearings:

- **Malaria treatment and prevention.** In May 2020, the FDA approved artesunate for injection to treat severe malaria in adult and pediatric patients.[247] Treatment of severe malaria with intravenous artesunate should always be followed by a complete treatment course of an appropriate oral antimalarial regimen. According to the CDC, approximately 2,000 cases of malaria are diagnosed in the United States each year, with 300 of those infected having severe disease.[248] In addition, the first phase 1 clinical trial, testing the safety and effectiveness of a monoclonal antibody against malaria, began. If effective, it would prevent malaria infections for several months with a single dose—a benefit to tourists, medical workers, and military personnel.[249]

- **Eastern Equine Encephalitis vaccine.** In June 2020, Bavarian Nordic announced topline results from the first-in-human trial of a prophylactic vaccine candidate against three equine encephalitis viruses (EEEV): western, eastern, and Venezuelan. The study, although small, showed that the vaccine was well tolerated and immunogenic across all dose groups, with injection-site pain as the most common vaccine-related adverse event.[250]

- **Ebola treatment.** In October 2020, the FDA approved Inmazeb, a mixture of three monoclonal antibodies made by Regeneron. This is the first FDA-approved treatment for Ebola virus infection in adult and pediatric patients, following a U.S. government-supported trial and expanded-access protocol in the Democratic Republic of the Congo.[251]

- **Universal flu vaccine study.** A universal influenza vaccine, FLU-v, which could confer long-lasting immunity from multiple influenza subtypes among all age groups, demonstrated immunogenicity and safety in its phase 2b study and will enter a larger phase 3 trial.[252] The FLU-v vaccine is designed to stimulate the production of flu-specific cytotoxic T lymphocytes, which kill and remove influenza-infected cells, by targeting internal viral proteins that are not as variable as the constantly mutating surface proteins currently targeted in seasonal flu vaccines.[253]

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Severe Weather and Natural Disasters

Notable Incidents:

- **Tornados.** In early March 2020 in the Nashville area, 24 people were killed by two tornadoes, one of which was an EF-4 traveling at 60 miles per hour (mph)—significantly harder to outrun (or take cover from) than a typical tornado's 10 to 20 mph speed.[254] Also during a two-day period in mid-March, over 100 tornadoes ravaged the South and Southeast,[255] causing over $450 million in damage and 32 fatalities.[256]

- **Extreme heat.** In the United States, extreme heat kills more people than any other weather-related threat.[257] July 2020 nearly tied July 2019's record of the hottest month ever recorded on Earth—coming in just 0.02 degrees shy.[258,259] In August 2020, Death Valley reached 130 degrees Fahrenheit, and on September 6, 2020, Los Angeles County recorded its highest temperature ever, at 121 degrees Fahrenheit.[260] September 2020 was also the hottest September on record.[261]

- **Hurricanes.** The 2020 Atlantic hurricane season was the most active—breaking the record for the most named storms in a season, including six major hurricanes.[262] In the United States, Hurricane Isaias made landfall in North Carolina as a Category 1 and killed nine people as it moved up the coast,[263] causing more than $4 billion in damage.[264] Laura formed in the Caribbean, leaving nine dead, before developing into a Category 4 storm and making landfall in Louisiana, where it killed 27 people[265] and caused an estimated $10 to $12 billion in damage.[266] In September 2020, Hurricane Sally hit Alabama as a Category 2 and caused major flooding but no deaths,[267] though damage is estimated at $8 to $10 billion.[268] Hurricane Delta hit Louisiana in October 2020, killing at least four.[269] Central America was hit hard in 2020 with two back-to-back Category 4 storms: just weeks after Hurricane Eta made landfall and killed over 130 people, Hurricane Iota (a massive Category 5 storm while in the Atlantic) hit the same area. Together, the storms killed over 200 people.[270] In addition, the pandemic made hurricane preparations, evacuations, and sheltering more difficult.

- **Iowa derecho.** A powerful derecho—a fast wind storm associated with strong thunderstorms—tore through central Iowa in August 2020. Winds topped 100 mph and destroyed miles of crops, homes, businesses, and vehicles, and killed four people. The derecho was officially the costliest thunderstorm event in recorded U.S. history—estimated at $7.5 billion in damages.[271]

- **Wildfires in California and other states.** Several states experienced wildfires in 2020, including California, Oregon, and Colorado.[272,273] California experienced another historic fire season in 2020—five of the six largest wildfires since 1932 in California happened in 2020.[274] As of November 29, 2020, over 4 million acres had burned, compared with just under 260,000 acres burned during the same period in 2019.[275] Thirty-three people, including four firefighters, died in California in 2020 due to wildfires.[276] California's average temperature has increased by about 3 degrees Fahrenheit over the past century, which is three times the global temperature increase of 1 degree Fahrenheit.[277] Heavy spring rains promoted extensive vegetation growth, which withered in the heat and became fuel for wildfires to spread quickly through dry land.[278] In addition, the 2020 season was a La Niña cycle—colder than average surface-water temperatures in the Pacific—which often trigger hotter and drier weather in the Southwest.[279] Oregon also experienced an especially destructive wildfire season: 4,009 homes burned down in 2020, compared with 93 homes total from 2015 to 2019.[280] In Colorado, wildfires have consumed 9 percent of Rocky Mountain National Park and destroyed several historic buildings.[281] Exacerbating these fires is an ongoing pine-beetle outbreak, which has increased the number of dead trees for fuel.[282] Across the United States, 9.5 million acres have burned as of December 4, 2020, compared with 4.6 million acres for the same period in 2019.[283]

- **California power outages.** In an attempt to reduce the risk of overloading the power grid during an extreme heatwave, California's Independent System Operator, which manages the state's power supply, ordered utilities to impose temporary blackouts for the first time in 19 years.[284] While these outages only lasted an hour or two,[285] there is potential for unplanned and planned outrages to create health emergencies for some residents, including by presenting significant risks to patients in healthcare and long-term care facilities; people with electrically dependent medical equipment or medicines, such as oxygen, wheelchairs, and insulin; and the safety of food and water.[286]

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Notable Events and Policy Actions:

- **Public health emergency declarations.** In January 2020, HHS Secretary Azar declared a public health emergency for Puerto Rico following the late-December 2019 earthquakes and continuing aftershocks.[287] Azar declared emergencies in Louisiana and Texas due to Hurricane Laura and in Oregon and California due to wildfires. The declarations and related waivers give HHS's Centers for Medicare & Medicaid Services (CMS) beneficiaries and their healthcare providers and suppliers greater flexibility in meeting emergency health needs.[288,289]

- **Health center support.** In September 2020, HHS, through HRSA, awarded more than $79 million in construction and other capital support for 165 HRSA-funded health centers impacted by Hurricanes Florence and Michael, Typhoon Mangkut, and Super Typhoon Yutu, as well as for wildfires and earthquakes that occurred in 2018 and tornadoes and floods that occurred in 2019.[290]

Notable Research Findings, Meetings, and Federal Hearings:

- **Extreme rain.** Research from the National Oceanic and Atmospheric Administration on all Atlantic hurricanes affecting the southeastern and eastern United States during the 20th century found that extreme rain risk is highest after hurricanes weaken into tropical storms. The heaviest rainfall over the largest areas occurs after major hurricanes become tropical storms, not during the hurricanes—even major hurricanes—themselves.[291]

- **National Risk Index.** In November 2020, the Federal Emergency Management Agency (FEMA) released the National Risk Index, an online tool to help illustrate the nation's communities most at risk of natural hazards. It provides a holistic view of community-level risk nationwide by combining 18 hazards with socioeconomic and built-environment factors. The tool determines risk by reviewing a community's expected annual loss, by measuring hazard frequency, exposure, and historic loss rate; social vulnerability, by measuring the susceptibility of impacted social groups; and community resilience, by measuring the ability of a community to recover from the impacts of natural hazards. These data can help in developing a FEMA-approved hazard-mitigation plan to help increase community resilience, which is a prerequisite for applying for FEMA's mitigation grants.[292]

- **Climate reports.** The United Nations' World Meteorological Organization released two reports on climate in 2020. The State of Climate Services (2020) found that between 1970 and 2019, 79 percent of disasters worldwide involved weather-, water-, and climate-related hazards, which accounted for 56 percent of deaths and 75 percent of economic losses from disasters. The report highlights progress made in early warning systems' capacity, and it identifies where and how governments can invest in effective early warning systems to strengthen countries' resilience to multiple weather-, water-, and climate-related hazards. United in Science 2020, a new multi-agency report from leading science organizations, highlights the increasing and irreversible impacts of climate change and documents how COVID-19 has impeded the ability to monitor these changes through the global observing system.[293]

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CLIMATE CHANGE & HEALTH: MEASURING STATES' VULNERABILITY AND PREPAREDNESS

TFAH and JHU Bloomberg School of Public Health study reports on states' vulnerability to and readiness for the health impacts of climate change.

Climate change poses serious, immediate threats to human health. Catastrophic impacts are well-understood, such as death and injury from more frequent and more intense hurricanes and wildfires. Many dangers, however, lack a singular, spectacular event and are therefore more insidious: longer-lasting heatwaves; poorer air quality; chronic flooding; increases in vector-, water-, and food-related infections; and the toll all of this takes on people's mental health and well-being.

The release of greenhouse gases through human activities over the past two centuries has made some level of global warming inevitable. Humans must learn to live with the effects of this change (adaptation), even as they pursue the essential objective of minimizing future warming by reducing greenhouse gas emissions (mitigation).

Climate change, however, does not affect all people and places equally. A person's experience depends, in large part, on where she lives. Many health outcomes are linked to environmental factors and, therefore, sensitive to changes in climate. Social and demographic factors also drive vulnerability, meaning that the health of some communities or people could be more affected than others. In many cases, vulnerability reflects existing health risk factors and disparities, which are in turn tied to structural and systemic racism.

Fortunately, important opportunities to protect people's health from the impacts of climate change exist at the state and local level. Adaptation, which seeks to reduce injuries, illness, death, and suffering, is an extension of public health approaches that emphasize prevention and preparedness. Many of these actions are driven by state-level plans, policies, and programs, which provide a critical foundation and supply of resources to support additional efforts at the community level.

Given the size and diversity of the country, each state and its communities will experience climate change differently. State leaders must understand their particular risks and vulnerabilities in order to plan effectively. In areas of a state where vulnerability is higher, state leaders should invest more in adaptation and preparedness. Likewise, states that are more vulnerable overall should go to greater lengths to adapt to climate-related hazards.

A December 2020 report, *Climate Change & Health: Assessing State Preparedness*, by TFAH and the Johns Hopkins Bloomberg School of Public Health, examined states' readiness to protect residents from the health impacts of climate change in light of the nature and level of risks they face.[294] While every state had engaged in at least some level of planning and preparation, there was significant variation, and, in many places, a great deal of room for improvement. Of greatest concern, states with the highest

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levels of vulnerability—predominantly located in the Southeast—tended to be among the least prepared. (See Table 14.)

Leaders at all levels of government must act with urgency and persistent focus to ensure that their people, particularly those who are most vulnerable, are safe and secure. The report offers federal and state policy and program recommendations, including enacting legislation requiring a national strategic plan, fully funding the CDC's Climate and Health program, bolstering states' core public health preparedness capabilities, and establishing ongoing, dedicated state funding and staff for climate-related preparations.

Table 14. States Grouped by Level of Vulnerability and Preparedness

Vulnerability Group	State	Vulnerability Score Least Vulnerable: 3.4-4.7 More Vulnerable: 4.8-5.3 Most Vulnerable: 5.4-6.3	Preparedness Score Least Prepared: 4.0-5.0 More Prepared: 5.1-5.8 Most Prepared: 5.9-6.6
Least Vulnerable	Utah	3.8	6.6
	Maryland	4.4	6.3
	Vermont	4.3	6.3
	Colorado	4.0	6.2
	Wisconsin	4.4	6.1
	New Hampshire	4.1	6.0
	District of Columbia	4.5	5.9
	Maine	4.5	5.9
	Minnesota	4.4	5.8
	Washington	4.5	5.8
	Michigan	4.7	5.8
	Alaska	3.4	5.4
	North Dakota	4.1	5.2
	Nebraska	4.6	5.1
	Idaho	4.2	5.0
	Montana	4.3	4.8
	Wyoming	4.2	4.5
More Vulnerable	Virginia	4.8	6.3
	Massachusetts	4.9	6.2
	Rhode Island	4.9	6.0
	Illinois	4.9	6.0
	New York	5.3	5.9
	Pennsylvania	5.3	5.9
	Connecticut	4.9	5.9
	Oregon	4.8	5.8
	Delaware	4.9	5.7
	Kansas	5.1	5.3
	Iowa	4.9	5.3
	Indiana	5.0	5.0
	Ohio	5.1	5.0
	New Jersey	5.2	4.9
	Hawaii	5.3	4.8
	Nevada	4.9	4.6
	South Dakota	4.8	4.5
Most Vulnerable	North Carolina	5.5	6.0
	Arizona	5.4	5.9
	Alabama	5.8	5.8
	California	5.5	5.8
	Louisiana	5.9	5.7
	New Mexico	5.8	5.7
	Arkansas	6.1	5.5
	Missouri	5.4	5.5
	Florida	6.3	5.1
	Tennessee	5.5	4.9
	Georgia	5.6	4.9
	Kentucky	5.9	4.8
	South Carolina	5.9	4.8
	Texas	5.5	4.6
	Mississippi	5.9	4.5
	Oklahoma	5.5	4.5
	West Virginia	5.8	4.0

"Most prepared," among states that were "least vulnerable."

"Least prepared," among states that were "least vulnerable."

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All Hazards Events and Policy Actions

Notable Incidents:

- **E-cigarette and vaping injuries and deaths.** According to the CDC, as of February 18, 2020, a total of 2,807 hospitalized e-cigarette or vaping-associated lung injuries (EVALI) or deaths were reported to the CDC from all 50 states, DC, Puerto Rico, and the U.S. Virgin Islands. Sixty-eight deaths have been confirmed in 29 states and DC. Due to continued declines in new EVALI cases since September 2019, and the identification of vitamin E acetate as a likely primary cause of EVALI, the CDC is no longer collecting case reports.[295]

- **Mass shootings.** During 2020, in the United States, there were 611 mass shootings—defined as an incident in which at least four people are shot, excluding the shooter—in 2020.[296] This is a significant increase since 2019, when there were 417 total mass shootings.[297] These events have long-term health effects on communities and survivors, including post-traumatic-stress disorder, substance abuse, anxiety, and depression.[298]

- **Terror attacks.** On Christmas day, a bomb detonated in downtown Nashville, damaging over 40 businesses in the area and injuring three people. Quick evacuations by first-responders likely saved lives in the area.[299] While the motivation for the Christmas Day bombing is not known, the Center for Strategic and International Studies reported that white supremacists and other like-minded extremists conducted two-thirds of terrorist plots and attacks in the United States as of October 2020.[300]

Notable Events and Policy Actions:

- **Animal disease research.** The U.S. Department of Homeland Security is transferring a new facility—the National Bio and Agro-Defense Facility, which will research foreign animal diseases—to the U.S. Department of Agriculture. Foreign animal diseases pose a risk to livestock (and in rare cases, people) and the facility will develop countermeasures for these diseases. A report by the Government Accountability Office (GAO) found that it may not be ready to open in December 2022 as planned, despite both departments following practices for a successful transfer.[301]

- **Radiological detection.** The Defense Advanced Research Projects Agency (DARPA) greenlit an automated, networked radiation detection system known as SIGMA for use by the Port Authority of New York and New Jersey, which is theoretically capable of providing counterterrorism support through constant monitoring for radiological and nuclear threats. DARPA has further developed and tested sensors for SIGMA to add chemical, biological, and explosive threat detection to its list of capabilities. SIGMA is based in worn, portable sensors, vehicular-mounted sensors, and stationary sensors at key transportation nodes, and it can be constantly improved through regular software updates. Officials and first-responders can use SIGMA to track alerts and threats in real time, allowing for enhanced coordination.[302]

- **Next Generation 911.** The U.S. Department of Homeland Security Science and Technology Directorate and the U.S. Department of Transportation have begun systems interoperability and compatibility testing for the Next Generation 911 (NG911) through a contract with the Critical Infrastructure Resilience Institute of the University of Illinois at Urbana-Champaign. NG911 will update the current nationwide emergency response system to an Internet Protocol (IP) platform, which will enable voice, video, photographs, text, and future communications technologies to be transmitted to and by the public and first-responders for assistance.[303] No system launch date has been announced.

- **HHS/ASPR Strategic Plan.** In April 2020, the U.S. Office of the Assistant Secretary for Preparedness and Response (ASPR) released the ASPR Strategic Plan for FY 2020-23, which organizes and identifies how ASPR will fulfill its mission of saving lives and protecting Americans from 21st-century health security threats and achieve its strategic vision: "the nation's health care and response systems and the communities they serve are prepared, responsive, and resilient, thereby limiting the adverse health impacts of emergencies and disasters." The plan builds on the successful foundation established by the ASPR strategic plans issued in 2011 and 2014, and aligns with the HHS Strategic Plan FY 2018-2022 and other relevant national strategies and legislation. It is also informed by experience and lessons from real-world incidents, exercises, and training activities occurring over more than a decade. The plan organizes ASPR's efforts under four priority goals: (1) foster strong leadership; (2) sustain robust and reliable public health security capabilities; (3) advance an innovative medical countermeasures enterprise; and (4) build a regional disaster health response system.[304]

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Notable Research Findings, Meetings, and Federal Hearings:

- **Retention of the public health workforce.** As of November 2020, at least 70 top public health officials had been fired, resigned, or planned to leave their posts since the beginning of the pandemic.[305] The alarming trend often resulted from threats, both in-person and via social media, scapegoating, or political retribution. Even before the pandemic and related recession, state health agencies had lost nearly 10 percent of their full-time equivalent (FTE) workforce from 2012 to 2019,[306] while local health departments lost about 16 percent of their FTE staff from 2008 to 2019.[307]

- **Recruitment and retention of scientists.** A May 2020 GAO report found that HHS has had trouble recruiting and retaining medical, engineering, and other science and technology professionals to support activities like biomedical and clinical research. The 21st Century Cures Act provides additional hiring and retention authority—allowing HHS to hire up to 2,000 scientists with certain specialized graduate degrees and to increase the top pay to hire and retain an expert staff.[308]

- **Rebuilding the Public Health Workforce.** State and local revenue losses due to the COVID-19 economic crisis is likely to lead to budget cuts at the state and local level and is expected to worsen the public health workforce staffing shortfall. COVID response funding did allow for short-term staffing increases but not for the hiring of the permanent public health professionals necessary to meet 21st-century challenges.[309]

- **Antibiotic resistance.** Two novel investigative drugs that target antibiotic-resistant infections began advanced development through the Biomedical Advanced Research and Development Authority to begin phase 2 and 3 clinical trials. One drug tackles Clostridioides difficile (C. difficile) infections, which causes an estimated12,800 deaths per year.[310] The second uses CRISPR technology to kill Escherichia coli (E. coli) bacteria that cause recurring or drug-resistant urinary tract infections. If successful, it would be the first CRISPR-engineered bacteriophage therapy to be FDA-approved.[311] Bacteriophages are viruses that infect and replicate only in bacterial cells. They cannot infect human cells, and because each type of bacteriophage only kills a specific set of bacteria, it's less likely to disturb the beneficial bacteria in the human body.[312] In addition, the FDA approved cefiderocol for hospital-acquired, ventilator-associated bacterial pneumonia due to multidrug-resistant gram-negative bacteria.[313]

- **Legislative pandemic preparation blueprint.** In July 2020, then–Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander released "Preparing for the Next Pandemic," a legislative blueprint with five recommendations for legislators to address future pandemics based on lessons learned from COVID-19 and the past 20 years of pandemic planning. The five recommendations involve: (1) accelerated research and development for tests, treatments, and vaccines; (2) expanded disease surveillance; (3) improved stockpile capacity and distribution process; (4) improved state and local response capacity; and (5) improved federal coordination.[314] Leading public health experts sent the committee over 350 recommendations of short-term and long-term proposals to address future pandemics on a range of topics, including sustaining onshore manufacturing, creating and sustaining state stockpiles, and improving the federal stockpile.[315]

- **Preparedness Summit.** In August 2020, more than 1,300 attendees—who work in all levels of government, emergency management, volunteer organizations, healthcare coalitions, and academia—participated in the first ever virtual Preparedness Summit, "Fixing Our Fault Lines: Addressing Systemic Vulnerabilities." Attendees participated in more than 115 demonstrations, workshops, and educational sessions, and heard from expert-led panels, which provided an opportunity to prepare for, respond to, and recover from the waves of the COVID-19 pandemic and the many other threats to public health and health security.[316]

- **COVID-19 and Achieving Health Equity Report.** In September 2020, then–Senate HELP Committee Ranking Member Patty Murray also released a report, "COVID-19 & Achieving Health Equity: Congressional Action is Necessary to Address Racism and Inequality in the U.S. Health Care System." The report included 30 recommendations to Congress, including dedicated funding for COVID-19 relief for communities of color, requiring an equitable vaccine distribution plan, and a federal right to paid sick days and family and medical leave.[317]

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Appendix B: Methodology

Trust for America's Health (TFAH) made major refinements to its methodology for Ready or Not in 2018. For more information, see the 2019 edition of the series, Appendix A: Methodology.[318]

To meet TFAH's criteria, each indicator must be:

- **Significant.** The indicator needed to be a meaningful measure of states' public health emergency preparedness. The NHSPI first measured significance by using a multistage Delphi process with a panel of experts and then again by TFAH through interviews with additional experts.
- **Broadly relevant and accessible.** The indicator needed to be relevant—and timely data needed to be accessible—for every state and the District of Columbia.
- **Timely.** Data for the indicator needed to be updated regularly.
- **Scientifically valid.** Data supporting the indicator needed to be credible and rigorously constructed.
- **Nonpartisan.** The indicator, and data supporting the indicator, could not be rooted in or seen as rooted in any political goals.

Using these criteria, TFAH aims to select a broad set of actionable indicators with which it—and other stakeholders, including states themselves—can continue to track states' progress. (Complete data were not available for U.S. territories.) TFAH will strive to retain all or most of these indicators for multiple years to assist states in tracking their progress against each measure.

TFAH seeks measures that are incorporated in the NHSPI and that most closely meet TFAH's criteria. There is one exception: a measure of state public health funding-level trends that the NHSPI does not track.

Indicator Data Collection

The NHSPI provided TFAH with data for every indicator except five (those data tied to the NLC, public health funding, flu vaccination, hospital patient safety, and laboratory surge capacity). In cases where newer data were available than those modeled in the 2020 edition of the NHSPI, TFAH collected and verified figures from their original sources.

Public Health Funding Data Collection and Verification

To collect public health funding data for this report, TFAH examined states' publicly available funding documents and surveyed state officials. Informed by the Public Health Activities and Services Tracking project at the University of Washington, TFAH defines public health programming and services as inclusive of communicable disease control; chronic disease prevention; injury prevention; environmental public health; maternal, child, and family health; and access to and linkage with clinical care. Specifically, this definition includes:

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- **Communicable disease control.** Public health services related to communicable disease epidemiology, hepatitis, HIV/AIDS, immunization, sexually transmitted diseases, tuberculosis, etc.
- **Chronic disease prevention.** Public health services related to asthma, cancer, cardiovascular disease, diabetes, obesity, tobacco, etc.
- **Injury prevention.** Public health services related to firearms, motor vehicles, occupational injuries, senior falls prevention, substance-use disorder, other intentional and unintentional injuries, etc.
- **Environmental public health.** Public health services related to air and water quality, fish and shellfish, food safety, hazardous substances and sites, lead, onsite wastewater, solid and hazardous waste, zoonotic diseases, etc.
- **Maternal, child, and family health.** Public health services related to the coordination of services; direct service; family planning; newborn screening; population-based maternal, child, and family health; supplemental nutrition; etc.
- **Access to and linkage with clinical care.** Public health services related to beneficiary eligibility determination, provider or facility licensing, etc.

TFAH excludes from its definition insurance coverage programs, such as Medicaid or the Children's Health Insurance Program, as well as inpatient clinical facilities.

TFAH, under the guidance of state respondents, revised data for the base year. (In this report, that was FY 2019.) For some states, this was necessary to improve comparability between the two years when a reorganization of departmental responsibilities had occurred over the period.

All states and the District of Columbia verified their funding data.

Scoring and Tier Placements

TFAH grouped states based on their performances across the 10 indicators, and TFAH gave partial credit for some indicators to draw finer distinctions among states and within states over time. TFAH placed states into three tiers—high tier, middle tier, and low tier—based on their relative performance across the indicators.

Specifically, TFAH scored each indicator as follows:

- Adoption of the NLC: 0.5 point. No adoption: 0 points.
- Percent of hospitals participating in healthcare coalitions: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - Within one standard deviation above the mean (and states with universal participation): 1 point.
  - Within one standard deviation below the mean: 0.75 point.
  - Between one and two standard deviations below the mean: 0.5 point.
  - Between two and three standard deviations below the mean: 0.25 point.
  - More than three standard deviations below the mean: 0 points.
- Accreditation by the PHAB: 0.5 point. Not accredited: 0 points.
- Accreditation by the EMAP: 0.5 point. Not accredited: 0 points.
- Size of state public health budget compared with the past year (nominally, not inflation-adjusted).
  - No change or funding increase: 0.5 point.
  - Funding decrease: 0 points.
- Percent of population who used a community water system that failed to meet all applicable health-based standards: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - Within one standard deviation above the mean (and states with 0 percent of residents who used a noncompliant community system): 1 point.
  - Within one standard deviation below the mean: 0.75 point.
  - Between one and two standard deviations below the mean: 0.5 point.
  - Between two and three standard deviations below the mean: 0.25 point.
  - More than three standard deviations below the mean: 0 points.
- Percent of employed population with paid time off: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - Between one and two standard deviations below the mean: 0.25 point.
  - More than two standard deviations below the mean: 0 points.

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- Percent of people ages 6 months or older who received a seasonal flu vaccination: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - Between one and two standard deviations below the mean: 0.25 point.
  - More than two standard deviations below the mean: 0 points.
- Percent of hospitals with a top-quality ranking ("A" grade) on the Leapfrog Hospital Safety Grade. TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - Positive number, more than one standard deviation below the mean: 0.25 point.
  - No hospitals with a top-quality ranking ("A" grade): 0 points.
- Public health laboratory has a plan for a six- to eight-week surge in testing capacity: 0.5 point. Did not report having a plan: 0 points.

The highest possible score a state could receive was 7.5 points.

TFAH placed states whose scores ranked among the top 17 in the high-performance tier. TFAH placed states whose scores ranked between the 18th-highest and 34th-highest in the middle tier. TFAH placed states with scores ranked between the 35th-highest and 51st-highest in the low-performance tier. (Ties in states' scores can prevent an even distribution across the tiers.)

This year, states in the high tier had scores ranging from 6 to 7; states in the middle tier had scores ranging from 5.25 to 5.75; and states in the low tier had scores ranking from 4 to 5.

Assuring data quality

TFAH conducted several rigorous phases of quality assurance to strengthen the integrity of the data and to improve and deepen TFAH's understanding of states' performance, especially that of outliers on specific indicators. During collection of state public health funding data, researchers systematically inspected every verified data file to identify incomplete responses, inconsistencies, and apparent data entry errors. Following this inspection, TFAH contacted respondents and gave them the opportunity to complete or correct their funding data.

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Date:	Wednesday, March 9, 2022 12:27:15 PM
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FYSA

From: Meredith Allen <mallen@astho.org>
Sent: Tuesday, March 8, 2022 4:27 PM
To: Meredith Allen <mallen@astho.org>
Subject: TIME SENSITIVE and EMBARGOED: TFAH's Ready or Not 2022 report on public health emergency preparedness

Dear Directors of Public Health Preparedness,

Attached is the embargoed copy, with supporting information, of the Trust for America's 2022 Health Ready or Not Preparedness Report which is **EMBARGOED UNTIL 12:01 AM, MARCH 10, 2022**.

We anticipate that this release will generate some level of national, regional, and local media coverage as well as possibly inquiries from state legislatures and/or your governors' offices, especially given ongoing response to the COVID-19 pandemic. As such, we recommend that states be prepared to share specific examples of progress, accomplishments and, yes, unmet needs, associated with all-hazards readiness, including specific recent high profile incident responses.

ASTHO has also shared this embargoed report with State and Territorial Health Officials and Senior Deputies.

Thank you,
Meredith

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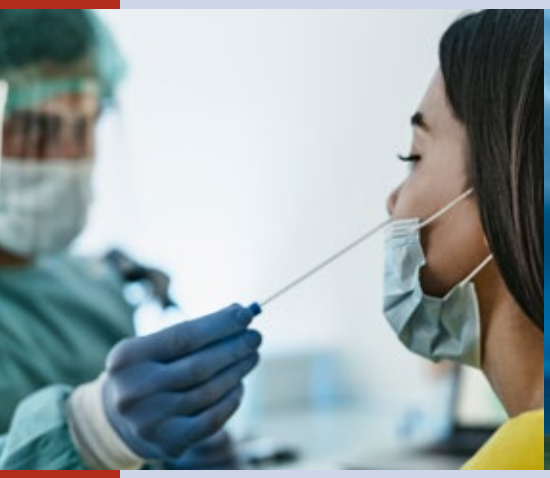
ISSUE REPORT

Ready or Not:

PROTECTING THE PUBLIC'S HEALTH FROM DISEASES, DISASTERS, AND BIOTERRORISM 2022

SPECIAL SECTION: Lessons of the Pandemic's Tragic Death Toll: What Needs to be Done to Save Lives During the Next Public Health Emergency?



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Ready or Not and the NHSPI are complementary projects that work together to measure and improve the country's health security and emergency preparedness. TFAH looks forward to a continued partnership in order to protect the public's health.

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Ready or Not 2022

Executive Summary

As this report was being prepared, over 900,000 people in the United States and nearly 6 million worldwide had died due to COVID-19,[1] and the world had experienced two years of economic and social disruption. In addition, 2021 saw record heat in many states, extensive flooding, a highly active Atlantic hurricane season, and unusual and deadly December tornados. These events led to nearly unprecedented levels of illness, social upheaval, and economic hardship, including overwhelmed hospitals, job loss, property loss, children's learning loss, and mental health concerns.

During 2021, the nation made progress in many areas in its response to the pandemic. As this report was being produced, 62 percent of the nation's population was fully vaccinated,[2] averting an estimated 1.1 million COVID-19 deaths and over 10 million COVID-19-related hospitalizations.[3] The Biden Administration restored the White House Directorate on Global Health Security and Biodefense and created the Presidential COVID-19 Health Equity Task Force (see sidebar on pg. 15). And the approval of new treatments for COVID-19 has increased the likelihood of survival for many patients.[4]

At the same time, major challenges remained. Hospital systems in many states were overwhelmed during pandemic waves. Testing was difficult to access during surges—at-home tests were particularly difficult to find—and in some cases testing was expensive, misinformation was abundant, and public patience with and trust in public health guidance wore thin. Of great concern, lawmakers in many states introduced or enacted laws to restrict the authority of public health officials.[6] In addition, according to *The New York Times,* approximately 500 public health officials nationwide had left the field since the start of the pandemic. Some

Editor's note: as of January 16, 2022, the Centers for Disease Control and Prevention (CDC) defined "fully vaccinated" as a person who has received their primary series of COVID-19 vaccines. CDC is also using "Up to Date" to denote that a person has received all recommended COVID-19 vaccines including any booster dose(s) when eligible.[5]

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retired, some left due to threats and harassment, some due to firings when public health guidance clashed with what elected officials wanted to do.[7]

In addition, the pandemic has illuminated two stark realities: the nation and the world's public health systems are inadequate and in immediate need of significant and sustained funding. And, once again, the nation's health inequities led to some population groups, particularly communities of color and low-income communities, experiencing a disproportionate burden during the pandemic, with less access to resources like vaccines during the response, and having more barriers to recovery.[8,9]

To better meet the challenges of future public health emergencies, including climate change, the nation must address underlying drivers of economic and health inequities, including ongoing discrimination, structural racism, and social determinants of health. Investments in public health infrastructure alone, while critical, will not make the United States more resilient. Equity must be an explicit and foundational principle in all public health preparedness, response, and recovery.[8,9]

The COVID-19 pandemic's impact—including its high death tolls and extreme economic disruption—was, at least to some degree, an avoidable tragedy. But with this tragedy comes opportunity. The pandemic has shined a bright light on what's needed: robust, flexible, and sustained investment in public health infrastructure, modernization of data systems and surveillance capacity, increased public health laboratory capacity, sustained growth and increased diversity in the public health workforce, and addressing the social determinants of health. Today, only half of all U.S. residents are protected by a comprehensive local public health system,[10] and it is estimated that state and local health departments need to hire a minimum of 80,000 additional full-time workers to be able to meet their communities' basic public health needs.[11]

It is estimated that state and local health departments need to hire a minimum of 80,000 additional full-time workers to be able to meet their communities' basic public health needs.

This annual report, *Ready or Not: Protecting the Public's Health from Disease, Disasters, and Bioterrorism,* has tracked the nation's public health emergency preparedness since 2003. The report is designed to give policymakers at all levels of government actionable data and recommendations with which they can target policies and spending to strengthen their jurisdiction's emergency preparedness. The report's 10 key public health preparedness indicators give state officials benchmarks for progress, point out gaps within their states' all-hazards preparedness, and provide data to compare states' performances against similar jurisdictions.

These data points are meant to measure states' readiness on a broad set of health security measures and have been the focus of this report for over a decade. However, for this 2022 edition of the report (and going forward), there is one change to the indicators set: the hospital participation in healthcare coalitions indicator, which was based on 2017 data that has not been recently updated by the National Health Security Preparedness Index (NHSPI), has been replaced with a new indicator, also tracked by NHSPI, that measures the percentage of state populations served by a comprehensive public health system.

Readers should note that this report is not designed to be an assessment of a given state's response to the COVID-19 pandemic, as widescale political, funding, economic, and social factors all influenced the virus's impact and local responses. Controlling the pandemic has been extremely challenging in every state. Moreover, the pandemic has illustrated that being prepared to adequately respond to a public health emergency the scale of a pandemic—and execute that response—is enormously complex and beyond the sole control of state and local officials. However, this report measures critical capacities that are foundational to protecting the public's health every day and during emergencies, including robust and sustained public health funding, disease surveillance capacity, healthcare, public health laboratory and hospital surge capacity, access to safe water, and access to paid time-off. In addition, the pandemic has shown that there is no substitute at the state or local level for a strong federal response during an emergency.

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This Year's Findings

In this 2022 report, Trust for America's Health (TFAH) found that 12 states improved their relative standing—for each indicator and overall, states were scored relative to one another—compared with last year, while 16 fell behind. Nine states improved by one tier, three states improved by two tiers, and 16 states dropped one tier. *(Note:* There was greater year-over-year state movement between tiers this year than in past years—in both directions—in part because of the introduction of a new indicator.)

TABLE 1: Top-Priority Indicators of State Public Health Preparedness

INDICATORS			
1	**Incident Management:** Adoption of the Nurse Licensure Compact.	6	**Water Security:** Percentage of the population that used a community water system that failed to meet all applicable health-based standards.
2	**Public Health System Comprehensiveness:** Percentage of state population served by a comprehensive public health system **(new)**.	7	**Workforce Resiliency and Infection Control:** Percentage of employed population that used paid time off in a given month.
3	**Institutional Quality:** Accreditation by the Public Health Accreditation Board.	8	**Countermeasure Utilization:** Percentage of people ages 6 months or older who received a seasonal flu vaccination.
4	**Institutional Quality:** Accreditation by the Emergency Management Accreditation Program.	9	**Patient Safety:** Percentage of hospitals with a top-quality ranking ("A" grade) on the Leapfrog Hospital Safety Grade.
5	**Institutional Quantity:** Size of the state public health budget compared with the past year.	10	**Health Security Surveillance:** The public health laboratory has a plan for a six- to eight-week surge in testing capacity.

Notes: The 2022 edition of the report introduces a new indicator, measuring the percentage of state populations served by a comprehensive public health system. This new indicator replaces a previous indicator tracking the percentage of hospitals participating in healthcare coalitions. The National Council of State Boards of Nursing organizes the Nurse Licensure Compact. Systems for Action uses the National Longitudinal Survey of Public Health Systems to measure public health system comprehensiveness. The U.S. Environmental Protection Agency assesses community water systems. Paid time off includes sick leave, vacation time, or holidays, among other types of leave. The Leapfrog Group is an independent nonprofit organization. TFAH drew every indicator, and some categorical descriptions, from the National Health Security Preparedness Index, with one exception: public health funding. See "Appendix B: Methodology" for a description of TFAH's funding data-collection process, including its definition.

Source: National Health Security Preparedness Index[12]

The *Ready or Not* report groups states and the District of Columbia into one of three tiers (high, middle, and low) based on their relative performances across the 10 indicators. This year, 17 states and the District of Columbia scored in the high-performance tier, 20 placed in the middle-performance tier, and 13 were in the low-performance tier (see Table 2). (See "Appendix B: Methodology" for more information on the scoring process.)

Nine states showed notable improvement, moving up a tier: Alabama, Florida, Illinois, Iowa, New Jersey moved from the middle tier to the high tier, and Arizona, Missouri, New Hampshire, and New York moved from the low tier to the middle tier. As an example of the factors behind such movement, New Hampshire's rise from the low tier to the middle tier had three primary drivers. First, while still below average, the state performed better in the new indicator (Public Health System Comprehensiveness) than it had in the now-replaced measure of hospital participation in healthcare coalitions. Second, its share of employed residents who used paid time off based on a one-month sample increased, while the national average stayed flat. Third, the state's hospitals made marked improvement in the area of patient safety.

Three states—Ohio, Pennsylvania, and South Carolina—demonstrated exceptional progress, elevating from the low tier to the high tier. Ohio adopted the Nurse Licensure Compact in 2021, and its score also benefited from the introduction of the new Public Health System Comprehensiveness indicator. Pennsylvania also adopted the Nurse Licensure Compact, benefited from the new indicator, increased its public health funding, and experienced only a small reduction in the share of its hospitals who received an "A" rating for patient safety at a time when the national average fell by a greater extent. Collectively, these improvements were sufficient to offset some decline in the share of its employed residents who used paid time off. Finally, South Carolina's score benefited from the new indicator, in addition to the state achieving accreditation by the Public Health Accreditation Board and greater usage of paid time off.

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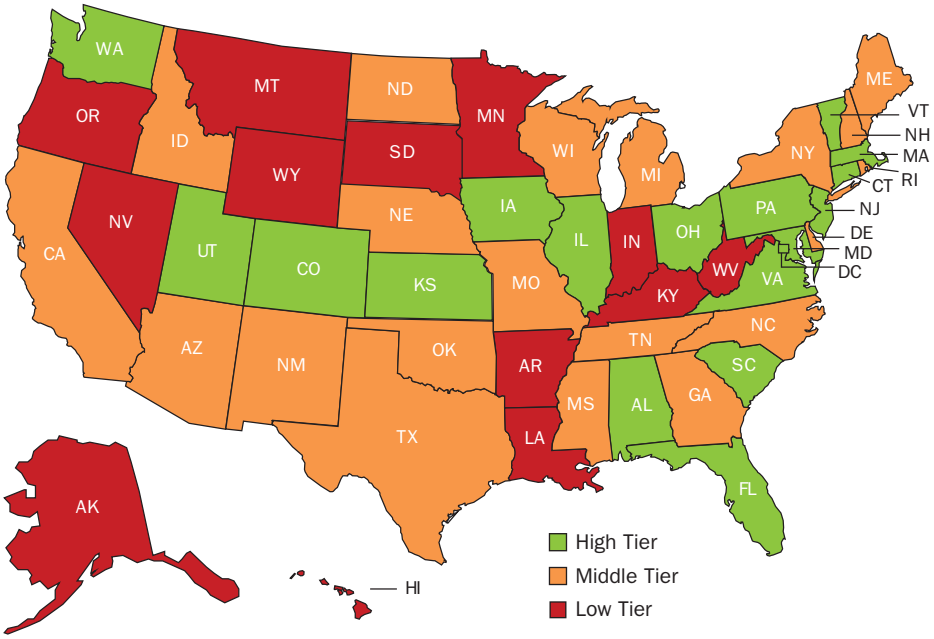
Sixteen states fell one tier: Delaware, Georgia, Idaho, Maine, Mississippi, Nebraska, New Mexico, North Carolina, Oklahoma, Rhode Island, and Wisconsin moved from the high tier to the middle tier, and Kentucky, Louisiana, Minnesota, Montana, and Oregon moved from the middle tier to the low tier). New Mexico, for instance, saw its score fall because it lost its accreditation from the Emergency Management Accreditation Program, vaccinated a smaller percentage of its residents against seasonal flu, and had a slightly smaller share of its hospitals receive an "A" rating for patient safety.

TABLE 2: State Public Health Emergency Preparedness
State performance, by scoring tier, 2021

Performance Tier	States	Number of States
High Tier	AL, CO, CT, DC, FL, IA, IL, KS, MA, MD, NJ, OH, PA, SC, UT, VA, VT, WA	17 states and DC
Middle Tier	AZ, CA, DE, GA, ID, ME, MI, MO, MS, NC, ND, NE, NH, NM, NY, OK, RI, TN, TX, WI	20 states
Low Tier	AK, AR, HI, IN, KY, LA, MN, MT, NV, OR, SD, WV, WY	13 states

Note: See "Appendix B: Methodology" for scoring details. Complete data were not available for U.S. territories.

Indicators of State Public Health Emergency Preparedness
State performance, by scoring tier, 2021



TFAH's Analysis Found:

A majority of states have made preparations to expand healthcare and public health capabilities in an emergency. Thirty-seven states participated in the Nurse Licensure Compact, up from 26 in 2017,[13] with Ohio, Pennsylvania, and Vermont being the most recent adopters.[14] The compact allows registered nurses and licensed practical or vocational nurses to practice in multiple jurisdictions with a single license. In an emergency, this enables health officials to quickly increase their staffing levels. For example, nurses may cross state lines to work at evacuation sites or other healthcare facilities. In addition, only the District of Columbia reported not having a plan to ensure public health laboratories are prepared for a large influx of testing needs. (The District of Columbia reported that it was in the process of updating its Continuity of Operations Plan and developing a discrete plan for laboratory surges.) All other states had a plan to surge public health laboratory capacity for six to eight weeks as necessary during overlapping emergencies or large outbreaks.

Most residents who received their household water through a community water system had access to safe water. On average, just 5 percent of state residents used a community water system in 2019 (latest available data) that did not meet all applicable health-based standards, down slightly from 7 percent in 2018. Water systems with such violations increase the chances of water-based emergencies in which contaminated water supplies place the public at risk.

Most states are accredited in the areas of public health, emergency management, or both. As of November 2021, the Public Health Accreditation Board or the Emergency Management Accreditation Program accredited 42 states and the District of Columbia; 32 states and the District of Columbia were accredited by both groups, a net increase of three since December 2020. Eight states (Alaska, Hawaii, Kentucky, New Hampshire, South Dakota, Texas, West Virginia, and Wyoming) were not accredited by either group. Both programs help ensure that necessary emergency prevention and response systems are in place and staffed by qualified personnel.

Seasonal flu vaccination rates, while still too low, have risen significantly in recent years. The seasonal flu vaccination rate among Americans ages 6 months and older rose from 42 percent during the 2018–2019 season to 52 percent during the 2019–2020 and 2020–2021 seasons.[15,16] However, *Healthy People 2030,* a set of federal 10-year objectives and benchmarks for improving the health of all Americans by 2030, set a seasonal influenza vaccination-rate target of 70 percent annually.[17]

Still, despite these positive steps, just half of the U.S. population is served by a comprehensive public health system—an indicator newly tracked in the 2022 edition of this series. Such systems tend to engage in a wide array of recommended activities to assess their communities' health and needs, develop evidenced-based public policy that promotes health and safety, ensure that necessary services are accessible to all residents, and cultivate a broad coalition of stakeholder partners. Comprehensive systems have been shown to contribute to positive health outcomes in a cost-effective manner. In just eight states and the District of Columbia were a majority of residents served by a comprehensive public health care system.

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In March 2020, 55 percent of employed state residents, on average, used paid time off, the same percentage as in 2018 and 2019. Those without paid leave are more likely to work when they are sick and risk spreading infection. In the past, the absence of dedicated paid sick leave has been linked to or has exacerbated some infectious disease outbreaks.[18] This has become particularly relevant during the COVID-19 pandemic, as isolation and quarantine are important tools for controlling the outbreak. The Families First Coronavirus Response Act helped address this issue during the early stages of the pandemic for employers with fewer than 500 employees and certain public employers, temporarily requiring employees to be paid up to 80 hours of sick leave benefits under certain conditions, but these protections expired on December 31, 2020.[19] Importantly, the United States could join numerous countries across the world in establishing a national minimum standard of paid family or medical leave, if proposed provisions of the Build Back Better Act become law.

Only 28 percent of hospitals, on average, earned a top-quality patient safety grade, down slightly from 31 percent in 2020. Hospital safety scores measure performance on such issues as healthcare-associated infection rates, intensive-care capacity, and an overall culture of error prevention. In the absence of diligent actions to protect patient safety, deadly infectious diseases can take hold or strengthen.

POLICY RECOMMENDATIONS

Based on the data collection and analysis summarized in this report, and consultation with public health and emergency preparedness experts, the report includes recommendations for policy action in seven priority areas:

1. **Providing stable and sufficient funding for public health security.** Congress and state and local governments must invest in the foundations of public health, including public health infrastructure, workforce, and data systems.
2. **Preventing disease outbreaks and pandemics.** Policymakers should support the vaccination infrastructure, fight antibiotic resistance, and support paid leave for all workers.
3. **Building resilient communities and promoting health equity in preparedness.** Congress and leaders at all levels of government should prioritize investments in health equity, incorporate equity leadership into preparedness and response, and invest in social determinants of health.
4. **Ensuring effective leadership and coordination.** Policymakers should strengthen public health leadership and communications and reject attempts to weaken public health authorities. Congress should create a COVID-19 Commission to review and address gaps in pandemic response.
5. **Accelerating development and distribution of medical countermeasures (MCMs).** Congress should invest in the entire MCM enterprise to enable rapid development and effective deployment of life-saving products during emergencies.
6. **Readying the healthcare system to respond during and recover from public health emergencies.** Federal and state policymakers and the healthcare system must prioritize effective coordination and planning for a surge of patients.
7. **Preparing for environmental threats and extreme weather.** Congress and the White House should develop a strategic plan, along with funding, to minimize the health impacts of climate change and promote health equity.

For a full description of the report's recommendations, see the recommendations section beginning on page 40.

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Report Purpose and Methodology

TFAH's annual *Ready or Not* report series tracks states' readiness for public health emergencies based on 10 key indicators that collectively provide a checklist of top-priority issues and action items for states and localities to continuously address. By gathering timely data on all 50 states and the District of Columbia, the report assists states in benchmarking their performance against comparable jurisdictions. TFAH completed this analysis after consultation with a diverse group of subject-matter experts and practitioners.

See Appendix B for more detail on the report's methodology.

READY OR NOT AND THE NATIONAL HEALTH SECURITY PREPAREDNESS INDEX

The indicators included in this report were drawn from, and identified in partnership with, the National Health Security Preparedness Index (NHSPI),[20] with one exception: a measure of state public health funding-level trends, which reflects how well-resourced key agencies are to prepare for and respond to emergencies. The NHSPI is a joint initiative of the Robert Wood Johnson Foundation, the University of Kentucky, and the University of Colorado. (See "Appendix B: Methodology" for a detailed description of how TFAH selected and scored the indicators.)

While state rankings in *Ready or Not* and the NHSPI largely align, there are some important differences. The two projects have somewhat different purposes and are meant to be complementary, rather than duplicative. With more than 100 indicators, the NHSPI paints a broad picture of national health security, allowing users to zoom out and holistically understand the extent of both individual states and the entire nation's preparedness for large-scale public health threats. In slight contrast, *Ready or Not,* with its focus on 10 select indicators, focuses attention on state performances on a subset of the Index and spotlights important areas for stakeholders to prioritize a smaller, more focused set of improvement goals. TFAH and the NHSPI work together to help federal, state, and local officials use data and findings from each project to make Americans safer and healthier.

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SPECIAL SECTION:

Lessons of the Pandemic's Tragic Death Toll: What Needs to be Done Now to Save Lives During the Next Public Health Emergency?

The over 900,000 U.S. lives lost due to the COVID-19 pandemic[21] is made even more tragic by the fact that many of these deaths were preventable. If the public health community's warnings of over a decade that the country's public health infrastructure was dangerously inadequate had been heeded lives would have been saved and economic upheaval lessened. In addition, misinformation, mistrust in government, and political division have driven anti-public health and anti-vaccine policies and actions. Furthermore, underinvestment in health equity and social determinants of health contributed to high rates of chronic disease, leaving some populations vulnerable to severe outcomes during the pandemic. Confusing and disjointed leadership and messaging led to disparate responses in every state. And the healthcare system, which operates near capacity on many days, was unprepared for multiple surges throughout the pandemic.

But within this tragedy is opportunity. The pandemic has shined a light on what is needed: Congress and states must work to create robust and sustained investment in public health infrastructure, modernization of data systems and surveillance capacity, increased public health laboratory capacity, sustained growth in a diverse and highly skilled public health workforce, and improved public health messaging and communications. However, these investments in public health infrastructure alone will not make America more resilient in the face of the next public health emergency. Protecting health in every community will also require addressing the systemic inequities that led to COVID-19's disproportionate health and economic impacts, particularly in communities of color and low-income communities.

What went wrong?

Policymakers did not heed the decades-long call by public health experts to fund public health on a sustained basis and not just in response to an emergency. Underfunding contributed to understaffed and overworked health departments using out-of-date technologies. In addition, lack of support and outright threats against public health officials contributed to hundreds of senior-level state and local public health officials leaving the profession.[22]

The nation's public health data systems are woefully dated and not up to the task of tracking an infectious disease outbreak on the scale of a pandemic. While data collection has improved as Congress has invested in data modernization, early in the outbreak basic questions such as how many people were infected by the virus, which population groups were at the highest risk, and where infections were surging were largely unanswerable in a timely manner due to insufficient testing and reporting processes. Where data were collected, they were spread across multiple data sets with no way to quickly roll up into one national picture.[23]

Communities of color were disproportionately affected in large part due to the ways in which structural racism and classism impacts where people are born, grow, live, work, and age; the resources available in their community; their access to healthcare; and the prevalence of chronic disease in their communities. According to the Centers for Disease Control and Prevention (CDC), as of November 2021, nationwide American Indians and Alaska Natives died due to COVID-19 at a rate that was 2.2 times higher than whites. Hispanic/Latino Americans died at a rate that was 2.1 times higher than whites Americans. Black Americans died from COVID-19 at a rate that was 1.9 times higher than the rates of deaths among whites. Asian Americans died at a rate that was 0.9 times that of whites.[24,25] In addition, as of mid-November 2021, an estimated

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167,082 children had lost a parent, guardian, or caregiver due to COVID-19; many of these children were already experiencing significant social and economic adversity.[26]

During the early stages of the pandemic (2020) the federal government lacked an evidence-based leadership role in the pandemic response, and science and public health expertise were often not heeded. In addition, political polarization at the federal and state levels confounded critical public health guidance and contributed to a confusing spectrum of responses across the country, from some areas issuing mask mandates to other jurisdictions limiting public health authorities. An October 2020 Columbia University report concluded that earlier implementation of lockdowns, a national mask-wearing mandate, and federal guidance on social distancing could have saved between 130,00 and 210,000 American lives.[27] Similarly, Peterson-Kaiser Family Foundation reported in October 2021 that between June and December 2021, approximately 163,000 U.S. COVID-19 deaths could have been prevented through vaccination.[28]

Social media platforms were (and still are) greenhouses for misinformation about the virus and vaccines. The Global Health Security Index found that, despite strong health security capacity, the United States had the lowest possible score on public confidence in the government, a factor that has been common in countries with higher rates of COVID-19 cases and deaths.[29]

Public health leaders Daniel Dawes, executive director of the Satcher Health Leadership Institute, and Dr. Brian Castrucci, president and CEO of the de Beaumont Foundation, wrote in their February 2021 op-ed in *STAT* that while COVID-19 does not discriminate by race, it undeniably exposed the "devastating inequities that come with being a person of color in America."[30] Structural racism impacts people of color in nearly every facet of their lives, from where they live and work to their access to healthcare. Racism is often at the root of conditions that drive poor health outcomes in communities of color. The disproportionate impact of COVID-19—higher rates of infection, hospitalization, and death—in communities of color were stark illustrations of this fact according to Dawes and Castrucci. A baseline goal in public health must be increasing the health status (and therefore the strength and resilience) of every community. In order to improve the health status within communities of color, long-standing racist policies and practices, and their legacies, in employment, housing, education, and healthcare must be changed. Dawes and Castrucci write that America's pre-COVID-19 "normal" "was not equitable or just"; therefore, a return to pre-COVID normal would allow the inequities that fueled the pandemic to persist.

What's needed?

Increased, flexible, and sustained funding. Funding for public health must be increased, flexible, and sustained over time. The pattern of public health funding in this country has long been that money is found (often borrowed from other public health priorities like chronic disease prevention) to fund needed response during an emergency. Once the emergency has passed, governments return to a pattern of inadequate levels of funding for public health. Without increased, predictable, and sustained funding—for personnel, equipment, training, and data systems—the next public health emergency response will be less effective than it needs to be, putting lives and livelihoods at risk.

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It is also important to note that while the pandemic response and recovery funding authorized in 2020 and 2021 were critical to meet the urgent needs of the pandemic response, those resources were one-time appropriations. What's needed to protect all Americans from the next public health emergency is year-in, year-out sustained, predictable funding.

Editor's note: In November 2021, the U.S. House of Representatives passed the $1.75 trillion Build Back Better Act, including approximately $10 billion for public health—about $7 billion over five years for public health infrastructure and about $3 billion for other pandemic preparedness.[31] These funds, if ultimately appropriated, would be an important down payment toward rebuilding the nation's public health system.

Federal leadership. In an event as large and complex as a pandemic, there is no substitute for a strong, coordinated federal response. TFAH has made a number of policy recommendations designed to ensure strong federal leadership during future public health emergencies, including the creation of a White House Health Security Directorate.[32]

Editor's note: The Biden Administration created a National Security Council Directorate on Global Health Security and Biodefense, led by a senior director for global health security and biodefense, in January 2021.[33] Future administrations should strengthen this senior-level advisory structure at the White House.

A diverse and highly skilled public health workforce. According to an October 2021 report released by the de Beaumont Foundation and the Public Health National Center for Innovations, a division of the Public Health Accreditation Board, state and local public health departments need approximately 80 percent more full-time staff to meet the nation's basic public health needs. According to the report, years of budget cuts have reduced essential state and local public health staff by 15 percent over the last decade. These reductions in the size of the workforce make local and state health departments less able to meet community health needs, including responding to emergencies. The report concludes that the nation needs to hire an additional 80,000 full-time public health staff to ensure that basic community health needs are met in all jurisdictions.[34]

Modernized health data and disease tracking systems, including disaggregated data collection and reporting. Improved response to public health emergencies requires 21st-century data collection and management, including real-time data on the social determinants of health. Achieving health equity is rooted in understanding health disparities and what causes them. Such understanding begins with a health data systems infrastructure that is able to surveil, collect, disaggregate, interpret, and share data in a timely fashion, including on race, ethnicity, income, disability, social determinants, other demographic factors, and the drivers of health. These capacities and these data are often missing from many federal and state data sets that currently provide data on white, Black, and Hispanic people but lack data on other groups, such as American Indians, Alaska Natives, Asian Americans, and Native Hawaiians or other Pacific Islanders, or treat these groups as one homogeneous population.[35]

The Robert Wood Johnson Foundation created the National Commission to Transform Public Health Data Systems to review how public health data are collected, shared, and used, as well as to make recommendations to ensure that such data are comprehensive and create a blueprint for health equity. Among the recommendations included in its October 2021 report was to ensure that public health measurement captures race and ethnicity information at the individual level whenever person-level data is collected, and addresses structural racism and other inequities.[36]

Also released in October 2021, a report from Grantmakers in Health and the National Committee for Quality Assurance stated that having more complete data will require action across multiple sectors, including changes in data standards and systems; regulations, including a clear and sufficient federal standard for data completeness; and a roadmap for collecting and reporting on data in ways that will reduce health inequities and provide incentives, requirements, resources, and technical assistance as needed.[37]

Editor's note: Congress has allocated over $1 billion through the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), the America Rescue Plan Act (P.L. 117-2), and annual appropriations to support rapid public health data modernization.[38] In August 2021, CDC announced plans to use some of this funding for a new analytics center to better forecast and track disease outbreaks.[39]

Modernize public health labs and increase their surge capacity. Congress must sufficiently fund CDC to support sustained modernization of state and local public health laboratories, so they are better connected and ready to meet public health threats.[40] Also needed is better coordination between public health and private laboratories, including clinical and academic settings. Public and private laboratories both

played critical roles during the pandemic response. (See interview: pg. 15.)

Strengthen public health departments' emergency response functioning by providing sufficient funding and requiring plans in order to allow for execution of rapid hiring, rapid procurement, and project scale-up and management in response to a public health emergency.

Combat misinformation and increase the public's trust in science and government. U.S. Surgeon General Dr. Vivek Murthy has identified health misinformation as a serious threat to Americans' health. In July 2021, the Surgeon General issued an advisory, *Confronting Health Misinformation: The Surgeon General's Advisory on Building a Healthy Information Environment,* including ways in which institutions in education, media, medicine, research, social media and technology companies, and government stakeholders can address the issue.[41] Distrust of government and science was at the root of at least some vaccine hesitancy. Addressing this distrust will be critical to being prepared to respond to future public health emergencies.

Invest in the social determinants of health and anti-poverty programs to support the public's health and promote resilience. Key drivers of everyone's health are the conditions in which they are born, grow, live, work, and age. These health drivers, also known as "social determinants of health," in large part determine if a population group or community has the resources and resilience to weather and recover from a public health emergency. In an emergency, every community needs access to healthcare, food, clean water, and transportation. Communities without these resources tend to have poorer health outcomes at the individual and population level and are more vulnerable during an emergency.

A 2017 report from the National Academies of Sciences, Engineering, and Medicine stated that "health inequities are in large part a result of poverty, structural racism, and discrimination."[42] In addition, as illuminated and exacerbated by COVID-19, structural racism has contributed to a public health crisis in the United States—rates of illness are higher and life expectancy is lower for people of color, including Black people and American Indian people, than for white people.[43]

COVID-19 HEALTH EQUITY TASK FORCE REPORT ADDRESSES HEALTH INEQUITIES

The Biden Administration created the Presidential COVID-19 Health Equity Task Force in January 2021. The October 2021 *COVID-19 Health Equity Task Force Report* and proposed implementation plan made recommendations to the President for mitigating the health inequities caused or exacerbated by the pandemic and for preventing such inequities in the future.[44] The task force, chaired by Dr. Marcella Nunez-Smith, included multisector experts and people with lived experience concerning communities suffering disproportionate rates of illness and death from COVID-19.

In its report, the task force made 55 recommendations to address and eliminate health disparities, many of which mirrored TFAH policy recommendations. Among the report's five high-level recommendations to the President were:

1. Invest in community-led solutions to address health equity.
2. Enforce a data ecosystem that promotes equity-driven decision making.
3. Increase accountability for health equity outcomes.
4. Invest in a representative healthcare workforce, and increase equitable access to quality healthcare for all.
5. Lead and coordinate implementation of the COVID-19 Health Equity Task Force's recommendations from a permanent health equity infrastructure in the White House.

Within those areas, the task force recommended increased and sustained funding for the public health workforce and emergency response, investment in modernized public health data systems and equity-centered public health data collection, and systems to address the social determinants of health and increase access to behavioral healthcare.

In a statement applauding the report, TFAH President and CEO Dr. J. Nadine Gracia, said: "The COVID-19 Health Equity Task Force has laid out a road map for reducing inequities during the pandemic and before the next public health emergency. As the report acknowledges, we must engage in a multisector effort to address the upstream factors that contribute to underlying health inequities in order to promote optimal health and build resilience in all communities."

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The Critical Role of Public Health Laboratories During COVID-19 and Beyond

An Interview with Scott Becker, MS, CEO of the Association of Public Health Laboratories

TFAH: How did public health laboratories perform during the pandemic?

Becker: Public health laboratories have performed remarkably well despite a number of challenges. Performance issues with the initial CDC assay presented significant hurdles and delays at the beginning of the pandemic. The laboratories were resilient, though, quickly notifying CDC and the Association of Public Health Laboratories (APHL) of assay issues and identifying solutions, such as using their own laboratory-developed tests. For instance, Wadsworth Center, New York State Department of Health, secured an emergency-use authorization for its real-time PCR assay. Other ongoing challenges included the limited national supply chain for reagents and consumables.

Typically, public health laboratories identify novel threats, perform initial testing, and then hand off to the private sector for high-throughput surge testing. The state public health laboratory traditionally maintains ongoing responsibility for testing in high-priority or potential outbreak situations, as well as for regional surveillance. In the case of COVID-19, public health laboratories have been in response mode for an extended period, providing sustained surge capacity for their jurisdictions and, in some locations, serving as the primary test provider. We are almost at the two-year mark for the COVID-19 pandemic, and during this time public health laboratories have tested more than 21 million specimens for SARS-CoV-2. All of APHL's member public health laboratories—that is, most laboratories nationwide—are meeting the testing demands within their jurisdictions.

The emergence of the Omicron variant created an increase in demand for COVID-19 testing for all public health laboratories. Many of these same laboratories are also sequencing SARS-CoV-2 samples to monitor for Omicron and other variants, and they report cases to CDC for surveillance purposes.

TFAH: What lessons—on lab performance/capacity and beyond—should the nation learn as a result of the pandemic?

Becker: There are significant lessons from this pandemic as well as previous responses to Zika and Ebola viruses. First, we must look at the coordination, or lack thereof, of the U.S. national laboratory system and how this limits our ability to respond to novel threats. APHL believes that we need to develop a national laboratory system that better integrates public and private laboratories, including large commercial facilities, hospitals, and academic institutions. We also need to transform the public health laboratory system to be more agile and interconnected to respond to all threats.

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Another area of concern is the shrinking public health workforce and lack of diversity within its ranks. A key place to address this is by building and supporting a diverse, equitable, and inclusive public health laboratory workforce. The fundamental purpose of public health laboratories is to serve their communities, so it is vital that lab staff represent the diverse communities in which they are working. A representative workforce not only creates a better work environment for all staff, but it also allows a public health lab to better serve the community's health needs.

Finally, there are lessons on the use of various technologies for screening and testing. For instance, point-of-care diagnostics and at-home testing play a pivotal role in reducing the testing burden on laboratories. Such technologies also ensure access to testing for underserved communities. Understanding the quality of these screening tools and sharing results with public health agencies will be critical for surveillance and contact tracing for future pandemics.

TFAH: Does the nation have the needed level of lab capacity for when another pandemic happens?

Becker: Responding to a pandemic is complex and encompasses the actual laboratory test (assay), instruments, supplies (reagents), test results (electronic laboratory reporting), safe and secure facilities, personal protective equipment, and trained personnel.

Whether or not we are ready for the next threat will vary. We often prepare for what we have experienced instead of preparing for a true unknown. We may have instrument capacity, but we still need to collaborate with the private sector and other governmental agencies, beyond CDC, to develop and pre-position tests in laboratories. We also need to rebuild and strengthen the laboratory workforce as well as the broader public health workforce.

TFAH: What's the role of public health labs in overall healthcare? Has that relationship worked during the COVID-19 pandemic?

Becker: The quintessential role of public health laboratories is to monitor the diseases and health status of populations. This role has evolved over time, especially given increasing threats such as natural disasters, human-caused incidents, emerging and pandemic infectious diseases, and acts of terrorism. In executing their 11 core functions, public health laboratories engage the entire healthcare community to varying degrees in the state public health laboratory system. While there were some initial bumps in the response, overall, public health laboratories worked well with healthcare—including commercial laboratories and other private institutions including in nontraditional testing sites, such as prisons and nursing homes.

Public health and healthcare take different yet equally important approaches to serving and protecting the nation's health. At the foundation of both approaches is laboratory testing, which is necessary for health departments to monitor disease in the population and identify novel threats, and for healthcare providers to make decisions to treat patients. The interdependency of public- and private-sector testing has never been more important than as seen with the COVID-19 response. These two systems must work together to provide timely and accurate testing, covering a significant portion of the U.S. population. As is the case with novel infectious threats, prompt and quality testing is critical as it shapes treatment options and epidemiological actions such as contact tracing, and as it influences larger public health decisions, including quarantine.

TFAH: Are rapid, self-administered tests, followed by a lab test if positive, part of the right approach to ending the pandemic?

Becker: As noted earlier, a multilayered approach of laboratory testing, point-of-care diagnostics, and self-administered ("at-home") tests is critical to alleviating the testing burden and providing information on community transmission. These tests must be based in sound science and have performance data that support their use. Further, such tests should also have a reporting component, so public health agencies can determine community transmission rates and can utilize these data for public health actions.

TFAH: New monies within the federal pandemic recovery packages have been dedicated to lab building and renovation. Is it enough?

Becker: The American Rescue Plan Act has provided funding to public health laboratories for COVID-19 testing and surveillance, for expanding and sustaining a stronger workforce, for genomic sequencing and analytics, for global health security beyond just COVID-19, and for supporting the Data Modernization Initiative and more.

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While this funding is much needed and appreciated, public health laboratories have been chronically underfunded. This is a great boost, especially at a time when they need it most, but these laboratories need a consistent increase in funding to be able to keep up with changing technologies and threats. Federal funding to significantly improve public health data management operations at the state and local levels of government requires an additional $7.8 billion over the next five years, and state and local public health laboratory construction needs are likely to be around $5 billion over that same time frame.

TFAH: How does the overall modernizing of the public health data systems and the strengthening of lab systems work together?

Becker: Like many aspects of public health, the effective, efficient movement of public health data has been chronically underfunded, resulting in a fragmented and obsolete national information technology system. This issue has limited the ability of the nation's public health system to make actionable decisions. The perpetual funding issue, combined with a sharp increase in data production from new laboratory techniques, such as sequencing, have added great volumes of data to an already overburdened system.

On the positive side, Congress has allocated over $1 billion through the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), the American Rescue Plan Act (P.L. 117-2), and annual appropriations to continue public health data modernization activities. Within this funding CDC received $500 million to advance surveillance and analytics infrastructure. In August 2021, CDC announced plans to use some of this funding for a forecasting center to better track emerging biological threats.

TFAH: It seems like Omicron identification is moving at a faster pace than earlier detection. Is that accurate? What accounts for the improved performance?

Becker: If you are comparing the pace with the detection of the Alpha variant (or B.1.1.7), which emerged in December 2020, then yes, the pace is faster. However, the pace with which we've detected other emerging variants like the Delta variant has been strong for many months. This is almost entirely because of the investments and improvements to genomic-sequencing capability and capacity in the U.S. public health system. Public health laboratories as well as other key laboratory partners are a critical part of the CDC-led National SARS-CoV-2 Strain Surveillance (NS3) program. In January 2021, the network was publishing between 3,000 and 5,000 sequences to public databases every week. Today, the network consistently publishes between 15,000 and 20,000 specimens per week. In November 2021 alone, 190,000 SARS-CoV-2 sequences were published across the U.S. public health system. This significant increase in capacity positions us to quickly detect emerging variants, even when circulating at low levels.

Editor's note: this interview was conducted in December 2021.

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Assessing State Preparedness

Every state needs to be prepared to respond to a variety of potential public health emergencies; such readiness requires understanding an individual state's preparedness strengths, risks, and vulnerabilities. To help states assess readiness, and to highlight a checklist of top-priority concerns and action areas, this report examines a set of 10 select indicators. The indicators, overwhelmingly consistent from year to year, draw heavily on the National Health Security Preparedness Index (NHSPI), a joint initiative of the Robert Wood Johnson Foundation, the University of Kentucky, and the University of Colorado. They capture core elements of emergency preparedness. Based on states' standing across the 10 indicators (see "Appendix B: Methodology" for scoring details) and TFAH analysis, the states were placed into three performance tiers: high, middle, and low. (See Table 3.)

Importantly, the implications of this assessment, and responsibility for continuously improving, extend beyond any one state or local agency. Such improvement typically requires sustained engagement and coordination by a broad range of policymakers and administrators. Moreover, some indicators are under the direct control of federal and state lawmakers, whereas improvement in other indicators requires multisector, statewide efforts, including by residents.

TABLE 3: State Public Health Emergency Preparedness
State performance, by scoring tier, 2021

Performance Tier	States	Number of States
High Tier	AL, CO, CT, DC, FL, IA, IL, KS, MA, MD, NJ, OH, PA, SC, UT, VA, VT, WA	17 states and DC
Middle Tier	AZ, CA, DE, GA, ID, ME, MI, MO, MS, NC, ND, NE, NH, NM, NY, OK, RI, TN, TX, WI	20 states
Low Tier	AK, AR, HI, IN, KY, LA, MN, MT, NV, OR, SD, WV, WY	13 states

Note: See "Appendix B: Methodology" for scoring details. Complete data were not available for U.S. territories.

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INDICATOR 1: ADOPTION OF NURSE LICENSURE COMPACT

KEY FINDING: 37 states participate in the Nurse Licensure Compact.

Workforce shortages can impair a state's ability to effectively manage disasters or disease outbreaks, potentially resulting in poorer health outcomes for those affected. This reality has been on display during the COVID-19 pandemic, as healthcare capacity in most parts of the country has at times been pushed to the brink amid regional waves of infections and hospitalizations. In an event like a pandemic, the ability to quickly surge qualified medical personnel by bringing in healthcare workers from out of state is a key component of healthcare readiness.

This indicator examines whether states have adopted legislation to participate in the Nurse Licensure Compact (NLC). Launched in 2000 by the National Council of State Boards of Nursing, the NLC permits registered nurses and licensed practical nurses to practice with a single multistate license—physically or remotely—in any state that has joined the compact. The NLC provides standing reciprocity, with no requirement that an emergency be formally declared.

The COVID-19 pandemic has placed extraordinary pressure on hospitals across the country when surging infections send admissions soaring, primarily among unvaccinated people. States that were members of the NLC were well positioned to bring in nurses from other member states, without harmful delays, or to send nurses to other member states that were experiencing acute shortages. "I think the COVID-19 [pandemic] is going to cause the states that are not in the compact now to really take a second look at it," said NLC Director Jim Puente in June 2020. "If the NLC was expanded to all 50 states, none of the guesswork with emergency orders would be necessary because nurses could travel to other states where they are needed. No applications, fees, or background checks would be necessary."[45]

As of November 2021, 37 states had adopted the NLC, with Ohio, Pennsylvania, and Vermont being the most recent adopters.[46] This was a net increase of 11 since 2017.

When Lisa M. Boscola, a state senator in Pennsylvania who represents a district bordering Allentown's east side,[47] first learned of the NLC, she recalls contacting her staff immediately and saying, "get bills introduced ASAP."[48] Sen. Boscola believes "the pandemic has only shown us more proof as to why we need these compacts in the medical field." As she puts it: "As the country several times saw geographic swells with positive COVID cases and surges, the nurses and doctors nationally were able to respond to this. If the Northeast was struggling and the Midwest was not, then thousands and thousands of doctors and nurses came to the Northeast to help in the response. And when that changed in the other direction, we were able to send physicians and nurses to the areas of greater impact. In our state, because we were not in the nurse compact, the governor had to issue emergency waivers to permit out-of-state licensed nurses and doctors to come in and help with the surges."

Noah Logan of the Pennsylvania State Nurses Association agrees. "COVID definitely had a huge impact on us," he says. "We needed to be able to move nurses around quickly. All the things that were going through the nurses' minds in March, April, and May [2020]; those were rough months. Having to deal with the hassle of licensing, especially during that time, was an unneeded stressor."[49]

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TABLE 4: 37 States Participate in the Nurse Licensure Compact

Participants and nonparticipants, 2021

Participants			Nonparticipants	
Alabama	Maine	Pennsylvania	Alaska	Michigan
Arizona	Maryland	South Carolina	California	Minnesota
Arkansas	Mississippi	South Dakota	Connecticut	Nevada
Colorado	Missouri	Tennessee	District of Columbia	New York
Delaware	Montana	Texas	Hawaii	Oregon
Florida	Nebraska	Utah	Illinois	Rhode Island
Georgia	New Hampshire	Vermont	Massachusetts	Washington
Idaho	New Jersey	Virginia		
Indiana	New Mexico	West Virginia		
Iowa	North Carolina	Wisconsin		
Kansas	North Dakota	Wyoming		
Kentucky	Ohio			
Louisiana	Oklahoma			

Note: Ohio, Pennsylvania, and Vermont joined the NLC in 2021. Ohio's and Vermont's planned implementation dates are January 1, 2023, and February 1, 2022, respectively. Pennsylvania had not set a date for implementation as of November 2021.

Source: National Council of State Boards of Nursing.[50]

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INDICATOR 2: COMPREHENSIVE PUBLIC HEALTH SYSTEMS

KEY FINDING: Only about half of the U.S. population—a state average of 45 percent—is served by a comprehensive public health system. Comprehensive public health systems have been shown to contribute cost-effectively to residents' health and safety. At the state level, in 2018, the share of residents served by such a system ranged from more than two-thirds in the District of Columbia (86 percent), New York (77 percent), Arizona (67 percent), and Pennsylvania (67 percent) to fewer than one-third in Arkansas (31 percent), South Dakota (28 percent), and Indiana (25 percent).

The 2022 edition of the Ready or Not *report introduces a new indicator, measuring the percentage of state populations served by a comprehensive public health system, based on survey responses from a representative sample of local health departments. This new indicator replaces a previous indicator tracking the percentage of hospitals participating in healthcare coalitions. The move to this new indicator was made because (1) The National Health Security Preparedness Index (NHSPI) has not recently updated data on coalition participation (NHSPI provides data for several indictors used in this report), and (2) public health system comprehensiveness is a proven measure of a jurisdiction's overall health outcomes and public health emergency preparedness.*

Since 1998, a team of researchers who are now part of Systems for Action, a joint initiative of the Robert Wood Johnson Foundation and the Colorado School of Public Health, have periodically administered the National Longitudinal Survey of Public Health Systems to a nationally representative cohort of U.S. communities.[51] Through the survey, they estimate the percentage of the U.S. population who reside in communities with a comprehensive public health system, defined as a place in which "a broad array of the recommended public health activities are available in the community, AND in which a relatively broad range of organizations contribute to implementing these activities, AND/OR in which the local public health agency contributes [a] relatively large share of the effort to implement these activities."[52]

The survey asks local public health officials whether their agencies or community partners:[53]

1. Conduct community needs assessments that systematically describe the prevailing health status in the community.
2. Survey the population for behavioral risk factors.
3. Conduct on an ongoing basis timely investigations of adverse health events, including communicable disease outbreaks and environmental health hazards.
4. Make necessary laboratory services available to support investigations of adverse health events and meet routine diagnostic and surveillance needs.
5. Complete periodic analyses of the determinants of and contributing factors to priority health needs, the adequacy of existing health resources, and the population groups most effected.
6. Complete periodic analyses of age-specific participation in preventive and screening services.
7. Cultivate a network of support and communication relationships that includes health-related organizations, the media, and the general public.
8. Make formal efforts at least annually to inform public officials about the potential public health impact of decisions under their consideration.
9. Periodically prioritize community health needs based on a community needs assessment.
10. Implement community health initiatives that are consistent with priorities established from a community health needs assessment.
11. Develop and periodically update a community health action plan with community participation to address community health needs.
12. Develop and periodically update plans to allocate resources in a manner consistent with community health action plans.
13. Deploy resources as necessary to address priority health needs identified in the community health needs assessment.

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14. Periodically conduct an organizational assessment of the public health agency.

15. Address age-specific priority health needs through the provision of or linkage to appropriate services.

16. Regularly evaluate the effects of public health services on community health status.

17. Regularly use professionally recognized process and outcome measures to monitor public health programs and to redirect resources as appropriate.

18. Regularly make public information about current health status, health care needs, health behaviors, and health care policy issues.

19. Regularly report to media on health issues affecting the community.

20. Implement mandated public health programs or services as required by state or local law, ordinance, or regulation.

For each activity, surveyors ask respondents how well the measure is being performed (five-point Likert scale), the proportion of effort contributed by the local public health agency, and which types of other organizations (state health agency; other federal, state, or local agencies; faith-based organizations; hospitals; health insurers; employers/business groups; physician practices; community health centers; other nonprofits; k-12 schools; colleges/universities; tribal organizations; or others) are also involved, among other questions. It also asks how respondents would rate their agencies' effectiveness at assuring the conditions in which their residents can be healthy, and how they would rate the overall health of their jurisdictions' people.[54]

The researchers aggregate respondents' answers to determine whether a comprehensive public health system is serving a jurisdiction; that is, one in which there is high availability of recommended activities, a high level of organizational contributions, and/or a high level of local health agency effort. There is evidence that when localities improve from having a noncomprehensive system to a comprehensive one, they enjoy significant reductions in premature mortality rates from potentially preventable conditions, such as infant mortality, cardiovascular disease, diabetes, and cancer.[55] Moreover, these places tend to be more cost-effective, using relatively fewer resources despite supporting a broader array of public health activities.[56]

Since 1998, when the survey began, the estimated percentage of U.S. residents who are served by a comprehensive public health system has increased markedly, from 25 percent[57] to 49 percent in 2020.[58] Still, the survey documented much of that improvement during its early years, as the percentage hasn't increased since 2006.[59] In 2018, the latest year for which state-level estimates were available, the states where a comprehensive public health system served the greatest percentage of residents were the District of Columbia (86 percent), New York (77 percent), Arizona (67 percent), and Pennsylvania (67 percent), compared with Indiana (25 percent), South Dakota (28 percent), and Arkansas (31 percent). (No data were available for Hawaii and Rhode Island.)

This wide range demonstrates that the capacities of a person's local health department, a meaningful contributor to one's health and safety, depends significantly on where the person lives. Of note, there seems to be a persistent and expanding gap between rural and urban jurisdictions, with rural areas providing fewer recommended public health activities and engaging narrower networks of partners compared with their urban counterparts.[60] Researchers suggest that these disparities are due to several factors, including rural departments having relatively lower levels of funding and staffing, as well as marketplace and policy dynamics such as a greater prevalence of hospital closures and health insurer consolidations in rural areas and greater health insurance coverage gains recently in urban areas.

TABLE 5: Only About Half of the U.S. Population Has a Comprehensive Public Health System

Percent population served by a comprehensive public health system, 2018

States	Percent of Residents
DC	86%
NY	77%
AZ, PA	67%
MA	63%
AK	62%
CA	59%
NV, UT	55%
FL, WA	49%
IL, MN, NJ	47%
MI	46%
ME, VT, WV	45%
CO, LA, NC, NE, SC, VA	44%
GA, MD, MO	43%
DE, OR, WI	42%
ID, OK	39%
IA, KS, NH, TX	38%
CT, KY, NM, OH	37%
MT, TN, WY	36%
AL, MS	35%
ND	34%
AR	31%
SD	28%
IN	25%

Note: No data were available for Hawaii or Rhode Island. The District of Columbia's value was imputed by Systems for Action.

Source: NHSPI analysis of data from the National Longitudinal Survey of Public Health Systems.[61]

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INDICATORS 3 AND 4: ACCREDITATION

KEY FINDING: Most states are accredited by one or both of two well-regarded bodies—the Public Health Accreditation Board and the Emergency Management Accreditation Program—but eight are not accredited by either.

The Public Health Accreditation Board (PHAB), a nonprofit organization that administers the national public health accreditation program, advances quality within public health departments by providing a framework and a set of evidence-based standards against which they can measure their performance. Among standards with direct relevance to emergency preparedness are assurances of laboratory, epidemiologic, and environmental expertise to investigate and contain serious public health problems, policies, and procedures for urgent communications, and maintenance of an all-hazards emergency operations plan.[62] Through the process of accreditation, health departments identify their strengths and weaknesses, increase their accountability and transparency, and improve their management processes, which all promote continuous quality improvement.[63]

Emergency management, as defined by the Emergency Management Accreditation Program (EMAP), encompasses all organizations in a given jurisdiction with emergency or disaster functions, which may include prevention, mitigation, preparedness, response, and recovery. The EMAP helps applicants ensure—through self-assessment, documentation, and peer review—that they meet national standards for emergency response capabilities.[64]

The PHAB and the EMAP each provide important mechanisms for improving evaluation and accountability. Accreditation and reaccreditation by these entities demonstrate that a state's public health and emergency management systems are capable of effectively responding to a range of health threats. The priority capabilities that the PHAB and the EMAP test include identification, investigation, and mitigation of health hazards; a robust and competent workforce; incident, resource, and logistics management; and communications and community-engagement plans.[65,66] States sometimes aim to meet applicable standards but do not pursue accreditation.

As of November 2021, 32 states and the District of Columbia were accredited by both the PHAB and the EMAP—a net increase of three since December 2020. South Carolina and Virginia joined this group after gaining accreditation from the PHAB; Maryland rejoined the group after being reaccredited by the EMAP; Washington joined after receiving its first accreditation from EMAP; New Mexico's EMAP accreditation lapsed. Indiana is now accredited by the PHAB, alongside an additional nine states that have received accreditation from just one of the two. (See Table 6.)

After receiving accreditation from the PHAB in February 2021, Dr. Edward Simmer, MD, MPH, DFAPA, the director of the South Carolina Department of Health and Environmental Control (DHEC), said, "At a time in our nation's history when public health has been thrusted into the spotlight, DHEC hopes that achieving national accreditation will help reaffirm our commitment to putting people and their needs first."[67] PHAB President and CEO Paul Kuehnert, DNP, RN, FAAN, said of the achievement: "People living and working in communities served by these health departments can be assured that their health department is strong and has the capacity to protect and promote their health. Just going through the accreditation process itself helps health departments pinpoint the areas that are critical to improving the work they do for their communities."

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Just eight states (Alaska, Hawaii, Kentucky, New Hampshire, South Dakota, Texas, West Virginia, and Wyoming) received no accreditation from either body. A state without an accreditation has not necessarily been denied; the state may not have pursued one or may still be in the process of seeking accreditation. It is also important to note that this analysis includes state-level accreditation only. It does not include local or tribal health departments that may be accredited.

TABLE 6: 42 States and the District of Columbia Accredited by the PHAB and/or EMAP
Accreditation status by state, November 2021

PHAB and EMAP			PHAB only	EMAP only	No Accreditation
Alabama	Illinois	North Dakota	Indiana	Michigan	Alaska
Arizona	Iowa	Ohio	Maine	Nevada	Hawaii
Arkansas	Kansas	Oklahoma	Minnesota	North Carolina	Kentucky
California	Louisiana	Pennsylvania	Montana	Tennessee	New Hampshire
Colorado	Maryland	Rhode Island	New Mexico		South Dakota
Connecticut	Massachusetts	South Carolina	Oregon		Texas
Delaware	Mississippi	Utah			West Virginia
District of Columbia	Missouri	Vermont			Wyoming
Florida	Nebraska	Virginia			
Georgia	New Jersey	Washington			
Idaho	New York	Wisconsin			
32 states + DC			**6 states**	**4 states**	**8 states**

Note: These indicators track accreditation by the PHAB and the EMAP. TFAH classified states with conditional or pending accreditation at the time of data collection as having no accreditation. States sometimes aim to meet applicable standards but do not pursue accreditation. This analysis includes state-level accreditations only, it does not include accredited local or tribal health departments. In some instances, local public health departments have an accreditation in states that do not.

Sources: PHAB[68] and EMAP.[69]

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INDICATOR 5: STATE PUBLIC HEALTH FUNDING TRENDS

Key Finding: A majority of states held their public health funding steady or increased it in FY 2021, but at least 15 reduced funding. (Data were not available for five states.)

The COVID-19 pandemic showed how sufficient and sustained funding for a comprehensive public health system is integral to preparedness and response, including the ability to detect, prevent, and control disease outbreaks and mitigate the health consequences of disasters. General public health capabilities—such as those pertaining to epidemiology, environmental hazard detection and control, infectious disease prevention and control, and risk communications—and targeted emergency response resources are necessary to ensure that officials maintain routine capabilities and that surge capacity is readily available for emergencies. A trained and standing-ready public health workforce, and one that knows its community, is critical to the surge capacity that is so often necessary during an emergency.

According to the Public Health Activities and Services Tracking project at the University of Washington, state public health programming and services span six core areas:[70]

1. **Communicable disease control.** Public health services related to communicable disease epidemiology, hepatitis, HIV/AIDS, immunization, sexually transmitted diseases, tuberculosis, etc.
2. **Chronic disease prevention.** Public health services related to asthma, cancer, cardiovascular disease, diabetes, obesity, tobacco use, etc.
3. **Injury prevention.** Public health services related to firearms, motor vehicles, occupational injuries, senior fall prevention, substance-use disorder, other intentional and unintentional injuries, etc.
4. **Environmental public health.** Public health services related to air and water quality, fish and shellfish, food safety, hazardous substances and sites, lead, onsite wastewater, solid and hazardous waste, zoonotic diseases, etc.
5. **Maternal, child, and family health.** Public health services related to the coordination of services; direct service; family planning; newborn screening; population-based maternal, child, and family health; supplemental nutrition; etc.
6. **Access to and linkage with clinical care.** Public health services related to beneficiary eligibility determination, provider or facility licensing, etc.

The overall infrastructure of public health supports states' ability to promote health equity, build resilience in the population, and carry out emergency response activities. But public health funding is typically discretionary, making it vulnerable to neglect or retrenchment, especially when times are tight. This can undermine emergency preparedness activities and weaken response and recovery efforts. State investment in public health is important for the operations of health agencies: about 28 percent of state and territorial health department revenues are from state sources,[71] while 21 percent of local health department revenue is from state sources, on average.[72]

Fortunately, at least 30 states and the District of Columbia maintained or increased public health funding in FY 2021. (See Table 7.) But at least 15 states reduced the money they directed to these vital activities, increasing the likelihood that they will be less prepared and less responsive in the moments that

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matter most. (This indicator does not assess the adequacy of states' public health funding. It should also be noted that due to inflation and population growth, stable funding is in some cases a funding reduction.)

From FY 2019 to FY 2020, and again from FY 2020 to FY 2021, some states experienced sizeable fluctuations in the state-supported funding allotted to public health services, owing to a host of pandemic-related funding actions. For example, in some cases, a temporary infusion of state-supported funds might have been appropriated for just one year. In other cases, state-supported funding might have been temporarily cut and replaced by pandemic-related federal aid. Importantly, states are asked to report to TFAH only their state-supported funding.

TABLE 7: State Public Health Funding Held Stable or Increased in at Least 30 States and DC

Public health funding, by state, FY 2020 to 2021

State	Percentage Change
Alabama	12%
Alaska	-58%
Arizona	-36%
Arkansas	-6%
California	-49%
Colorado	1%
Connecticut	7%
Delaware	Not reported
District of Columbia	3%
Florida	1%
Georgia	12%
Hawaii	-4%
Idaho	-3%
Illinois	3%
Indiana	3%
Iowa	9%
Kansas	Not reported
Kentucky	-17%
Louisiana	58%
Maine	32%
Maryland	1%
Massachusetts	8%
Michigan	10%
Minnesota	-14%
Mississippi	-1%
Missouri	-7%
Montana	-2%
Nebraska	-1%
Nevada	13%
New Hampshire	4%
New Jersey	4%
New Mexico	6%
New York	7%
North Carolina	-1%
North Dakota	0%
Ohio	20%
Oklahoma	168%
Oregon	2%
Pennsylvania	15%
Rhode Island	Not reported
South Carolina	0%
South Dakota	4%
Tennessee	28%
Texas	10%
Utah	Not reported
Vermont	7%
Virginia	7%
Washington	88%
West Virginia	Not reported
Wisconsin	-1%
Wyoming	-5%

Note: In Alaska, at the beginning of the COVID-19 pandemic, the state established a dedicated supplemental fund for related activities, as necessary. As federal aid became available, it supplanted the state funds, creating the appearance of a major reduction in FY 2021. In New Jersey, the end of FY 2020 was extended by three months and the beginning of FY 2021 was delayed by three months.

Because of differences in organizational responsibilities and budgeting, funding data are not necessarily comparable across states. Owing to the significant and persistent demands on the time of state public health officials that responding to the COVID-19 pandemic has necessitated, five states (Delaware, Kansas, Rhode Island, Utah, and West Virginia) were unable to provide TFAH with public health funding data for FY 2021.

See "Appendix B: Methodology" for a description of TFAH's data-collection process, including its definition of public health funding.

Source: TFAH analysis of states' publicly available funding data.

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INDICATOR 6: COMMUNITY WATER SYSTEM SAFETY

KEY FINDING: Few Americans drink from community water systems that are in violation of applicable health-based standards required by the Safe Drinking Water Act. But room for improvement remains.

Access to safe water is essential for consumption, sanitation, hygiene, and the efficient operation of the healthcare system and other critical infrastructure. In the United States, the vast majority of the population gets water from a public water system,[73] and the U.S. Environmental Protection Agency (EPA) sets legal limits on contaminants in drinking water, including microorganisms, disinfectants, and their byproducts, other chemicals, and radionuclides.[74] The EPA also requires states to periodically report drinking-water quality information from public water systems in their jurisdictions.[75] Water systems must report any violations, such as failing to follow established monitoring and reporting schedules, failing to comply with mandated treatment techniques, violating any maximum contaminant levels, and failing to meet customer-notification requirements.[76]

The United States has one of the safest public drinking-water supplies in the world, but some communities, particularly low-income communities, do not have constant access to safe water. When water safety issues occur, it can require a multisector emergency response, as well as a long-term public health response. The most prominent water-contamination crisis in recent years occurred in Flint, Michigan, where a 2014 change in water source caused distribution pipes to corrode and to leach lead and other contaminants into the drinking water. Tens of thousands of residents, including young children, were exposed to high levels of lead and other contaminants.[77] In 2019, residents of Newark, New Jersey, had to rely on bottled water due to high levels of lead in their tap water, though nearly all of the city's 23,000 lead service lines have since been replaced with pipes, and in July 2021 the state enacted laws requiring public water systems to inventory and replace lead service lines within 10 years.[78,79] In children, even low levels of lead exposure can damage the nervous system and contribute to developmental delays, learning disabilities, and weight and hearing loss.[80] These incidents could have long-term consequences on the health and brain development of children, as well as the mental health and trust of the community.

As climate change contributes to more frequent wildfires, a residual danger is the release of toxic chemicals into community water systems. For example, months after the deadly Camp Fire in Paradise, California, in 2018, experts still advised residents not to drink or cook with the water due to concerns about benzene contamination.[81,82] Long-term exposure to unsafe levels of benzene can lead to numerous adverse health outcomes, including anemia and excessive bleeding, and can impair the immune system. Exposure to high levels increases the risk for leukemia.[83]

Major storms, which are made more frequent and more intense by climate change,[84] can damage water infrastructure and lead to power outages, sometimes causing potable water to become inaccessible or tainted. When Hurricane Ida devastated coastal Louisiana in August 2021, pumps and treatment plants serving hundreds of thousands of residents were left without power.[85] In Jefferson Parish to the west and south of New Orleans, the state's second-largest parish,[86] most residents either had dry taps or were under boil advisories. Power outages are a particular concern in rural areas where smaller utilities may not have enough

backup power to meet the demands of the water and sewage services. Water shortages can have a particularly dire impact on healthcare systems, which rely on clean water for many procedures and hygiene practices.

Other water-related hazards in the United States include harmful algal blooms that cause algal toxins and the emerging presence of per- and polyfluoroalkyl substances (PFAS) from industrial chemicals.[87]

CDC data indicate waterborne pathogens cause nearly 7,000 deaths, 7 million illnesses, and more than $3 billion in healthcare costs each year. The risks from contaminated drinking water disproportionately threaten communities of color, highlighting the impact that structural racism can have on a critical resource most Americans consider a basic service. In some areas, redlining has kept peri-urban communities of color, tribal lands, and rural agricultural areas out of municipal water systems, thereby increasing their potential exposure to waterborne illness. In addition, older buildings are more vulnerable to waterborne pathogens in their pipes.[88]

Encouragingly, the federal Infrastructure Investment and Jobs Act, enacted in November 2021, took several significant steps toward expanding access to safe drinking water. Among its provisions were $24 billion in grants to states under the existing Clean Water Act (focused on regulating pollution and protecting surface water quality[89]) and the Safe Drinking Water Act (focused on protecting waters actually or potentially designed for drinking[90]); $15 billion to replace lead pipes and service lines; $9 billion to address emerging contaminants (PFAS); and a number of initiatives to provide dedicated assistance to small, disadvantaged, low-income, rural, and/or tribal communities.[91,92]

According to the EPA, across the nation, 5 percent of state residents on average used a community water system in 2019 (the most recent year for which data were available) that failed to meet all applicable health-based standards, down from 7 percent in 2018.[93] That share was actually or effectively 0 percent in Hawaii, Maryland, Minnesota, Nevada, North Dakota, Vermont, and Washington. (See Table 8.) But in four states (New Jersey, New York, Oregon, and West Virginia), more than 15 percent of residents used a community water system with health-based violations.

It is also important to note that approximately 13 million U.S. households get their drinking water from private wells. The data reported by this indicator do not include water quality for those households.[94]

TABLE 8: Few Americans Used Contaminated Community Water Systems

Percent of state populations who used a community water system in violation of health-based standards, 2019

States	Percent of Population
HI, MD, MN, ND, NV, VT, WA	0%
CA, ID, IL, IN, ME, OH	1%
AL, CO, DE, MI, NC, NE, NH, WY	2%
CT, FL, SC, VA	3%
AK, IA, KY, RI, SD, TN, TX,	4%
AZ, DC, KS, UT, WI	5%
NM	6%
GA, MA	7%
AR, MS, MT	8%
MO, PA	9%
LA	13%
OK	15%
NJ, OR, WV	16%
NY	45%

Note: The EPA estimates that more than 13 million U.S. households get their drinking water from private wells.[95] The data reported by this indicator do not reflect the water quality of those households, though they are included in population percentage calculations. Only regulated contaminants are measured. These data do not include water safety on Indian reservations. According to health officials in New York, a drinking-water system in New York City is in violation due to an uncovered reservoir, but it has no current violations with respect to contaminants.

Source: NHSPI analysis of data from the EPA.[96]

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INDICATOR 7: USE OF PAID TIME OFF

KEY FINDING: Just over half of workers in states, on average, used some type of paid time off—sick leave, vacation, holidays—in a one-month sample. Most states were closely clustered to that midpoint, with few outliers.

Note: The specification of this indicator has been adjusted slightly in recent years from a measure of those who received paid time off to a measure of those who used it. Additionally, these figures reflect a one-month snapshot, intended to show relative usage across states, not a measure of the total percentage of workers who used paid time off during the entire year.

The need for paid time off has been evident during the pandemic, as frontline and essential workers—people whose jobs do not permit them to work remotely—have often been compelled to work when sick themselves, caring for a sick family member, or experiencing temporary side effects immediately after vaccination. Black and Hispanic workers typically have less access to paid sick leave and are overrepresented in groups of frontline workers.[97]

When workers without paid leave get sick, they face the choice of going to work and potentially infecting others or staying home and losing pay—or even their jobs. They encounter similarly impossible decisions when a child or another dependent family member gets sick. Therefore, access and the ability to use job-protected paid time off, especially dedicated paid sick leave, can strengthen infection control and resilience in communities by reducing the spread of contagious diseases and bolstering workers' financial security. This is particularly important for industries and occupations that require frequent contact with the public. For example, people working in the food-service, older adult and nursing care facilities, and childcare industries commonly have no paid sick leave.[98] Low-wage workers[99] and workers of color are also less likely to have access to paid leave compared with white and higher-earning workers.[100] This often leads employees to work throughout an illness or return to work before their symptoms have fully subsided, when time off could have dramatically reduced the potential of workplace infections.[101,102]

The public health benefit is clear: at a societal level, flu rates have been shown to be lower in cities and states that mandate paid sick leave.[103,104] When employees who previously did not have access are granted paid or unpaid sick leave, rates of flu infections decrease.[105]

Paid time off also increases access to preventive care among workers and their families, including routine checkups, screenings, and immunizations. Delaying or skipping such care can result in poor health outcomes and can ultimately lead to costlier treatments. Workers without paid sick days are less likely to get a flu shot, and their children are less likely to receive routine checkups, dental care, and flu shots.[106]

During the COVID-19 pandemic, studies have shown that access to paid sick leave helped slow the spread of the virus.[107] The Families First Coronavirus Response Act, enacted in March 2020, helped temporarily address this issue for employers with fewer than 500 employees and certain public employers, temporarily requiring employees to be provided with paid sick leave under certain conditions. This helped reduce the spread of the virus in workplaces and communities by removing a barrier to employees staying home when necessary. However, these protections expired on December 31, 2020, despite the ongoing need for the use of paid leave to control the pandemic; instead, Congress provided a tax credit for qualifying employers

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to offer paid sick leave from January 1, 2021, to September 30, 2021.[108,109] State and local paid leave laws helped fill in some of the gap, but most states and localities do not have them.[110]

Importantly, the United States could join numerous countries across the world in establishing a national minimum standard of paid family or medical leave if the Build Back Better Act, which the U.S. House of Representatives passed in November 2021, becomes law. The Act includes a requirement that, starting in 2024, employers provide four weeks of partially paid leave to employees who need time off after the birth of a child, to recover from a serious illness, or to care for a family member.[111,112]

In March 2020, 55 percent of all workers in states, on average, took some type of paid time off—the same percentage as in March 2019 and March 2018—according to the Current Population Survey, which is sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics.[113] Alaska (63 percent), Iowa (62 percent), Mississippi (65 percent), Oregon (61 percent), and Texas (65 percent) stood out as states where relatively high percentages of workers used such benefits, whereas fewer workers used them in Arkansas (48 percent), Kentucky (49 percent), Pennsylvania (47 percent), South Dakota (44 percent), and Wyoming (47 percent).[114] (See Table 9.)

TABLE 9: 55 Percent of Workers, On Average, Used Paid Time Off
Percent of employed population that took paid time off, March 2020

States	Percent of Workers
MS, TX	**65%**
AK	**63%**
IA	**62%**
OR	**61%**
DC, MA, NY	**60%**
AL, KS, MD, NM	**59%**
GA	**58%**
CT, DE, ND, VA	**57%**
CO, HI, ID, WA, WI	**56%**
CA, FL, LA, NH, OK, VT	**55%**
AZ, MO, MT	**54%**
NC, NJ	**53%**
IL, IN, NE, OH, RI, TN, WV	**52%**
MN, NV, SC	**51%**
ME, MI, UT	**50%**
KY	**49%**
AR	**48%**
PA, WY	**47%**
SD	**44%**

Note: Paid time off includes sick leave, vacations, and holidays. The data are measured based on a survey of a sample of the general population. The specification of this indicator has been adjusted slightly from a measure of those who received paid time off to a measure of those who used it. Additionally, these figures reflect a one-month snapshot, intended to show relative usage across states, not a measure of the total percentage of workers who used paid time off during the entire year.

Source: NHSPI analysis of data from the Annual Social and Economic Supplement of the Current Population Survey.[115]

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INDICATOR 8: FLU VACCINATION RATE

KEY FINDING: Flu vaccination coverage held at a relatively high level for the second consecutive year during the 2020–2021 season, with an especially high rate for older adults. Overall, 52 percent of U.S. residents ages 6 months and older received vaccinations—still well below the overall target level of 70 percent of the population vaccinated annually.

CDC recommends that, with few exceptions, everyone ages 6 months and older get vaccinated for seasonal influenza annually; yet, year after year, even with a steady increase among adults over the past three decades,[116] coverage estimates indicate that just over half of Americans do. *Healthy People 2030* set federal 10-year benchmarks for improving the health of all Americans, including an overall seasonal influenza vaccination-rate target of 70 percent annually.[117]

Vaccination is the long-standing best prevention against the seasonal flu, particularly for people at high risk of severe flu-related outcomes, including people with certain chronic health conditions and older adults, groups that are also at higher risk from COVID-19. In addition to protecting Americans from the seasonal flu, establishing a cultural norm of vaccination, building vaccination infrastructure, and establishing policies that support vaccinations can all help prevent or limit other illnesses for which there is a vaccine, including COVID-19. A major concern as the 2020–2021 flu season opened was that a high incidence of seasonal flu coupled with the amount of illness caused by the pandemic would overwhelm health systems. Fortunately, that scenario was avoided, as COVID-related mitigation measures also helped to tamp down transmission of seasonal flu,[118] but experts fear that the 2021–2022 season could be worse, in part because of looser mitigation measures and the dominance of a particularly virulent strain.[119,120]

Under the Affordable Care Act, all routine vaccines recommended by the Advisory Committee on Immunization

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Practices, including flu vaccines, are fully covered when provided by in-network providers, except in states that have not expanded their Medicaid programs in accordance with the law. Some barriers to flu vaccination may include a belief that the vaccine does not work very well; misconceptions about the safety of the vaccine;[121] or a belief that the flu does not carry serious risks.[122]

There are a number of policy options available to states and localities seeking to increase vaccination levels. To help increase access, states can expand the number of qualified healthcare workers who can administer vaccines. There is evidence, for example, that pharmacists can play a key role in facilitating broader access and controlling epidemics and their costly consequences.[123] States and localities can also target residents at high-risk (e.g., people in long-term care facilities, older adults, young children, and people with chronic conditions) and promote vaccination through public information campaigns.[124]

According to the National Conference of State Legislatures, states have recently taken creative steps to broaden the scope of qualified vaccine administrators. For example, Indiana recently began allowing pharmacy technicians to administer flu vaccines, and New Hampshire and West Virginia permit qualified pharmacy interns to do so. Ohio even allows podiatrists to administer flu vaccines. Virginia requires certified long-term care facilities to provide or arrange for vaccination for their residents, and New Mexico requires hospitals to offer the influenza vaccine to patients over 65 on discharge.

During the 2020–2021 flu season, 52 percent of U.S. residents ages 6 months and older were vaccinated, according to CDC, tying the 2019–2020 season for the highest rate in at least a decade. This was a notable and welcome uptick from 42 percent during the 2017–2018 flu season. Massachusetts (67 percent), Rhode Island (66 percent), and Connecticut (62 percent) had the highest coverage, while vaccination rates were lowest in Florida (42 percent), Mississippi (42 percent), Wyoming (43 percent), Nevada (43 percent), and Georgia (43 percent). (See Table 10.)

Children, particularly young children, were more likely to receive vaccinations than were adults. Nearly 59 percent of those ages 6 months to 17 years received flu vaccinations in 2020–2021, compared with 50 percent of adults. The most highly vaccinated age group was people ages 65 or over at 75 percent.[125]

TABLE 10: Just Over Half of U.S. Residents Received a Seasonal Flu Vaccination
States' seasonal flu vaccination rates for people ages 6 months and older, 2020–2021

State	Vaccination Rate, Ages 6 Months or Older
Massachusetts	66.5
Rhode Island	66.4
Connecticut	62.3
New Hampshire	60.7
Vermont	59.9
Nebraska	58.7
Maryland	58.5
Pennsylvania	58.5
Iowa	58.4
Delaware	58.3
District of Columbia	58.3
South Dakota	58.1
Minnesota	57.6
Illinois	56.9
Washington	56.5
Maine	56.4
Wisconsin	56.2
Virginia	56.0
New York	55.6
Colorado	55.4
New Jersey	55.2
North Dakota	54.4
Hawaii	54.2
Michigan	53.7
North Carolina	53.3
Kansas	53.0
Utah	52.5
Ohio	52.4
Missouri	52.2
Arkansas	51.5
Oregon	51.4
Indiana	51.1
New Mexico	51.1
Tennessee	50.4
California	49.4
West Virginia	48.9
Montana	48.5
Alabama	48.3
Arizona	48.3
South Carolina	48.1
Kentucky	46.7
Texas	46.7
Idaho	46.0
Oklahoma	45.9
Alaska	45.4
Louisiana	44.2
Georgia	43.1
Nevada	43.0
Wyoming	42.6
Mississippi	42.1
Florida	41.7

Note: Data are calculated from a survey sample, with a corresponding sampling error.

Source: Centers for Disease Control and Prevention.[126]

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INDICATOR 9: PATIENT SAFETY IN HOSPITALS

KEY FINDING: On average, 28 percent of hospitals received an "A" grade in the fall 2021 hospital safety assessment administered by the Leapfrog Group, a nonprofit advocate for safety, quality, and transparency in hospitals.

Every year, hundreds of thousands of people die from hospital errors, injuries, accidents, and infections, collectively making such incidents a leading cause of death in the United States.[127,128] Keeping hospital patients safe from preventable harm is an important element of preparedness; those hospitals that excel in safety are less likely to cause or contribute to a public health emergency and are better positioned to handle any emergencies that put routine quality standards to the test.

During the COVID-19 pandemic, hospitals, were one of numerous settings for viral transmission, threatening the safety of patients, staff, and visitors. The pandemic also discouraged people in need of urgent or emergency care from going to the emergency department, likely contributing to overall excess mortality.[129] Universal masking and availability and proper use of personal protective equipment (PPE)—in addition to other steps, such as adequate ventilation, limiting the sharing of patient rooms, and universal hand hygiene—proved to be critical in preventing outbreaks in hospitals. Still, hospital crowding from regional waves of infection during the pandemic has been shown to contribute to adverse outcomes, such as increased medical errors and reduced quality of care as well as delays in treatment, medication error, longer patient stays, poorer outcomes, and increased mortality.[130]

The Leapfrog Group calculates its hospital safety score by using more than two dozen evidence-based metrics that measure the success of healthcare processes and outcomes. The measures track such issues as healthcare-associated infection rates, the number of available beds and qualified staff in intensive-care units, patients' assessments of staff communications and responsiveness, and a hospital's overall culture of error prevention.[131] These measures are especially critical for health systems' readiness for emergencies and outbreak prevention and control, which include workforce training and availability, surge capacity, and infection-control practices.

In the Leapfrog Group's fall 2021 assessment, 28 percent of general acute-care hospitals across the United States, on average, met the requirements for an "A" grade—a slight decrease from fall 2020, when the share was 31 percent. But results varied widely from state to state, with no hospitals in Delaware, the District of Columbia, and North Dakota receiving the top score, to a majority of hospitals doing so in Virginia (56 percent), North Carolina (55 percent), Idaho (54 percent), and Massachusetts (52 percent). (See Table 11.)

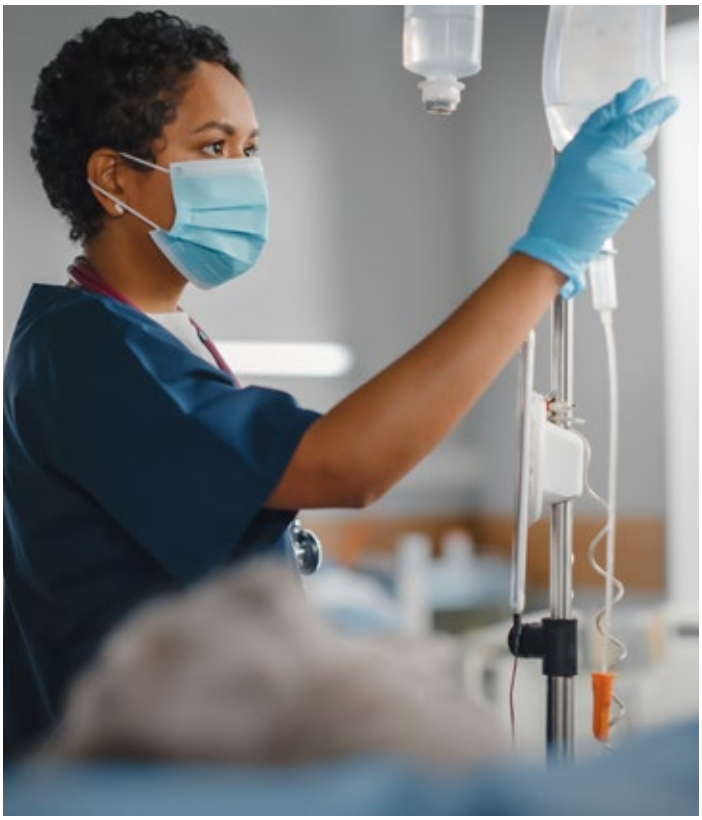

TABLE 11: Hospital Patient Safety Scores Vary Significantly by State

State percentage of hospitals with "A" grade, fall 2021

State	Percent of Hospitals
Virginia	56%
North Carolina	55%
Idaho	54%
Massachusetts	52%
Colorado	49%
Utah	48%
Hawaii	46%
Pennsylvania	46%
New Jersey	43%
Michigan	43%
Maine	41%
Oregon	41%
Florida	36%
Kansas	36%
Tennessee	35%
Texas	35%
Ohio	34%
Missouri	33%
Rhode Island	33%
California	33%
Washington	33%
Mississippi	32%
New Hampshire	31%
Arkansas	30%
South Carolina	29%
Illinois	29%
Connecticut	28%
Louisiana	27%
Minnesota	26%
Kentucky	25%
Oklahoma	24%
Indiana	24%
Arizona	24%
Wisconsin	23%
Maryland	21%
Nevada	21%
Montana	20%
Georgia	20%
Alabama	19%
Alaska	17%
Nebraska	17%
Vermont	17%
Iowa	15%
New Mexico	14%
Wyoming	13%
South Dakota	10%
New York	8%
West Virginia	5%
Delaware	0%
District of Columbia	0%
North Dakota	0%

Note: This measure captures only general acute-care hospitals.

Source: The Leapfrog Group.[132]

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INDICATOR 10: STATE PUBLIC HEALTH LABORATORY SURGE CAPACITY

KEY FINDING: Only the District of Columbia reported not having a plan in 2021 for a six-to-eight week surge in laboratory-testing capacity to respond to an outbreak or other public health event.

Public health laboratories have been essential to emergency response and effective disease surveillance systems throughout the pandemic. They help detect and diagnose health threats as they emerge, and they track and monitor the spread of those threats, which can help public health officials learn how to control them. Public health labs exist in every state and territory and are the backbone of the Laboratory Response Network (LRN), a national network of laboratories that provide the infrastructure and capacity to respond to public health emergencies.[133]

When a disaster or disease outbreak strikes, public health laboratories must be able to surge to meet increased demand, just like hospitals and other responders. The Association of Public Health Laboratories defines internal surge capacity as a "sudden and sustained increase in the volume of testing that a LRN reference laboratory can perform in an emergency situation, implementing substantial operational changes as defined in laboratory emergency response plans and using all resources available within the laboratory."[134] Surging capacity can require staff movement or reassignment, extra shifts, and hiring. Labs also have to plan for infrastructure factors, such as sufficient biological safety cabinets and chemical fume hoods; amount and type of supplies; space for intake, processing, and storage of samples; versatility and capacity of analytical equipment and instruments; availability of PPE; and power supply.[135] It should also be noted that while the existence of surge plans are important, these plans have to be funded, tested, and regularly updated.

State public health laboratories have been critical assets throughout the COVID-19 pandemic, especially in early 2020, when they were the only laboratories outside CDC authorized to conduct testing.[136] Despite early challenges in the tests rolled out to states, at least one public health laboratory in every state, DC, Puerto Rico, and Guam was able to test for COVID-19 as of June 2020.[137] Testing capacity increased over time, as private labs received authorization and ramped up capacity, and as a variety of rapid antigen tests were manufactured and approved for use at home; but the processing of CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel assisted officials with monitoring throughout the course of the pandemic.

In Minnesota, for instance, once officials recognized in spring 2020 that their normal sample receiving area would not be able to handle the exploding number of COVID-19-related specimens on top of added social distancing and other safety restrictions, they converted the state's training laboratory into a triage unit. In days, leaders held walk-through meetings to organize the space, collaborated with state technology staff to procure necessary equipment, and set up supplies (racks, proper waste bins, transport containers). The site was up and running as the state's primary public COVID-19 testing facility within two weeks.[138]

In addition, public health laboratories are studying the genomic sequencing of the COVID-19 virus to identify variants. Such genomic surveillance is critical to understanding and preventing the

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spread of the virus,[139] and proved critical during the emergence of the Delta and Omicron variants, which were each more transmissible than earlier strains.[140] Throughout 2021, the scale of sequencing increased dramatically from fewer than 3,000 samples per week in January to about 80,000 samples per week by early December,[141] an increase that coincided with a $2 billion increase in federal investments, much of which was made possible by the American Rescue Plan Act.[142,143] However, the slow rollout of data modernization funding, the need to update these systems after years of underfunding, and a dwindling public health workforce continued to hamper rapid surveillance efforts at the end of 2021.[144]

Going forward, challenges to the effectiveness of public health laboratory preparedness include funding gaps to invest in infrastructure and modernization; a lack of standardized platforms to exchange data electronically; a limited ability to detect radiological, nuclear, and chemical threats; and perhaps most significantly, workforce shortages.[145] California, for example, has long been losing public health lab staff—as of November 2021, the state operated 29 labs, down from nearly 40 before the Great Recession—and this trend has accelerated over the past year as lab workers join a broader exodus of experienced public health officials.[146,147]

In 2021, the District of Columbia was the only jurisdiction that reported to the Association of Public Health Laboratories that it did not have a plan for a six- to eight-week surge in testing capacity. (See Table 12.) Massachusetts and Oklahoma did not indicate whether they had such a plan, though each reported having one in 2020.[148] The District of Columbia reported being in the process of developing a discrete plan for its laboratory surge capacity.

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TABLE 12: Nearly Every State Planned for a Laboratory Surge

State public health laboratories with a plan for a six- to eight-week surge in testing capacity, 2021

Had a Plan			No Plan
Alabama	Kentucky	North Dakota	District of Columbia
Alaska	Louisiana	Ohio	
Arkansas	Maine	Oregon	
Arizona	Maryland	Pennsylvania	
California	Michigan	Rhode Island	
Colorado	Minnesota	South Carolina	
Connecticut	Mississippi	South Dakota	
Delaware	Missouri	Tennessee	
Florida	Montana	Texas	
Georgia	Nebraska	Utah	
Hawaii	Nevada	Vermont	
Idaho	New Hampshire	Virginia	
Illinois	New Jersey	Washington	
Indiana	New Mexico	West Virginia	
Iowa	New York	Wisconsin	
Kansas	North Carolina	Wyoming	

Note: Massachusetts and Oklahoma did not indicate whether they had a plan, though each reported having one in 2020. The District of Columbia reported not having a current plan, indicating that it was in the process of updating its Continuity of Operations Plans and developing a discrete plan for laboratory surges. This indicator tracks only the existence of a plan, not its quality or comprehensiveness, or the frequency in which it is used or tested.

Source: Association of Public Health Laboratories.[149]

TABLE 13: INDICATORS OF PUBLIC HEALTH EMERGENCY PREPAREDNESS

	Nurse Licensure Compact (NLC)	Public Health System Comprehensiveness	Public Health Accreditation Board (PHAB)	Emergency Management Accreditation Program (EMAP)	Public Health Funding	Water Security	
	State participates in NLC, 2021	Percentage of population served by a comprehensive public health system, 2018	Accredited by PHAB, 2021	Accredited by EMAP, 2021	Percentage change, FY 2020-21	Percent of population who used a community water system in violation of health-based standards, 2019	
Alabama	✓	35%	✓	✓	12%	2%	
Alaska		62%			-58%	4%	
Arizona	✓	67%	✓	✓	-36%	5%	
Arkansas	✓	31%	✓	✓	-6%	8%	
California		59%	✓	✓	-49%	1%	
Colorado	✓	44%	✓	✓	1%	2%	
Connecticut		37%	✓	✓	7%	3%	
Delaware	✓	42%	✓	✓	-	2%	
D.C.		86%	✓	✓	3%	5%	
Florida	✓	49%	✓	✓	1%	3%	
Georgia	✓	43%	✓	✓	12%	7%	
Hawaii		-			-4%	0%	
Idaho	✓	39%	✓	✓	-3%	1%	
Illinois		47%	✓	✓	3%	1%	
Indiana	✓	25%	✓		3%	1%	
Iowa	✓	38%	✓	✓	9%	4%	
Kansas	✓	38%	✓	✓	-	5%	
Kentucky	✓	37%			-17%	4%	
Louisiana	✓	44%	✓	✓	58%	13%	
Maine	✓	45%	✓		32%	1%	
Maryland	✓	43%	✓	✓	1%	0%	
Massachusetts		63%	✓	✓	8%	7%	
Michigan		46%		✓	10%	2%	
Minnesota		47%	✓		-14%	0%	
Mississippi	✓	35%	✓	✓	-1%	8%	
Missouri	✓	43%	✓	✓	-7%	9%	
Montana	✓	36%	✓		-2%	8%	
Nebraska	✓	44%	✓	✓	-1%	2%	
Nevada		55%		✓	13%	0%	
New Hampshire	✓	38%			4%	2%	
New Jersey	✓	47%	✓	✓	4%	16%	
New Mexico	✓	37%	✓		6%	6%	
New York		77%	✓	✓	7%	45%	
North Carolina	✓	44%		✓	-1%	2%	
North Dakota	✓	34%	✓	✓	0%	0%	
Ohio	✓	37%	✓	✓	20%	1%	
Oklahoma	✓	39%	✓	✓	168%	15%	
Oregon		42%	✓		2%	16%	
Pennsylvania	✓	67%	✓	✓	15%	9%	
Rhode Island		-	✓	✓	-	4%	
South Carolina	✓	44%	✓	✓	0%	3%	
South Dakota	✓	28%			4%	4%	
Tennessee	✓	36%		✓	28%	4%	
Texas	✓	38%			10%	4%	
Utah	✓	55%	✓	✓	-	5%	
Vermont	✓	45%	✓	✓	7%	0%	
Virginia	✓	44%	✓	✓	7%	3%	
Washington		49%	✓	✓	88%	0%	
West Virginia	✓	45%			-	16%	
Wisconsin	✓	42%	✓	✓	-1%	5%	
Wyoming	✓	36%			-5%	2%	
51-state average	**N/A**	**45%**	**N/A**	**N/A**	**7%**	**5%**	

Note: See "Appendix B: Methodology" for a description of TFAH's data-collection process and scoring details. For the measure of public health system comprehensiveness, no data were available for Hawaii and Rhode Island. States with conditional or pending accreditation at the time of data collection were classified as having no accreditation. Public health funding data for FY 2021 were not available for Delaware, Kansas, Rhode Island, Utah, and West Virginia. Some state residents use private drinking-water sources, rather than community water systems. Private sources are not captured by these data.

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TABLE 13: INDICATORS OF PUBLIC HEALTH EMERGENCY PREPAREDNESS

	Paid Time Off	Seasonal Flu Vaccination	Patient Safety	Public Health Lab Capacity	State Performance
	Percent of employed population who used paid time off, March 2020	Seasonal flu vaccination rate for people ages 6 months or older, 2020–21	Percentage of hospitals with "A" grade, fall 2021	Public health laboratories had a plan for a six- to eight-week surge in testing capacity, 2021	Scoring tier, 2021
Alabama	59%	48.3%	19%	✓	High
Alaska	63%	45.4%	17%	✓	Low
Arizona	54%	48.3%	24%	✓	Middle
Arkansas	48%	51.5%	30%	✓	Low
California	55%	49.4%	33%	✓	Middle
Colorado	56%	55.4%	49%	✓	High
Connecticut	57%	62.3%	28%	✓	High
Delaware	57%	58.3%	0%	✓	Middle
D.C.	60%	58.3%	0%		High
Florida	55%	41.7%	36%	✓	High
Georgia	58%	43.1%	20%	✓	Middle
Hawaii	56%	54.2%	46%	✓	Low
Idaho	56%	46%	54%	✓	Middle
Illinois	52%	56.9%	29%	✓	High
Indiana	52%	51.1%	24%	✓	Low
Iowa	62%	58.4%	15%	✓	High
Kansas	59%	53%	36%	✓	High
Kentucky	49%	46.7%	25%	✓	Low
Louisiana	55%	44.2%	27%	✓	Low
Maine	50%	56.4%	41%	✓	Middle
Maryland	59%	58.5%	21%	✓	High
Massachusetts	60%	66.5%	52%	✓	High
Michigan	50%	53.7%	43%	✓	Middle
Minnesota	51%	57.6%	26%	✓	Low
Mississippi	65%	42.1%	32%	✓	Middle
Missouri	54%	52.2%	33%	✓	Middle
Montana	54%	48.5%	20%	✓	Low
Nebraska	52%	58.7%	17%	✓	Middle
Nevada	51%	43%	21%	✓	Low
New Hampshire	55%	60.7%	31%	✓	Middle
New Jersey	53%	55.2%	43%	✓	High
New Mexico	59%	51.1%	14%	✓	Middle
New York	60%	55.6%	8%	✓	Middle
North Carolina	53%	53.3%	55%	✓	Middle
North Dakota	57%	54.4%	0%	✓	Middle
Ohio	52%	52.4%	34%	✓	High
Oklahoma	55%	45.9%	24%	✓	Middle
Oregon	61%	51.4%	41%	✓	Low
Pennsylvania	47%	58.5%	46%	✓	High
Rhode Island	52%	66.4%	33%	✓	Middle
South Carolina	51%	48.1%	29%	✓	High
South Dakota	44%	58.1%	10%	✓	Low
Tennessee	52%	50.4%	35%	✓	Middle
Texas	65%	46.7%	35%	✓	Middle
Utah	50%	52.5%	48%	✓	High
Vermont	55%	59.9%	17%	✓	High
Virginia	57%	56%	56%	✓	High
Washington	56%	56.5%	33%	✓	High
West Virginia	52%	48.9%	5%	✓	Low
Wisconsin	56%	56.2%	23%	✓	Middle
Wyoming	47%	42.6%	13%	✓	Low
51-state average	**55%**	**53%**	**28%**	**N/A**	**N/A**

Only regulated contaminants are measured. Paid time off includes sick leave, vacations, and holidays. The patient safety measure captures only general acute-care hospitals. Data were not available in 2021 to verify the existence of a laboratory surge plan in Massachusetts or Oklahoma, so a response of "yes" was imputed for both, given that each had a plan in 2020. While the District of Columbia reported having a plan in 2020, it indicated that in 2021 it was in the process of replacing it.

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Recommendations for Federal and State Policy Actions

The nation's struggle to emerge from the COVID-19 pandemic is a reminder of the need for urgent action to prepare for the next public health emergency. Policymakers must recognize and address the lessons of the pandemic through science-based leadership and investment in equity-based health security for all communities. Without significant and sustained attention to the nation's preparedness and response capabilities, Americans will enter the next public health crisis with the same lack of readiness they experienced during the early stages of the COVID-19 pandemic.

TFAH based the following policy recommendations on research and analysis, consultation with experts, and a review of gaps in federal and state preparedness, and makes the following recommendations for federal, state, local, tribal, and territorial policymakers and other stakeholders to improve public health emergency readiness. They are intended to strengthen the nation's preparedness for possible future pandemics and to build a stronger foundation on which to respond to a range of public health emergencies.

Priority Area 1: Provide Stable, Flexible, and Sufficient Funding for Domestic and Global Public Health Security

The chronic underfunding of the nation's public health capacity at all levels has had deadly consequences. On top of over 900,000 lives lost in the United States alone, the pandemic has contributed to a disproportionate health, economic, and mental health toll on people of color, low-income people, people with disabilities, LGBTQ people, and other underserved groups.[150] Health departments have never received the funding needed to modernize, address health inequities, and prepare for emerging health threats. The Staffing Up project estimates an additional 90,000 full-time equivalent positions—an 80 percent increase—are needed in state and local health departments to comprise an adequate infrastructure and provide minimum public health services.[151] And disinvestment in health departments is often the most severe in places with larger populations of people of color.[152] Finally, short-term investments made through COVID-response funding legislation cannot fill the gaps left by ongoing public health funding shortfalls. Short-term resources do not allow for sustaining the public health workforce, nor can they address underlying health inequities that are making the nation less resilient.

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RECOMMENDATIONS FOR FEDERAL GOVERNMENT:

- **Rebuild and modernize the public health infrastructure, including by investing $4.5 billion per year to support foundational public health capabilities at the federal, state, tribal, local, and territorial levels.** The chronic underfunding of public health, combined with siloed funding tied to specific diseases and categories, has prevented health departments across the country from developing and maintaining strong foundational capabilities. Congress should invest in cross-cutting public health capacities, such as those proposed in the Public Health Infrastructure Saves Lives Act.[153] While mandatory funding would ensure sustainability and predictability, if that is not feasible, Congress should provide a robust annual investment in public health infrastructure through the appropriations process.

- **Increase funding for Public Health Emergency Preparedness and Hospital Preparedness Programs (HPP).** Funding for the Public Health Emergency Preparedness cooperative agreement, a critical source of funding for health departments to build capabilities to effectively respond to a range of public health threats, has been cut by nearly a third since FY 2003, or by about half, after adjusting for inflation.[154] The HPP, the primary federal source of funding to help the healthcare delivery system prepare for and respond to disasters, has been cut by nearly half over the same time period, or by nearly two-thirds, after adjusting for inflation. These state and local preparedness programs have demonstrated their value by establishing a foundation for national healthcare readiness, improving the speed and quality of response during emergencies, promoting a focus on patient outcomes during emergencies, and ensuring that local authorities can adequately respond to most local health emergencies and outbreaks without federal assistance. Congress should provide additional funding to modernize public health and response functions at CDC and ASPR and ensure the programs have the capacity to respond to any event.

- **Invest in continuous public health data modernization.** Sustained investment in public health data systems at the federal, state, and local levels is imperative. CDC is the world's premier public health agency, yet years of inadequate funding has meant that the agency and the public health partners that it supports are reliant on archaic data systems. Americans have felt the pain of delayed and disjointed disease surveillance throughout the pandemic, as the public health surveillance infrastructure relied on antiquated, disconnected, and slow systems and methods for tracking and responding to diseases. Congress has begun investing in public health data through the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), the American Rescue Plan Act (P.L. 117-2), and annual appropriations. These investments will help build the foundations for data sharing across public health, modernize CDC's services and systems, leverage new data sources, and ensure public health can act on innovative data analytics. However, these advancements must be augmented and sustained, making up for decades of neglect. Congress should build on these initial investments with at least $250 million per year to CDC's data modernization initiative to modernize and sustain these systems.

- **Ensure complete, disaggregated demographic data collection and reporting, especially during public health emergencies.** The gaps in COVID-19 data reporting by race, ethnicity, income, sexual identity, gender identity, primary language, disability status, pregnancy status, the intersections of these demographics, and other factors hindered the response and masked the true breadth of inequities during the pandemic. These gaps exposed long-standing shortcomings in demographic data collection and reporting in healthcare and public health. Consistent data on demographics and social determinants that influence health outcomes would enable a more effective, equitable response to public health emergencies. In addition to continued investment in data modernization, when implementing this initiative, CDC and public health departments should ensure that health equity and demographic data collection are central to these efforts, including prioritizing funding for under-resourced communities and ensuring sustained community engagement in decisions around public health data system design and use.[155] In addition, the U.S. Department of Health and Human Services (HHS) should stand up a task force—including but not limited to, Office of the Assistant Secretary for Planning and Evaluation, CDC, Office of the National Coordinator on Health Information Technology, Office of Minority Health, Centers for Medicare & Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration, and the Agency for Healthcare Research and Quality, in consultation with state, local, territorial,

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and tribal agencies, community leaders, and private-sector stakeholders—to identify and address barriers to the collection and regular reporting of disaggregated, detailed demographic data during the pandemic and beyond. If needed, Congress should provide HHS agencies the authority to require jurisdictions and healthcare facilities to report race and ethnicity during public health emergencies.[156]

- **Fund the recruitment and training of public health personnel.** The health security enterprise requires trained, experienced personnel. Federal, state, and local governments must prioritize stable, long-term funding for recruitment and retention of a diverse workforce, including one with experience in public health informatics, laboratory science, health equity, epidemiology, and other foundational public health capacities. Congress should also invest in public health workforce development and retention programs, such as the proposed Public Health Workforce Loan Repayment Act and other incentives to serve in governmental public health, fellowships that increase workforce diversity, and recruitment in underserved areas and populations. Public health schools should incorporate health equity, data equity, and cultural competency into their curricula and training programs.

- **Accelerate crisis responses through a standing public health emergency response fund and faster supplemental funding.** In addition to stable core funding, the federal government needs readily available funds on hand to enable a rapid response while Congress assesses the necessity for supplemental funding. Congress should continue a no-year infusion of funds into the Public Health Emergency Rapid Response Fund and/or the Infectious Disease Rapid Response Reserve Fund to serve as available funding that would provide a temporary bridge between preparedness and supplemental emergency funds. Congress should replenish such funding on an annual basis, and funding should not come from existing preparedness resources, as response capacity cannot substitute for adequate readiness. The HHS secretary should only use such funding for acute emergencies that require a rapid response to save lives and protect the public.

- **Demonstrate a long-term commitment to global health security.** The United States should continue to strengthen partnerships with international bodies such as the World Health Organization (WHO), while working with bilateral foreign country partners to strengthen core public health capabilities. Congress should solidify America's role as a global health leader by committing sufficient resources to successfully implement the U.S. Government Global Health Security Strategy[157] and by investing in proven initiatives such as the Field Epidemiology Training and Global Laboratory Leadership Programs, Public Health Emergency Operations Centers, and National Public Health Institutes. Success will require sustained annual funding for global health security programs at CDC. Congress should fund and CDC should implement the modernization of the U.S. quarantine system, including IT systems, quarantine stations, regulatory framework, and traveler engagement and information.

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Priority Area 2: Prevent Outbreaks and Pandemics

The COVID-19 pandemic will not be the last infectious disease outbreak to threaten the country's health and economic security. Emerging infectious diseases have been increasing over the past five decades.[158] At the same time, the increasing polarization and misinformation around COVID-19 vaccines and nonpharmaceutical interventions could affect the prevention and control of more common outbreaks, such as seasonal influenza, vaccine-preventable diseases, and antibiotic resistance. The United States must be able to prevent and respond to both major pandemics and localized outbreaks.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT, HEALTHCARE, AND AGRICULTURE:

- **Support the vaccine infrastructure.** CDC's Section 317 Immunization Program supports state and local immunization systems to increase vaccination rates among uninsured and underinsured adults and children, respond to outbreaks, educate the public, target populations experiencing disadvantage, improve vaccine confidence, establish partnerships, and improve information systems. Yet, funding has not kept up with needs, as states have to spend immunization dollars to respond to outbreaks,[159] deal with increases in the numbers of residents who lack health insurance,[160] and attempt to manage the impact of vaccine underutilization. Health departments depended on this underfunded infrastructure to distribute and dispense the COVID-19 vaccines, with new money not available until January 2021, leading to a slow and chaotic vaccination rollout early in 2021. Congress should increase annual funding for CDC's immunization program as well as the seasonal influenza program and post-licensure vaccine safety monitoring. Congress should also provide annual appropriations to HHS to study and address the causes of vaccine resistance, improve community engagement, and to educate clinical providers on methods for improving vaccine acceptance, such as those included in the recently enacted VACCINES Act.[161]

- **Fund CDC to support state and local public health laboratories.** Congress should substantially increase annual funding for the Epidemiology and Laboratory Capacity cooperative agreement to support state and local public health laboratories. Prior to the pandemic, the Epidemiology and Laboratory Capacity grant was only funding approximately half of what laboratories and health department epidemiologists nationwide requested to combat infectious disease outbreaks. In addition, increasing the Public Health Emergency Preparedness cooperative agreement will allow LRN labs to improve protection of communities across a range of health threats.

- **Ensure first-dollar coverage for recommended vaccines under Medicaid, Medicare, and commercial insurance.** Public and private payers should ensure that all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are fully covered with no out of pocket payment by the consumer, as cost-sharing, such as co-pays, can be a significant barrier to vaccination.[162] Congress should require zero cost-sharing in Medicare Part D and B plans, and CMS should incentivize Part D plans to eliminate cost-sharing and increase receipt of vaccines.[163] An example of legislation that takes steps to improve older adult vaccination rates is the Protecting Seniors Through Immunization Act.

- **Significantly increase investments in public health initiatives to combat antibiotic resistance (AR).** Congress should increase funding for innovative prevention methods of detecting and containing outbreaks supported by the Antibiotic Resistance Solutions Initiative at CDC including its One Health program approach to surveillance and prevention. CDC is investing in prevention measures in every state to strengthen lab capacity, track infections across healthcare systems, detect new threats, disrupt pathogens, coordinate prevention strategies, educate healthcare providers on appropriate antibiotic use, and advocate for other innovations. To fully address the scope of AR spread, particularly in healthcare

settings, Congress should increase funding for the National Healthcare Safety Network and healthcare associated infection/antibiotic resistance programs and activities at state and local health departments. In addition, increases in funding and significant global coordination, as recommended by the National Academies, are necessary to build global capacity to prevent and detect resistant infections and to combat the threat to national security.[164]

- **Create incentives for new-product discovery to fight resistant infections.** The antibiotic development pipeline has failed, leaving patients at risk for antimicrobial-resistant infections. It is extremely challenging for companies to earn a return on their investments for the development of new antibiotics: (1) antibiotics are typically given for a short duration and do not return profits; (2) the most highly resistant infections are still relatively rare; and (3) new antibiotics must be used judiciously to preserve their effectiveness. These factors have resulted in nearly all major pharmaceutical companies exiting the antibiotics market, leaving the critical innovation domain of discovering and developing new antibiotics to small biotech companies that have struggled to survive. Legislation that includes development incentives that are de-linked from sales and strong stewardship and surveillance provisions, such as the PASTEUR Act, would strengthen the market for antibiotic developers, improving patient access for those who need it most.

- **Eliminate overuse of antibiotics in agriculture.** The Food and Drug Administration (FDA) should enforce rules regarding the judicious use of antibiotics in food animals, ensure data collection and publication, promote antibiotic stewardship programs, and track the impact of these policies on resistance patterns. Farmers and the food industry should stop using medically important antibiotics to promote growth and prevent disease in healthy animals, as recommended by WHO,[165] and they should invest in research to develop and adopt husbandry practices that reduce the need for routine antibiotics.

- **Decrease over prescription of antibiotics through implementation of antibiotic stewardship and antibiotic-use reporting.** CDC estimates that improving prescribing practices and preventing infections could save 37,000 lives over five years.[166] CMS should enforce stewardship requirements for hospitals and work with public health stakeholders to track progress in prescribing rates and resistance patterns.[167] CMS should also advance policies to improve outpatient antibiotic prescribing, such as through quality measures and value-based reimbursement programs. All relevant facilities must drastically improve their reporting of antibiotic use and resistance through the National Healthcare Safety Network and should adopt stewardship programs that meet CDC's Core Elements.[168]

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RECOMMENDATIONS FOR FEDERAL AND STATE GOVERNMENT:

- **Provide job-protected paid leave.** The pandemic has called attention to the fact that paid family, sick, and medical leave are important infection-control measures, protecting both workers and customers, in addition to creating economic security. Workers are unable to adhere to public health guidance to isolate if they risk losing their jobs or paychecks. While Congress temporarily expanded access to paid leave during the pandemic, a permanent fix is needed. Congress should enact a permanent federal paid family and medical leave policy and dedicated paid sick days protections, and states should ensure effective implementation by passing paid leave laws and/or removing preemption exemptions.
- **Minimize state vaccine exemptions for schoolchildren and increase vaccination of healthcare workers.** States should enact or strengthen policies that enable universal childhood vaccinations to ensure children, educators and other school personnel, and the general public are protected from vaccine-preventable diseases. This includes eliminating nonmedical exemptions and opposing legislation to expand exemptions.[169] States should require healthcare personnel to receive all ACIP-recommended vaccinations to protect staff and patients and achieve necessary healthcare infection control. Healthcare facilities should ensure access and education to vaccines for all staff and contractors, and they should remove any barriers to staff receiving vaccines. Healthcare facilities should also report healthcare worker vaccination status, such as for seasonal flu and COVID-19, to CDC's National Healthcare Safety Network.

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Priority Area 3: Build Resilient Communities and Promote Health Equity in Preparedness

Social, economic, and structural drivers of health inequities mean that some populations experience a disproportionate impact of disasters, receive fewer resources during the response, and take longer to recover. These same drivers were exacerbated by the pandemic, with communities of color experiencing more severe economic and health impacts. When the intersectionality of factors, such as homelessness, incarceration, disability, age, employment, LGBTQ+ status, and immigration status are taken into consideration, the inequities are compounded. The pandemic will have had both acute and cascading impacts on mental health and wellbeing for years to come. More than 140,000 children have lost caregivers.[170] Increases in mental health concerns have already been documented,[171] including substance use[172] and drug overdoses.[173,174] Rates of suicide among people ages 25 to 34 overall, among males 25 to 34, and among Hispanic males overall, increased significantly.[175] The recent response to the pandemic in some areas has demonstrated that there can be progress in reducing disparities if concerted attention is paid to equity. For example, racial and ethnic gaps in COVID-19 vaccination rates largely closed by the end of 2021.[176]

Addressing underlying inequities and intentionally and meaningfully engaging with the people and communities most likely to be disproportionately impacted throughout the emergency planning and response process are critical to promoting community resilience and ensuring that all receive appropriate services, regardless of circumstance. Equity must be an explicit and foundational principle in all emergency planning, response, and recovery.

RECOMMENDATIONS FOR FEDERAL, STATE, AND LOCAL GOVERNMENT:

- **Strengthen leadership for health equity and incorporate lessons learned into future preparedness and response capabilities.** The White House, Congress, and relevant federal, state, local, tribal, and territorial agencies should implement the recommendations of the COVID-19 Health Equity Task Force. [See box on pg. 14.] The White House should create a permanent health equity infrastructure to implement and ensure accountability for these recommendations and bolster equity leadership and coordination for future health crises.

- **Invest in policies and capacity to address the social determinants of health (SDOH):** People at highest risk during disasters and those who have the hardest time recovering are often those with unstable or unhealthy housing, those with limited access to transportation, and those who live in low-socioeconomic-status communities,[177] all of which bore out during the COVID-19 pandemic. Addressing SDOH can improve resilience, but it must be a cross-sector effort to increase healthy, affordable housing; improve transportation access; advance economic opportunity and fight poverty; and implement other policies proven to advance health. Congress should fund a public health approach to address SDOH, such as the approach proposed in the Improving Social Determinants of Health Act and in the President's FY 2022 CDC budget request. The legislation would strengthen SDOH capacity at CDC and enable grants to public health agencies to build cross-sector partnerships and develop community solutions to SDOH. For further discussion on policy options to address SDOH, see TFAH's Blueprint and Leveraging Evidence-Based Policies to Improve Health, Control Costs, and Create Equity reports.[178,179]

- **Provide resources and technical assistance to communities to enhance equity and resilience before, during, and after an event.** Rather than a top-down approach to promote equity and resilience, policymakers should support an asset-based approach that relies on communities identifying and leveraging their assets. Congress and federal agencies should direct targeted resources to community-based organizations and existing community health networks that focus on the health of communities of color, older adults, people with disabilities, and other groups that bear a disproportionate burden during disasters. Grants should support evidence-based, culturally relevant, and linguistically appropriate public health campaigns that address prevention and treatment, providing community leaders the opportunity to fully participate in planning activities, allowing organizations to hire and engage community members so emergency plans better reflect the community, as well as improving data collection and sharing. Federal and other grant makers and states should ensure that existing grants and sub-awards reach the grassroots level and communities most in need.

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- **Public health agencies should strengthen their health equity leadership and adopt strategies and accountability metrics to incorporate equity into preparedness.** Equity must not be considered separate from preparedness activities but must serve as the foundation for a more resilient community. Ensuring equity is central to all preparedness activities and requires integrating equity accountability measures into all elements of emergency response. Before an event occurs, public health and partner organizations—such as schools, agencies on aging, healthcare and behavioral health facilities, homeless service organizations, and community-based organizations—must plan together to identify and plan with communities at higher risk. HHS, CDC, and state, local, tribal, and territorial governments, including health departments, should build up internal infrastructure to drive equity, including by identifying a chief health equity officer who has a leadership role in the emergency operations center and/or incident command structure for all-hazards events and who is engaged in every emergency operation center activation with sufficient resources and authority. Health equity and emergency preparedness officials should work across programs to incorporate equity issues and goals into preparedness policies and plans;[180] to improve staff capacity to understand how the legacies of discrimination, current-day racial trauma, and other structural inequities affect disaster resilience and recovery; develop and disseminate communications materials that are culturally and linguistically tailored; and to collect and leverage data to identify unique community assets and measures of well-being and to advance equity before and during events. All jurisdictions should establish metrics and procedures for ensuring responses are equitable and for addressing inequities as they occur.

RECOMMENDATIONS FOR STATE AND LOCAL GOVERNMENT AND COMMUNITY LEADERS:

- **Plan with communities, not for them, and empower their involvement with resources.** Emergency planners must conduct meaningful engagement, partnerships, and listening efforts as well as ongoing inclusion and local hiring (especially from communities typically at higher risk in disasters) in emergency planning and response. Officials should establish relationships with services and organizations that serve these populations before emergencies take place, and government should fund community leaders and community-based organizations to participate in preparedness efforts. Health departments and emergency management agencies should rely on the expertise, community trust, and networks of those who may bear a disproportionate risk, such as older adults, people with disabilities, and individuals with chronic health conditions to ensure emergency plans, procedures, and evacuation shelters meet the needs of all in the community.

- **Address mental health and substance use gaps, bolster crisis resources, and incorporate mental health first-aid and long-term treatment into disaster response and recovery strategies.** All jurisdictions should assess existing mental health and substance use resources and gaps before the next emergency, strengthen partnerships across sectors, and incorporate these assets into preparedness planning. Policymakers must consider in advance what waivers may be needed to ensure continuity of care for people in treatment. Policymakers should also incorporate behavioral health needs into disaster planning, as required by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act. For additional discussion of strengthening prevention of alcohol, drug, and suicide deaths, see TFAH's *Pain in the Nation* report series.

Priority Area 4: Ensure Effective Leadership and Coordination

Political polarization, interference and threats against public health officials, and contradictory messaging at different points throughout the pandemic has contributed to a wide variation in how individuals and communities have responded. The undermining of public health at all levels has made the nation less secure. At the state level, as of May 2021, 15 legislatures have passed or are considering measures to limit the legal authority of health agencies to protect the public health,[181] and more than 100 of these laws have been approved.[182] These laws could have deadly consequences during COVID-19 and future public health emergencies. At the same time, public health officials at the state and local level have been subjected to threats and career reprisals. More than 500 top health officials have left their positions in the past two years,[183] which will have ramifications beyond the pandemic.

RECOMMENDATIONS FOR FEDERAL, STATE, AND LOCAL GOVERNMENT:

- **Strengthen federal leadership, guidance, and regulatory authorities for public health emergencies.** During the COVID-19 pandemic, authority and decision-making over the response was ceded to states to an unprecedented degree. This diffusion of responsibility meant wide variation in policy and response decisions regarding business closures, mask mandates, testing strategies, and other tactics. CDC must be empowered to lead the public health response during a pandemic and issue clear, feasible guidance and regulations for state, local, tribal, and territorial officials and to the public to minimize variation and public confusion across jurisdictions.
- **Create a COVID-19 commission to examine the pandemic and make recommendations to Congress.** Congress should authorize an independent commission to investigate the preparedness and response to the pandemic and make concrete recommendations for addressing gaps and missteps. A comprehensive, congressionally authorized commission would help inform future policymaking and pandemic preparedness and response. The commission should recommend ways to strengthen public health and healthcare system preparedness, health equity, medical countermeasures, PPE development and deployment, messaging and

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communications, and workforce before the next public health emergency.

- **Rebuild trust in public health agencies and leaders.** The COVID-19 pandemic has damaged faith in federal agencies, including public health agencies such as CDC and FDA. Policy decisions from the federal to the local levels should be based on the best available science, led by public health experts, and free from any real or perceived political interference. The president, the HHS secretary, and the leadership of federal public health and emergency response agencies, including CDC, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Homeland Security, Federal Emergency Management Agency, and FDA, must conduct a thorough review on the independence and performance of these agencies during the pandemic. Federal health agencies need to build capacity for more rapid response during a health emergency. Leaders should establish procedures and policies to ensure the scientific integrity and independence of their agencies, without political interference, and they must identify and correct any errors made during the COVID-19 response. At the same time, elected leaders at all levels must publicly support public health to rebuild confidence in those agencies and officials.

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- **Strengthen public health protections.** Governors and legislatures should reject laws that weaken public health powers, including such basic public health protections as vaccinations and quarantine.
- **Invest in public health communications.** Congress must make a significant investment in effective public health communications, including research into best practices for different audiences. CDC and other federal, state, and local public health agencies should engage with a diverse group of stakeholders to research and test effective public health messaging, translating complicated concepts to a lay audience, using social media, and countering misinformation and disinformation. While the substance of communications should be consistent, messages must acknowledge the historical context of distrust and be linguistically and culturally tailored for different populations, and trusted, nongovernmental messengers should receive funding to help deliver messages.

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Priority Area 5: Accelerate Development and Distribution of Medical Countermeasures

Robust Assistant Secretary for Preparedness and Response (ASPR) coordination of the multi-sector partners of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)[184] could improve medical countermeasure (MCM) development and negate a range of health threats. However, developed drugs or vaccines are only effective if they reach anyone who needs them, when they need them. Medical countermeasures are FDA-regulated products that could be used in the event of a public health emergency, such as vaccines, treatments, drugs, personal protective equipment (PPE) and devices.[185] The challenges faced in distributing scarce medical resources during the pandemic as well as the deployment of COVID-19 vaccine demonstrate the urgency of the right-product/right-time equation. Congress has made significant investments in research and development, but investments must match the size and scope of the threat.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT:

- **Provide significant, long-term funding for the entire MCM enterprise.** The MCM enterprise involves multisector partners that share capabilities such as: research, regulation, manufacturing, surveillance, distribution, dispensing, delivery, stockpiling, training, and monitoring. Long-term coordinated and transparent funding to the Biomedical Advance Research and Development Authority, Strategic National Stockpile, CDC, FDA, National Institutes of Health, and other components of the PHEMCE would offer more certainty to the biotechnology industry and researchers, would strengthen public-private partnerships, and would enable the purchase of ancillary medical supplies, such as PPE. The United States should grow its investment in innovative, flexible technologies and platforms that will enable faster production of products for a range of threats, rather than focusing on products for a single pathogen.[186]
- **Prioritize the distribution and dispensing of MCMs.** It is important that MCMs reach the right person at the right time during emergencies; the challenges in mass vaccination were predicted by CDC's MCM Operational Readiness Review.[187,188] HHS, along with state, local, tribal, and territorial health departments should be properly resourced and require integration of private-sector healthcare supply distributors and supply-chain partners into planning, exercises, and emergency responses to better leverage existing systems and resources. Once the COVID-19 vaccination campaign is complete, HHS should assess and address gaps in vaccine development, procurement, maintenance, deployment, and equitable administration.

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- **Clarify and strengthen PHEMCE leadership of MCM and supply-chain management for emergencies.** HHS should reinvigorate interagency PHEMCE coordination,[189] including regular interagency meetings; engagement with private-sector supply-chain partners; and improved transparency and communication with state, local, tribal, and territorial agencies and collaborative long-term planning and evaluation. These agencies should be included in planning and decision-making. HHS should take steps to minimize political interference with its decision-making and ensure transparency and communication with stakeholders. The HHS Secretary and ASPR should leverage its advisory board for strategic and policy advice. Federal agencies should also explore all available authorities, such as through the Defense Production Act, and communicate strategies with stakeholders to bolster the supply chain during emergencies. HHS should clarify roles and responsibilities for supply-chain management, in consultation with private-sector and public health partners, and should develop and disseminate best practices for supply management.[190]

RECOMMENDATIONS FOR FEDERAL, STATE, AND LOCAL GOVERNMENTS AND PARTNERS:

- **Improve MCM guidance and communications for groups at higher risk during an event.** HHS, including CDC, should consult with experts and work with healthcare professionals and state, local, and tribal public health partners to develop standardized guidance for dispensing MCMs to groups such as children, pregnant women, older adults, people with disabilities, and people who are homebound. And HHS and state, local, and tribal agencies should work with organizations that reach the public, especially communities at disproportionate risk—such as groups representing older adults, people with disabilities, and limited-English-proficient communities—to improve communications around MCM issues before an event. Communities need to be engaged before an outbreak or event to ensure their understanding of the risks, benefits, and distribution challenges of introducing a medical product to a large portion of the population and ultimately improving acceptance and access to MCMs. It is important to provide clear and accurate guidance to the public in multiple formats and languages, via trusted sources and multiple communications channels, including formats that are accessible to people with low literacy and hearing or vision loss.

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Priority Area 6: Ready the Healthcare System to Respond and Recover

Access to healthcare is a critical component of a resilient population and effective emergency response. In addition to harming day-to-day health of Americans, the Global Health Security Index found that failure to guarantee Americans' access to healthcare hurts the nation's ability to rapidly contain an outbreak.[191] The pandemic has illustrated the way compounding crises—including COVID-19 infections, delays in prevention and treatment of other health conditions, natural disasters, and a severe mental health burden among healthcare workers and the public—can strain the healthcare system beyond its level of preparedness. For several years, TFAH has warned that medical surge capacity for a pandemic remained a major gap in the nation's preparedness. This gap has been evident throughout the healthcare delivery system, from outpatient settings to long-term care to acute care hospitals, with troubling impacts on patients' outcomes.[192] In some areas, healthcare coalitions supported by the national HPP served a critical role in allocating resources, such as PPE and ventilators.[193,194] However, overstretched facilities, exhausted workforces, disruptions in the supply chain, interruptions in primary and preventive care, and lack of information-sharing and situational awareness have been among the significant challenges to the nation's healthcare system during the pandemic. There was also wide variation in implementation of crisis standards of care, with some states providing very little information to providers about legal and clinical issues when making triage decisions. The NHSPI has consistently found that healthcare delivery readiness scores are lowest among preparedness domains, with little progress in the past five years.[195] Policymakers need to strengthen existing systems and consider long-term mechanisms to create sustainable healthcare readiness across systems and geographic borders.

RECOMMENDATIONS FOR FEDERAL GOVERNMENT AND HEALTHCARE:

- **Strengthen the Hospital Preparedness Program and fund regional coordination.** HPP can help build strong healthcare coalitions capable of engaging and supporting members during disaster responses, but the program has been severely underfunded. Congress must provide more robust annual funding—which it has cut in half over the past decade. HHS should assess the role of HPP in the COVID-19 response and address funding gaps in the program.[196] HHS and the recipients should ensure healthcare leaders take the lead on HPP planning and implementation to the extent possible, with support and coordination from public health, emergency management, and others, and recipients should ensure as much funding as possible is reaching healthcare coalitions. Healthcare administrators should ensure their facilities have tools and support for meaningful participation in healthcare coalitions, including the ability to share information and resources across the coalition and with public health agencies. Congress should provide additional funding to the Regional Disaster Health Response System to coordinate across coalitions and states,[197] to map specialized disaster care (such as burn or pediatric care) across the country, and to leverage those assets in a coordinated way.[198]
- **Create incentives and ramifications to build sustainable preparedness and surge capacity across healthcare systems.** The shortages of beds, healthcare personnel, and equipment during the pandemic underscores the need for cooperation among healthcare entities, across systems, and across geographic borders. Although there has been progress in developing healthcare coalitions in many regions and progress in meeting CMS and other accreditation preparedness standards by individual healthcare facilities, these existing mechanisms have not provided enough incentive for many healthcare facilities to create meaningful surge capacity and cooperation across competing entities.

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In addition to strengthening existing systems, Congress and HHS should consider long-term sustainability for building healthcare readiness across the system, including meaningful incentives and disincentives, such as:

- An external self-regulatory body, in alignment with federal policy goals, could set, validate, and enforce standards for healthcare facility readiness, stratified by facility type, with authority for financial ramifications.[199]
- Payment incentives could sustain preparedness, surge capacity, regional disaster partnerships, and reward facilities that maintain specialized disaster care.

- **Expand access to healthcare.** Access to healthcare is always important for promoting health and well-being and particularly so during a pandemic or disaster. Federal and state governments must ensure every person has access to healthcare, including robust insurance coverage. Millions of Americans still lack insurance coverage, and disparities by race, ethnicity, sexual or gender identity, disability status, and other factors have been exacerbated by the pandemic-related job loss.[200] Congress and the Administration should strengthen incentives for states to expand Medicaid, make marketplace overage more affordable, and improve outreach and marketing for enrollment.[201]

- **Assess impact of CMS Preparedness Standards and improve transparency.** An external review by the Government Accountability Office or a similar entity should assess how CMS preparedness standards have affected overall healthcare readiness, and HHS should begin tracking progress on preparedness measures over time. CMS should also strengthen preparedness standards by adding medical surge capacity and other capabilities, including infection prevention and control, stratified by facility type, as a necessary requirement within the next iteration of the rule.[202]

RECOMMENDATIONS FOR STATE GOVERNMENT AND HEALTHCARE:

- **Integrate healthcare delivery into emergency preparedness and response.** Jurisdictions should continue and increase engagement and integration of the healthcare sector into emergency planning and responses, including plugging healthcare coalitions and other entities representing private healthcare and the healthcare supply chain into emergency planning and response and incident command. Health systems, healthcare coalitions, and public health should develop memoranda of understanding ahead of disasters to improve situational awareness across healthcare and to enable movement of patients, personnel, and supplies. Private-sector healthcare leadership should prioritize preparedness moving forward, including training and workforce protections, surveillance for emerging threats, stockpiling of supplies ahead of disasters, and full engagement in regional collaborations and coalitions.

- **Strengthen state policies regarding disaster healthcare delivery.** States should review credentialing standards to ensure healthcare facilities can call on providers from outside their states, and health systems should ensure they can receive outside providers quickly during a surge response. States should also adopt policies that promote healthcare readiness and ease the ability to surge care and services, such as the NLC, the Interstate Medical License Compact, the Recognition of EMS Personnel Licensure Interstate CompAct,[203] the Uniform Emergency Volunteer Health Practitioners Act,[204] emergency prescription refill laws and protocols, and implementation and education of providers regarding crisis standards of care guidelines.[205,206] State and healthcare leaders must take crisis standards of care planning and implementation seriously and ensure transparency for healthcare providers who must make decisions in constrained conditions. Jurisdictions must ensure equitable application of crisis standards of care so as not to create or exacerbate disparities.

Priority Area 7: Prepare for Environmental Threats and Extreme Weather

Climate change, environmental hazards, and extreme weather pose serious and growing threats to human health. According to a December 2020 report by TFAH and the Johns Hopkins Bloomberg School of Public Health, many of the states most at risk from climate change are also the least ready to deal with it. Environmental health involves detecting and protecting communities from hazardous conditions in air, water, food, and other settings, and it is therefore a critical component of the nation's health security. Environmental hazards like climate change and pollution impact communities differently and exacerbate disparities. People living in poverty, people of color, people with underlying health conditions or disabilities, and children and older people are all at higher risk for exposure to and impacts from environmental threats.[207,208,209]

RECOMMENDATIONS FOR FEDERAL AND STATE GOVERNMENT:

- **Enact legislation requiring a national strategic plan.** The United States urgently needs a strategic action plan to address the health impacts of climate change. Policymakers should enact legislation requiring HHS to develop such a plan and to fund development and ongoing maintenance of health system capacity specifically for this purpose.
- **Support climate and health, environmental health equity and environmental justice efforts.** Congress should fund the HHS Office of Climate Change and Health Equity[210] to expand its work to address the health effects of climate change, especially on those who are experiencing higher risks.
- **Support public health climate-adaptation efforts.** Funding for CDC's Climate and Health program stands at $10 million per year, while the annual health costs of climate change events were estimated to be more than $14 billion in 2008.[211] Climate-informed health interventions include identifying likely climate impacts, potential health effects associated with these impacts, and the most at-risk populations and locations.[212] Congress should increase funding for environmental health programs, including CDC's Climate and Health program and the National Environmental Public Health Tracking Network to conduct surveillance and target interventions.
- **Develop sustainable state and local vector-control programs.** As the threat and geographic distribution of mosquitos, ticks, and other vectors changes, Congress should expand funding for the vector-borne disease program at CDC to support state and local capacity to prevent and detect vector-borne diseases, such as Zika, West Nile Virus, and Lyme disease.
- **Guarantee clean water for all U.S. residents, including after disasters.** The Administration and Congress should restore the Clean Water Rule, which includes measures to protect a safe water supply, such as addressing the ongoing problem of lead, per- and polyfluoroalkyl substances, and algal toxins in drinking water; taking steps to reduce the potential for waterborne illnesses; and increasing protection against potential acts of terrorism on America's drinking and agricultural water systems. All states should include water security and wastewater management in their preparedness plans, and they should build relationships among health departments and local environmental and water agencies. CDC should include national guidance and metrics for planning for a range of water-related crises.

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RECOMMENDATIONS FOR STATE GOVERNMENT:

- **Every state should have a comprehensive climate vulnerability assessment and adaptation plan that incorporates public health.** Public health and environmental agencies should work together to track concerns, coordinate risk-management and communications, and prioritize necessary capabilities to reduce and address threats. States and localities should investigate what additional capacities are necessary and identify vulnerable populations and communities. State and local public health officials should incorporate environmental health into emergency operations planning and incident command.

- **Complete all steps of CDC's Building Resilience Against Climate Effects, or "BRACE," framework, and continuously work to enhance and refine preparations for climate change.** State agencies must conduct and facilitate rigorous vulnerability assessments at the state and local levels. The assessments should focus especially on populations at highest risk and the health threats most pertinent to them. States must also push ahead to complete all steps of the framework, including identifying and implementing evidence-based interventions to protect residents. Finally, as agencies implement interventions, they should continually evaluate effectiveness and strive for quality improvement.

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Year in Review: Overview of 2021's Major Public Health Emergencies, Threats, and Reports

Infectious Disease Outbreaks and Control

COVID-19 PANDEMIC

COVID-19 deaths

Deaths due to the COVID-19 pandemic neared 6 million globally and surpassed 900,000 in the United States as this report was being prepared for publication.[213]

In December 2020 and through spring 2021, COVID-19 was the leading cause of death in the United States, surpassing cancer and heart disease.[214] The impact of the COVID-19 vaccine being widely available was perhaps most noticeable in July as pandemic related deaths dropped to the seventh leading cause of death in the United States. But the Delta variant caused cases, hospitalizations, and deaths to increase in the late summer and fall.[215] In early December, the first U.S. case of an infection due to the Omicron variant was reported.[216] By the end of the month, COVID-19 infections were surging in many parts of the country further stressing the healthcare system.

Throughout the pandemic, communities of color were disproportionately affected in large part due to the ways in which structural racism contributes to underlying health inequities, as well as access to healthcare and COVID-19 services. According to CDC, as of November 2021, nationwide American Indians and Alaska Natives died at a rate that was 2.2 times higher than whites. Hispanic and Latino people died at a rate that was 2.1 times higher than whites. Black people died from COVID-19 at a rate that was 1.9 times higher than the rates of deaths among whites. Asian Americans died at a rate that was 0.9 times higher than whites.[217] [218]

The majority of COVID-19 deaths in the summer and fall of 2021 were in people who had not been vaccinated.[219]

Disruptions to other healthcare delivery; impact on life expectancy

According to WHO, prevention and treatment for noncommunicable diseases, including cancer and heart disease, were "severely disrupted" during the pandemic.[220] A study published in PubMed, found that in Canada, COVID-19 caused "significant healthcare service disruptions" that the authors believed could have led to delayed diagnoses and increased mortality.[221]

In December 2021, CDC released new data showing that U.S. life expectancy decreased by 1.8 years in 2020 to 77.[222]

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Vaccines and treatments

In December 2020, two vaccines, one manufactured by Pfizer-BioNTech and the other by Moderna, received emergency-use authorization from FDA. In February, a vaccine manufactured by the Johnson & Johnson Company received its emergency-use authorization. The Pfizer and Moderna vaccines are two-shot doses, the J&J vaccine a one-shot dose. The vaccines were initially made available for healthcare workers, people living and working in long-term care facilities, and other emergency responders. Availability then opened to older adults and people at heightened risk due to underlying medical conditions, and then opened to a phased approach by age. By year's end, the vaccine was recommended for everyone ages 5 and older.

On August 23, FDA issued full approval to the Pfizer-BioNtech COVID-19 vaccine, now known as Comirnaty, for people 16 years of age and older.[223] The vaccine continues to be administered for people 5 to 15 years of age under the emergency-use authorization.

By the fall, as the Delta variant caused cases, hospitalizations, and deaths to increase, booster doses of the vaccine were recommended for all adults ages 18 and older. In December, the Delta variant remained the cause of most new infections, and the Omicron variant was being studied.[224] Early data suggested that Omicron was highly contagious but might cause less serious illness.[225]

At year's end, 71 percent of the U.S. population had received at least one dose of a COVID vaccine, and 62 percent were fully vaccinated.[226] As this report was being prepared, the United States ranked 58th out of 180 countries worldwide for vaccination rate.[227] Native Hawaiian and Pacific Islanders had the highest fully vaccinated rate among all race/ethnic groups at 74.3 percent, 55 percent of the American Indian/Alaska Native population were fully vaccinated, 48 percent of Asian Americans were fully vaccinated, 45 percent of Hispanic Americans were fully vaccinated, 42 percent of the white population were fully vaccinated, and 36 percent of Black Americans were fully vaccinated.[228] In addition, vaccination rates were lagging in rural communities. According to CDC data reported in May 2021, 38.9 percent of residents in rural communities were vaccinated, while 45.7 percent of residents in urban communities were vaccinated.[229] By year's end, thanks to concerted efforts by the Biden Administration, states, and stakeholder groups, the gap between vaccination rates among population groups had narrowed.[230]

During the year, COVID-19 treatments in the form of monoclonal antibodies treatments were developed, and by January 2022, four were approved for emergency use by FDA.[231] Monoclonal antibodies treatments work by mimicking a person's immune system function to block the COVID-19 virus from entering cells or to help clear cells already infected.[232] These treatments lessen symptoms and speed recovery.

Editor's note: On January 25, 2022, the FDA stopped use of two COVID-19 antibody treatments, drugs manufactured by Regeneron and Eli Lilly, because they weren't effective against the Omicron variant. If the drugs prove effective against additional variants their use could be reauthorized, FDA said.[233]

COVID-19 and trends in deaths of despair

The COVID-19 pandemic had well-documented impacts on Americans' physical health and economic security. The pandemic also had significant impacts on mental health leading to increases in mental health distress, substance misuse, drug overdoses, and, in some population groups, an increase in suicide.[234] While one report found a tripling of reported symptoms of anxiety or depression in American adults between March 2020 and March 2021,[235] a February 2021 Milliman report found reduced utilization of mental and behavioral healthcare during 2020.[236]

Provisional data from CDC shows a rapid increase in drug overdose deaths since the beginning of the pandemic. Data from May 2020 through April 2021 shows 97,990 drug overdoses deaths compared with 77,007 between May 2019 and April 2020.[237]

According to the December 2021 U.S. Surgeon General's advisory, *Protecting Youth Mental Health*, rates of depression and anxiety among youths doubled during the pandemic, with 25 percent of youths reporting that they were experiencing depressive symptoms and 20 percent reporting they were experiencing anxiety. Compared with 2019, emergency room visits for suspected suicide attempts rose 51 percent for adolescent girls in early 2021. For boys, the rate of suspected suicide attempts rose by 4 percent.[238]

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Antimicrobial Resistance

According to CDC, more than 2.8 million antibiotic-resistant infections occur in the United States annually, leading to about 35,000 deaths.[239] In December, CDC announced two new programs and $22 million in awards funding to identify and prevent antimicrobial-resistant infections: The Global Action in Healthcare Network and the Global Antimicrobial Resistance Laboratory and Response Network.[240]

Childhood Immunizations

According to CDC data released in October 2021, routine vaccination among children remained high between 2018–2020. According to the latest National Immunization Survey-Child (NIS-Child), during 2018–2020, over 90 percent of children were fully vaccinated against measles, mumps, and rubella, polio, hepatitis B, and varicella by age 24 months. However, there are disparities in vaccination coverage based on health insurance status, race/ethnicity, poverty level, and jurisdiction, and the COVID-19 pandemic may increase these disparities.[241]

Foodborne Illness

During 2021, CDC and FDA released advisories concerning foodborne illness associated with soft cheeses (listeria and salmonella), alkaline water (non-viral hepatitis illness), shrimp and other seafood (salmonella), salad (salmonella and listeria), onions (salmonella), and spinach (e-coli).[242] In December, FDA released a Foodborne Outbreak Response Improvement Plan to modernize the agency's response to foodborne disease.[243]

Hepatitis A

Since outbreaks of hepatitis A were first identified in 2016, 43,084 cases have been reported in 37 states. People in the highest-risk category for contracting hepatitis A virus infection are people who use drugs, people experiencing unstable housing or homelessness, men who have sex with men, people who are currently or were recently incarcerated, and people with chronic liver disease including cirrhosis and hepatitis B and C.[244]

HIV/AIDS

An estimated 37.7 million people are living with HIV across the globe, over two-thirds of whom live in Africa. The majority of all new infections occurred in sub-Saharan Africa. In 2020, an estimated 680,000 people worldwide died due to HIV/AIDS.[245] In 2019, there were approximately 1.2 million people living with HIV in the United States and approximately 34,800 new infections in the United States, an 8 percent decrease in the infection rate since 2015.[246] People living with HIV experienced more severe outcomes and have higher comorbidities from COVID-19 than most people without HIV.[247]

Lyme Disease

Lyme Disease is the most common vector-borne disease in the United States. It is transmitted to humans through bites of blacklegged ticks. CDC estimates that approximately 476,000 people in the United States are diagnosed and treated for Lyme Disease annually.[248]

Measles.

Measles outbreaks, United States. In 2021, U.S. measles cases remained relatively low: 49 measles cases reported by five jurisdictions as of January 3, 2022. Although this is an increase from the 13 individual measles cases confirmed in 2020, the number of reported cases is still well below the 1,282 cases of measles in 2019. Measles is a highly contagious disease; outbreaks in the United States have been linked to sustained spread in U.S. communities, with pockets of unvaccinated people and/or an increase in the number of travelers who get measles abroad.[249]

Measles outbreaks, global. WHO reported that during 2019, there were more measles cases reported worldwide than in any year since 1996: 869,770 confirmed cases, leading to an estimated 207,500 deaths. The number of confirmed cases worldwide in 2020 and 2021 was much lower, although Nigeria, Pakistan, and Somalia reported high numbers and there were ongoing outbreaks in several other nations.

Almost 41 countries paused or considered pausing their measles campaigns for 2020 or 2021 due to the COVID-19 pandemic, which increases the risk of bigger outbreaks around the world and in the United States.[250] New data showed that 22 million children worldwide missed their first measles vaccine during 2020 and just 70 percent of children who were due for their second vaccination shot in 2021 received it. WHO and CDC officials are concerned that these low vaccination rates could lead to a global measles outbreak.[251]

Malaria Control and Prevention

According to a March 2021 CDC report, approximately 2,000 cases of malaria are diagnosed in the United States each year, reaching a high of 2,161 cases in 2017. Worldwide, the 2017 data continues a decades-long increase in malaria cases. The disease remains endemic in many countries, and global travel increases its spread.[252]

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Polio

The United States continues to be polio (poliovirus) free (no cases have originated in the United States) thanks to the polio vaccine.[253] However, polio continues to be a threat in some countries, including Afghanistan, Pakistan, China, Iran, and numerous African nations.[254]

Seasonal Flu

Season influenza cases and deaths were sharply down during the 2020–2021 flu season, likely due to the public health measures in place to combat COVID-19. Estimates suggest influenza vaccination during the 2021–2022 season was similar to the prior year, with a record number of influenza vaccines (193.8 million doses) distributed. However, at the time this report was being produced (winter 2022), influenza surveillance was showing the return of influenza activity, which was expected to continue to increase.[255]

Tuberculosis

WHO revealed in October that for the first time in over a decade, tuberculosis (TB) deaths had increased worldwide, with fewer people being diagnosed and treated and more deaths, due to the impact of the global pandemic on prevention and treatment efforts.[256] Kenya is one of the 30 countries with the majority (at least 83 percent) of TB cases. Last year, an estimated 140,000 people in Kenya were estimated to have TB, according to the country's Ministry of Health. COVID-19 also meant that the number of people with TB who go undetected increased. Nearly half of people with TB in Kenya last year were likely to have missed out on diagnosis and treatment. An estimated 15 percent reduction in case finding was "largely attributable to the pandemic," according to the Ministry of Health's national tuberculosis, leprosy, and lung disease program annual report.[257]

West Nile Virus

West Nile Virus is the leading cause of mosquito-borne disease in the United States. There were 2,695 reported cases of West Nile Virus in 2021, the majority of those (1,645) in Arizona.[258]

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Severe Weather and Natural Disasters

Drought Conditions

Nine states: California, Arizona, Nevada, Oregon, Washington, Idaho, Utah, Montana, and North Dakota experienced severe drought conditions during 2021. In October, 52 percent of the western states' land area was classified as experiencing extreme or exceptional drought.[259]

Most of California experienced extreme drought conditions throughout 2021, and May and June were the state's warmest months on record since 1896. The state's water shortages have been called "immediate and dire" by state officials, and water-use limitations have been imposed. Capacity of numerous critical water sources, such as Lake Oroville, the Sacramento-Sand Joaquin Delta, and the Russian River, are at greatly reduced capacity.[260]

Extreme Heat

A June heatwave broke all-time records for high temperatures across the western United States with multiple days of 100-plus-degree weather in many places. Between June 15–20, all-time-high temperatures were recorded in seven states: California, Arizona, New Mexico, Utah, Colorado, Wyoming, and Montana.[261]

High heat, drought, and increased risk for wildfires are strongly interrelated.

Flooding

By September, 116 people had died due to flooding in the United States, the highest number since 2017. Hurricane Ida caused extensive damage as it made landfall in Louisiana and tracked its way up the East Coast, including with deaths in Tennessee, New Jersey, New York City, Pennsylvania, and Connecticut. Additional deaths associated with other storms occurred in Arizona (10 deaths), New Mexico (six deaths), and Texas (six deaths).[262]

Hurricanes

The 2021 Atlantic hurricane season counted 21 named storms, including seven hurricanes. 2021 was the third most active hurricane year for named storms and was the sixth consecutive above-normal Atlantic hurricane season.[263]

Hurricane Ida made landfall in Louisiana in August 2021 as a Category 4 storm. It was the second most damaging hurricane to make landfall in the state. As of September 2021, a total of 115 deaths had been associated with Ida, including 95 in the United States. The storm caused approximately $65 billion in property damage.[264]

Tornadoes

During 2021, 1,376 tornados were reported, causing 101 deaths. The reported number of storms in 2020 was 1,075.[265]

On December 11 and 12, a massive storm spurned 41 tornados, including at the EF-3 and EF-2 levels, across eight states reaching from Mississippi to Illinois. Kentucky was hardest hit with whole communities leveled. December tornados are highly unusual, and the number and strength of these twisters was unprecedented. In Kentucky, one twister traveled over 200 miles destroying virtually everything in its path. In total, the tornados caused 90 deaths in five states, including 77 in Kentucky.[266]

Wildfires

In August, more than 100 wildfires were burning throughout the western United States with more than a dozen burning in northern California. Climate researchers believe that higher temperatures are increasing the length of the fire season and the number of places where wildfires can happen.[267]

The Dixie Fire, which burned in Northern California throughout the summer, was the second largest in the state's history and burned nearly 1 million acres.[268]

The Caldor Fire burned nearly 222,000 areas across three California counties: El Dorado, Amador, and Alpine. It burned for 67 days starting in mid-August and destroyed over 1,000 structures.[269]

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Reports, Risk Assessment Tools, and Convenings

The National Risk Index released in January 2021, is an online tool created by the Federal Emergency Management Agency to identify communities most at risk for 18 natural hazards.[270]

In April, the Group of Friends on Tackling AMR released a Call to Action on Antimicrobial Resilience (AMR) 2021. The call to action calls demands a strengthened global effort to decrease AMR through increased research and investment and improved antimicrobial stewardship. As of December 2021, 113 member states were signatories to the Call to Action, including the United States.[271]

In October, the de Beaumont Foundation and the Public Health National Center for Innovations, a division of the Public Health Accreditation Board, released a brief, Staffing up: Investing to improve public health services and protections, which reported that public health departments need an increase in full-time staff members of about 80 precent to meet their communities' basic public health needs. According to the brief, the staffing gap has been created by years of budget cuts.[272]

Also in October, the Global Health Security Agenda Annual Report, *Strengthening Health Security Across the Globe: Progress and Impact of United States Government Investments in the Global Health Security Agenda,* was released. The report details the U.S. government's impact in helping countries across the world build their health security capacity.[273]

In August and October, TFAH released a two-part case studies series as a follow-up to its December 2020 report *Climate Change & Health: Assessing State Preparedness* produced with the Johns Hopkins Bloomberg School of Public Health. The case-studies series identifies and reports on states and localities' efforts to implement climate change adaptation strategies that center on equity. The first case study features programs that advance procedural equity in climate adaptation. The second in the series features programs that advance distributional equity in climate adaptation.

In October, the Bipartisan Commission on Biodefense released its report *Saving Sisyphus: Advanced Biodetection for the 21st Century.* The report, released 20 years after the 2001 anthrax attacks, detailed "critical failures" in the nation's bio-detection program and makes recommendations for congressional action.[274]

The National Commission to Transform Public Health Data Systems, created by the Robert Wood Johnson Foundation, was established to review how public health data is collected, shared, and used and to make recommendations to ensure that such data is comprehensive and creates a blueprint for health equity. Among the recommendations included in its October 2021 report was to ensure the public health measurement captures and addresses structural racism and other inequities.[275]

In November, the Biden Administration's COVID-19 Health Equity Task Force released its report, including recommendations to the President for mitigating the health inequities caused by or exacerbated by the pandemic.[276] (See side bar on pg. 14.)

The Bipartisan Policy Center's December 2021 report *Public Health Forward: Modernizing the U.S Public Health System* described the ways the COVID-19 pandemic exposed weaknesses in the nation's public health system and pervasive disparities that affect Americans' health. The report outlined a five-year vision and action framework for how states, territorial, and local elected and public health officials can strengthen their jurisdiction's public health infrastructure.[277]

2021 Global Health Security Index, released in December, reported that no country is better prepared to respond to pandemics and epidemics than they were in 2019, the year of the initial index report. The Index, produced by NTI and the Johns Hopkins Bloomberg School of Public Health Center for Health Security, found that 90 percent of all countries worldwide had no plan for distributing vaccines or medications during an emergency, and 70 percent lack the amount of healthcare capacity that would be needed in an emergency. The United States ranked first in the index with a score of 75.9 out of 100, but the report found that high levels of mistrust in government hampered the U.S. pandemic response.[278]

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Appendix B: Methodology

TFAH made major refinements to its methodology for *Ready or Not* in 2018. For more information, see the 2019 edition of the series, Appendix A: Methodology.[279]

To meet TFAH's criteria, each indicator must be:

- **Significant.** The indicator needed to be a meaningful measure of states' public health emergency preparedness. The NHSPI first measured significance by using a multistage Delphi process with a panel of experts and then again by TFAH through interviews with additional experts.
- **Broadly relevant and accessible.** The indicator needed to be relevant—and timely data needed to be accessible—for every state and the District of Columbia.
- **Timely.** Data for the indicator needed to be updated regularly.
- **Scientifically valid.** Data supporting the indicator needed to be credible and rigorously constructed.
- **Nonpartisan.** The indicator, and data supporting the indicator, could not be rooted in or seen as rooted in any political goals.

Using these criteria, TFAH aims to select a broad set of actionable indicators with which it—and other stakeholders, including states themselves—can continue to track states' progress. (Complete data were not available for U.S. territories.) TFAH will strive to retain most of these indicators for multiple years to assist states in tracking their progress against each measure.

TFAH seeks measures that are incorporated in the NHSPI and that most closely meet TFAH's criteria. There is one exception: a measure of state public health funding-level trends that the NHSPI does not track.

Indicator Data Collection

The NHSPI provided TFAH with data for every indicator except five (those data tied to the NLC, public health funding, flu vaccination, hospital patient safety, and laboratory surge capacity). In cases where newer data were available than those modeled in the 2021 edition of the NHSPI, TFAH collected and verified figures from their original sources.

Public Health Funding Data Collection and Verification

To collect public health funding data for this report, TFAH surveyed state officials. Informed by the Public Health Activities and Services Tracking project at the University of Washington, TFAH defines public health programming and services as inclusive of communicable disease control; chronic disease prevention; injury prevention; environmental public health; maternal, child, and family health; and access to and linkage with clinical care. Specifically, this definition includes:

- **Communicable disease control.** Public health services related to communicable disease epidemiology, hepatitis, HIV/AIDS, immunization, sexually transmitted diseases, tuberculosis, etc.

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- **Chronic disease prevention.** Public health services related to asthma, cancer, cardiovascular disease, diabetes, obesity, tobacco, etc.
- **Injury prevention.** Public health services related to firearms, motor vehicles, occupational injuries, senior falls prevention, substance-use disorder, other intentional and unintentional injuries, etc.
- **Environmental public health.** Public health services related to air and water quality, fish and shellfish, food safety, hazardous substances and sites, lead, onsite wastewater, solid and hazardous waste, zoonotic diseases, etc.
- **Maternal, child, and family health.** Public health services related to the coordination of services; direct service; family planning; newborn screening; population-based maternal, child, and family health; supplemental nutrition; etc.
- **Access to and linkage with clinical care.** Public health services related to beneficiary eligibility determination, provider or facility licensing, etc.

TFAH excludes from its definition insurance coverage programs, such as Medicaid or the Children's Health Insurance Program, as well as inpatient clinical facilities.

TFAH, under the guidance of state respondents, revised data for the base year. (In this report, that was FY 2020.) For some states, this was necessary to improve comparability between the two years when a reorganization of departmental responsibilities had occurred over the period.

All states and the District of Columbia verified earlier funding data and provided new funding data, with five exceptions: Delaware, Kansas, Rhode Island, Utah, and West Virginia.

Scoring and Tier Placements

TFAH grouped states based on their performances across the 10 indicators, and TFAH gave partial credit for some indicators to draw finer distinctions among states and within states over time. TFAH placed states into three tiers—high tier, middle tier, and low tier—based on their relative performance across the indicators.

Specifically, TFAH scored each indicator as follows:

- Adoption of the NLC: 0.5 point. No adoption: 0 points.
- Percent of the state's population served by a comprehensive public health system, as determined through administration of the National Longitudinal Survey of Public Health Systems.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - More than one standard deviation below the mean: 0.25 point.
  - A score of .625—halfway between .25 point and 1 point—was assigned to Hawaii and Rhode Island, for which data were not available.
- Accreditation by the PHAB: 0.5 point. Not accredited: 0 points.
- Accreditation by the EMAP: 0.5 point. Not accredited: 0 points.
- Size of state public health budget compared with the past year (nominally, not inflation-adjusted).
  - No change or funding increase: 0.5 point.
  - Funding decrease: 0 points.
  - A score of .25—halfway between 0 points and .5 point—was assigned to Delaware, Kansas, Rhode Island, Utah, and West Virginia, which were not able to provide data for FY 2021.
- Percent of population who used a community water system that failed to meet all applicable health-based standards: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - Within one standard deviation above the mean (and states with 0 percent of residents who used a noncompliant community system): 1 point.
  - Within one standard deviation below the mean: 0.75 point.
  - Between one and two standard deviations below the mean: 0.5 point.
  - Between two and three standard deviations below the mean: 0.25 point.
  - More than three standard deviations below the mean: 0 points.
- Percent of employed population who used paid time off in March 2020: TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - More than one standard deviation below the mean: 0.25 point.
- Percent of people ages 6 months or older who received a seasonal flu vaccination: TFAH scored states according to the number of standard deviations above or below the mean of state results.

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- More than one standard deviation above the mean: 1 point.
- Within one standard deviation above the mean: 0.75 point.
- Within one standard deviation below the mean: 0.5 point.
- More than one standard deviation below the mean: 0.25 point.

- Percent of hospitals with a top-quality ranking ("A" grade) on the Leapfrog Hospital Safety Grade. TFAH scored states according to the number of standard deviations above or below the mean of state results.
  - More than one standard deviation above the mean: 1 point.
  - Within one standard deviation above the mean: 0.75 point.
  - Within one standard deviation below the mean: 0.5 point.
  - Positive number, more than one standard deviation below the mean: 0.25 point.
  - No hospitals with a top-quality ranking ("A" grade): 0 points.
- Public health laboratory has a plan for a six- to eight-week surge in testing capacity: 0.5 point. Did not report having a plan: 0 points.

The highest possible score a state could receive was 7.5 points.

TFAH placed states whose scores ranked among the top 17 in the high-performance tier. TFAH placed states whose scores ranked between the 18th-highest and 34th-highest in the middle tier. TFAH placed states with scores ranked between the 35th-highest and 51st-highest in the low-performance tier. (Ties in states' scores can prevent an even distribution across the tiers.)

This year, states in the high tier had scores ranging from 5.75 to 6.75; states in the middle tier had scores ranging from 5 to 5.625; and states in the low tier had scores ranking from 3.25 to 4.75.

Assuring data quality

TFAH conducted several rigorous phases of quality assurance to strengthen the integrity of the data and to improve and deepen TFAH's understanding of states' performance, especially that of outliers on specific indicators. During collection of state public health funding data, researchers systematically inspected every verified data file to identify incomplete responses, inconsistencies, and apparent data entry errors. Following this inspection, TFAH contacted respondents and gave them the opportunity to complete or correct their funding data.

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New Report: Fewer States Placed in Top Performance Tier for Public Health Preparedness in 2021

COVID-19 Pandemic Continues to Illustrate the Critical Need to Invest in Public Health Infrastructure and the Social Determinants of Health

(Washington, DC – March 10, 2022) – As the nation enters its third year of the COVID-19 pandemic, a new report calls for urgent investment to create a public health system able to protect all Americans' health during emergencies. The report, released today by Trust for America's Health, measures states' performance on 10 key emergency preparedness indicators and identifies gaps in states' readiness to respond to emergencies. The report includes policy recommendations for strengthening the nation's health security.

The report, *Ready or Not 2022: Protecting the Public's Health from Diseases, Disasters and Bioterrorism,* measures states' degree of preparedness to respond to a wide spectrum of health emergencies and to provide ongoing public health services, including disease surveillance, seasonal flu vaccination, safe water, and expanded healthcare services during emergencies. It tiers states and the District of Columbia into three performance levels: high, middle and low, placing **17 states and DC in the high-performance tier, 20 states in the middle performance tier, and 13 states in the low performance tier.** The 2021 report placed, 20 states and the District of Columbia in the high-performance tier.

States' Performance by Tiers

Performance Tier	States	Number of States
High Tier	AL, CO, CT, DC, FL, IL, IA, KS, MD, MA, NJ, OH, PA, SC, UT, VA, VT, WA	17 states and DC
Middle Tier	AZ, CA, DE, GA, ID, ME, MI, MO, MS, NE, NH, NM, NY, NC, ND, OK, RI, TN, TX, WI	20 states
Low Tier	AK, AR, HI, IN, KY, LA, MN, MT, NV, OR, SD, WV, WY	13 states

This year’s report found that 12 states improved their performance while 16 states slipped in their ranking. All states’ performance is relative to that of other states.

Three states, Ohio, Pennsylvania and South Carolina, improved their performance by two tiers.

Nine states improved by one tier: Alabama, Arizona, Florida, Illinois, Iowa, Missouri, New Hampshire, New Jersey, and New York.

Sixteen states fell one tier: Delaware, Georgia, Idaho, Kentucky, Louisiana, Maine, Minnesota, Mississippi, Montana, Nebraska, New Mexico, North Carolina, Oklahoma, Oregon, Rhode Island, and Wisconsin.

In addition, the report found:

- A majority of states had plans in place to expand healthcare and public health laboratory capabilities in an emergency.
- Most states are accredited in the areas of public health, emergency management or both.
- A large majority of Americans who receive their household water through a community water system had access to safe water.
- Only about half of the U.S. population is served by a comprehensive local public health system.
- Seasonal flu vaccination rates have risen significantly in recent years but are still lower than the goal set by *Healthy People 2030*.
- Just over half of workers used some kind of paid time-off in a one-month sample. The need for paid time off has become particularly apparent during the pandemic, as many workers became ill or needed to care for a sick family member.
- Only 28 percent of hospitals, on average, earned a top-quality patient safety grade during the year, down from 31 percent the year prior.

"The major takeaway of this report is that underinvestment in the nation's public health system, and attacks on its authority, have had deadly consequences during the COVID-19 pandemic. Action and investment are urgently needed. This report's findings can help federal and state officials identify gaps in public health preparedness and the steps needed to better protect lives and the economy during the next health emergency," said J. Nadine Gracia, MSCE, President and CEO of Trust for America's Health.

The report measured states’ performance during a year that presented intense demands on the nation’s public health system. In addition to the ongoing COVID-19 pandemic, 2021 saw record heat in many places, extensive flooding, wildfires throughout the Western U.S., a highly active hurricane season, and unusual and deadly December tornados in eight states. At the same time, hundreds of public health officials

having experienced burn-out, threats to their safety, and attempts to limit their public health authorities have resigned, retired, or been fired.

While critical progress was made in fighting COVID-19 during 2021, particularly through the widespread availability of vaccines and a more coordinated federal response, the pandemic continued to illuminate the ways in which health inequities put communities of color and low-income communities at heightened risk for worse health outcomes during an emergency.

“Social, economic, and health inequities undermine a community’s ability to prepare for, respond to, and recover from a public health emergency. If we enter the next public health crisis with the same magnitude of health inequities in our communities as has been evident during this pandemic, the impact will be similar: preventable loss of life, disproportionate impact on communities of color and low-income communities, and widespread social and economic disruption. It is impossible to separate strong public health emergency preparedness and health equity,” said Dr. Gracia.

Among the report’s policy recommendations:

- Congress and states should provide stable, flexible, and sufficient funding for public health, including for infrastructure, data systems, and the public health workforce.
- Congress should create a COVID-19 Commission to review and address gaps in the pandemic response, and leaders at all levels of government should reject attempts to weaken public health authorities.
- Policymakers should take steps to prevent disease outbreaks by investing in vaccination infrastructure, antibiotic resistance programs, and by providing paid leave for all workers.
- Congress should create programs to help build resilient communities by investing in health equity and the social determinants of health, including anti-poverty programs and programs that build financial security for families.
- Congress should invest in the development and distribution of medical countermeasures to enable rapid development and effective deployment of life-saving products during emergencies and federal and state policymakers and healthcare systems leaders should work together to prioritize effective coordination and communication during emergencies.
- The White House, Congress, and states should develop plans and provide funding to minimize the health impacts of climate change and do so in ways that address health equity.

Read the full report at: https://www.tfah.org/report-details/ready-or-not-2022

Trust for America's Health is a nonprofit, nonpartisan organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority. www.tfah.org. Twitter: @healthyamerica1

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- Gov. Lujan Grisham will Provide Keynote Address at #NASHPCONF21
- ARPA Provides States with Funds to Address Mental Health in Schools
- New State Option for Funding Mobile Crisis Intervention Services
- 2021 State Leg. Session Recap on States' Efforts to Lower Drug Costs

Governor Lujan Grisham will Provide Keynote Address

• Sept. 21, 2021, Governor Lujan Grisham will kick off #NASHPCONF21: State Health Policy Unmuted with remarks on lessons learned during COVID-19, continued challenges and how to think about recovery in New Mexico.

• A panel of state health leaders will follow to discuss their efforts to control the spread of COVID-19 and how they are preparing for recovery including the use of federal funds for strengthening the public health system, promoting health equity, and responding to trauma and behavioral health crises. This is a must-attend event that you don't want to miss. Learn more and register today!

REGISTER NOW

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ARPA Gives States Opportunities to Support Behavioral Health for Children and Youth

ARPA Provides States with Funds to Address Mental Health in Schools
• The American Rescue Plan Act (ARPA) allocates $122.8 billion to state and local education agencies to support students returning to school, including school mental health systems.

New State Option for Funding Mobile Crisis Intervention Services
• ARPA creates a new state option for funding MCIS through Medicaid. States can leverage this opportunity and design their policies to support MCIS for children and youth, whose behavioral health needs have increased during the pandemic.
State Grant Applications Due August 13, 2021.

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2021 State Legislative Session Recap on States' Efforts to Lower Drug Costs

• During the 2021 legislative session, 20 states enacted 43 laws to address rising drug costs.

• Enacted state laws include establishing a prescription drug affordability board (PDAB), limiting patients' out-of-pocket insulin costs, regulating pharmacy benefit managers (PBMs), and requiring prescription drug price transparency. Read more.

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A Case Study of the Virginia COVID-19 Equity Leadership Task Force and Health Equity Working Group

• This new case study is part of a learning network hosted by the National Governors Association, Duke-Margolis Center for Health Policy, and NASHP that convenes governor-appointed health equity COVID-19 task force leaders throughout the nation.

• The case study highlights efforts from the Virginia COVID-19 Equity Leadership Task Force and Health Equity Working Group. The Commonwealth of Virginia integrated principles of equity and inclusion into the infrastructure of state government; an approach that has been instrumental in the state's response to COVID-19 and beyond.

• The learning network hosted a summit last week on reimagining the collection, reporting, and use of race and ethnicity data across states which will result in a publication later this summer.

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States' COVID-19 Public Health Emergency Declarations, Mask Requirements and Travel Advisories

• On July 27, the CDC released new guidance recommending that all individuals, regardless of vaccination status, wear masks indoors in places with high COVID transmission rates.

• At least seven states have aligned with these recommendations, while Nevada and DC have reinstated indoor mask mandates for vaccinated individuals.

• NASHP is tracking the status of each state's mask requirements, as well as COVID-19 emergency orders and actions to reopen, here.

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Resource of the Month

A Case Study of Building Strong Brains Tennessee, an Approach to ACEs Mitigation

• This month, NASHP features A Case Study of Building Strong Brains Tennessee (BSBTN): An Initiative to Address Adverse Childhood Experiences (ACEs) and Become a Trauma-Informed State. The case study highlights BSBTN, a

public/private partnership established to prevent and mitigate the impacts of ACEs to promote statewide economic development and prosperity.

• In this case study, the National Governors Association Center for Best Practices, Duke-Margolis Center for Health Policy, and a former Tennessee leader highlight BSBTN and its key successful elements.

• View other state resources at the Healthy Child Development State Resource Center. Submit new resources to Elinor Higgins.

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Announcements

States-Only Roundtable Discussion on Increasing immunization in Advance of Back-to-School

Registration Open for NAHDO's 36th Annual Conference

Respite Workforce Pilot: Deadline for Interested Applicants is August 6

State Tracking

Costs
State Legislative Action to Lower Pharmaceutical Costs

State Drug Pricing Laws: 2017-2021

State Legislative Action to Lower Health System Costs

COVID-19
Vaccine Mandates Legislative Tracker

COVID-19 Federal Funding Earmarked for Hospitals, Providers, and States

States' COVID-19 Public Health Emergency Declarations, Mask Requirements and Travel Advisories

State Approaches to Contact Tracing during the COVID-19 Pandemic

How States Collect, Report, and Act on COVID-19 Race and Ethnicity Data

States Use Appendix K Waivers to Support Home- and Community-Based Services in Response to COVID-19

State Medicaid and CHIP Strategies to Protect Coverage during COVID-19

Coverage
States' Efforts to Extend Medicaid Coverage to Postpartum Women

State Actions that Support and Expand Palliative Care

Where States Stand on Exchanges

Careers

Policy Associate — Chronic and Vulnerable Populations Team

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Dear Health Department Colleagues,

Please see this week's highlights below. We have several items of note.

Additionally, get inspired! COVID-19 responder stories tell more about these public health heroes just like you!

Is there anything specific that you would like to see featured? Please do not hesitate to email any questions and suggestions to our Health Department Section Communications Team: eocevent501@cdc.gov

Thank you for all your continuing dedication to your communities,
STLT Support Task Force, Health Department Section

New + Notable

SARS-COV-2 Variants

Multiple variants of the virus that causes COVID-19 are circulating globally and within the United States. To date, four variants have been classified as a variant of concern (VOC). The variant of the virus that caused the first U.S. COVID-19 cases in January 2020 no longer circulates in the country. As new variants of the virus emerge and others fade away, the proportion of variants circulating in the United States will continue to rise and fall. Nationally, the proportion of cases attributed to the new VOCs are:

- B.1.617.2 (Delta) is predicted to increase to 51.7%, becoming the predominant lineage in the U.S.
- B.1.1.7 (Alpha) proportion is predicted to decrease to 28.7%.
- P.1 (Gamma) proportion is predicted to decrease to 8.9%.
- B.1.351 (Beta) is predicted to decrease slightly to 0.2%.
- B.1.617.2 (Delta) will increase in all HHS regions and be more than 70% in regions 7 and 8.
- B.1.1.7 (Alpha) is predicted to be less than 50% in all HHS regions.
- P.1 (Gamma) is predicted to be more than 10% in regions 1, 4, 5, 9, and 10.
- B.1.351 (Beta) is predicted to be less than or equal to 0.5% in all HHS regions.

Introducing Vira, the Vax Chatbot

COVID-19 vaccination is lagging in young adults nationally. Vira, the Vax Chatbot is designed to support and meet young people where they are with simple answers to common COVID-19 vaccine questions. Vira is adaptive, learning by listening to your questions and feedback to help scientists respond to emerging questions.

Vira was developed by the International Vaccine Access Center at the Johns Hopkins Bloomberg School of Public Health with experts from the Bloomberg School's Department of International Health and Johns Hopkins Whiting School of Engineering. Vira's knowledge base from Johns Hopkins vaccine scientists was developed with support from the COVID-19 Training Initiative, with funding from Bloomberg Philanthropies.

VaxChat, powered by IBM, was inspired by previous research that showed automated chatbots using AI can effectively communicate credible information and support health behavior changes.

Vira can help health workers or anyone who seeks help fielding questions from family and friends about the COVID-19 vaccines. Check out Vira, a vax chatbot that's here to help you and your loved ones make an informed decision. Explore at VaxChat.org. This information is provided by Johns Hopkins.

Vaccine Updates

A Needle Today Helps Keep COVID Away

The highly transmissible B.1.617.2 (Delta) variant continues to spread across the United States at a rapid pace. Early data suggest that B.1.617.2 now makes up more than 50% of COVID-19 cases. In some parts of the country, this percentage is even higher, especially in areas with low vaccination rates. This rapid rise is concerning and threatens the progress the United States has made toward ending the pandemic.

- As of July 8, 2021, 183.2 million people, or 55.2% of the total U.S. population, have received at least one dose of a COVID-19 vaccine. About 158.3 million people, or 47.7% of the total U.S. population, have been fully vaccinated.* However, cases and hospitalizations are on the rise in areas with low vaccination coverage. Data from recent weeks show that adults ages 18–49 account for more than 40% of COVID-19-associated hospitalizations.
- Fortunately, we have safe and effective vaccines that prevent severe disease, hospitalization, and death. People who are fully vaccinated are protected from B.1.617.2. We are turning the corner on the pandemic and starting to get back to normal. However, stopping the spread of B.1.617.2 requires all of us doing our part.

For more information, please see the current COVID Tracker Weekly Review and/or sign up for the newsletter.

* People are considered fully vaccinated 2 weeks after their second dose in a 2-dose series (such as the Pfizer or Moderna vaccines), or 2 weeks after a single-dose vaccine (such as Johnson & Johnson's Janssen vaccine).

Transfer of Vaccine Outside the U.S.

Additional information is often requested on the transfer of vaccine across international borders. Here are some key points for addressing this issue within your region, state, or community. Currently, it is not possible for states or awardees to transfer COVID-19 vaccine across international borders for the following reasons:

- Vaccine contracts with manufacturers prohibit the use, or authorization of use, of vaccines outside the U.S. and its territories (excluding Departments of Defense and State foreign compounds) which are covered under the PREP Act. Sharing of vaccine internationally would violate these contracts.
- USG limits donations of federal pharmaceutical assets to products that allow the U.S. to maintain pedigree knowledge to attest to the proper storage and handling of the vaccine. Even though COVID-19 vaccine is in state possession, it is still considered a federal asset (similar to vaccine in the VFC program).
- Countries are hesitant to accept vaccine that has been maintained outside of federally monitored storage and handling guidelines. Direct distribution of vaccine from USG helps ensure the safety of vaccine to foreign governments and limits liability to states.

CDC is working tirelessly to assist the U.S. Government with transfer and distribution of vaccine to foreign governments directly from federal depots. Through this channel of vaccine supply chain management, the global distribution of vaccine is both efficient and safe. Although contributing to this effort is desirable, the CDC appreciates your adherence to the policy at this time.

The Advisory Committee on Immunization Practices will meet next Wednesday, July 22 from 11:00 to 4:00 PM EST. Draft agenda can be found here.

Attached Documents

CDC Strategic Public Health Science AJPH early release.pdf

Evidence_Experience_Expertise.pdf

Website Updates

What's New & Updated | CDC

Critical Populations Webpages

V-safe COVID-19 Vaccine Pregnancy Registry

Toolkit for People with Disabilities

Videos about COVID-19 in American Sign Language

Vaccine Webpages

CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume

Selected Adverse Events Reported after COVID-19 Vaccination

Joint CDC and FDA Statement on Vaccine Boosters

Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination

Percent of Delivered First Vaccine Doses Administered by U.S. States and Territories

V-safe After Vaccination Health Checker

COVID-19 Webpages

Covid Data Tracker

CDC COVID-19 Response Staff Deployed Across America

Cruise Ship Color and Commercial Travel Status

Long-Term Effects of COVID-19

Science Brief: Transmission of SARS-CoV-2 in K-12 Schools and Early Care and Education Programs

Myths and Facts about COVID-19 Vaccines

SARS-CoV-2 Variant Classifications and Definitions

COVID-19 By the Numbers

Notable Publications

Acceptability of Adolescent COVID-19 Vaccination Among Adolescents and Parents of Adolescents

SARS-CoV-2 B.1.617.2 (Delta) Variant COVID-19 Outbreak Associated with a Gymnastics Facility

Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices

COVID-19 Vaccine Administration, by Race and Ethnicity — North Carolina

COVID-19 Vaccination Coverage Among Insured Persons Aged ≥16 Years, by Race/Ethnicity and Other Selected Characteristics — Eight Integrated Health Care Organizations

Calls, Trainings, + Webinars

President Biden Participated in Press Events This Week

President Biden participated in a joint press conference with German Chancellor Angela Merkel on **Thursday**,

July 15, who visited the White House for an official working visit. Please look out for a recording of this press briefing as they discussed the COVID-19 pandemic, including their shared desire to provide access to vaccines around the world, and to shore up global health security.

A press briefing by White House COVID-19 Response Team and Public Health Officials was held at **11:00 am, July 16**. Archived press briefings can be accessed here: Press Briefings Archives | The White House

cdc.gov/coronavirus

Toward a New Strategic Public Health Science for Policy, Practice, Impact, and Health Equity

Rebecca Bunnell, PhD, MEd, Juliet Ryan, MPH, Charlotte Kent, PhD, and the CDC Office of Science and CDC Excellence in Science Committee

The COVID-19 pandemic and its social and health impact have underscored the need for a new strategic science agenda for public health. To optimize public health impact, high-quality strategic science addresses scientific gaps that inform policy and guide practice.

At least 6 scientific gaps emerge from the US experience with COVID-19: health equity science, data science and modernization, communication science, policy analysis and translation, scientific collaboration, and climate science. Addressing these areas within a strategic public health science agenda will accelerate achievement of public health goals.

Public health leadership and scientists have an unprecedented opportunity to use strategic science to guide a new era of improved and equitable public health. (*Am J Public Health*. Published online ahead of print July 1, 2021:e1–e8. https://doi.org/10.2105/AJPH.2021.306355)

COVID-19 has exposed major unmet needs in our nation's public health system related to workforce, diagnostics, preparedness, health disparities, information systems, and response capacity. While there have been numerous calls for creating and sustaining a robust public health infrastructure and for prioritizing science, antiscience sentiments have also been widespread. Without a thoughtful, strategic approach to scientific research; rigorous evaluation of programs; and development of evidence-based public health policy and communication strategies, the United States will be underprepared again when the next pandemic occurs. Ensuring impactful science as the bedrock for decision-making will set a sound foundation for the future, and lessons from COVID-19 can provide direction for a strategic approach to public health science.[1]

Public health has a mandate to reduce morbidity and mortality and advance health equity at the population level. Metrics and frameworks used to rank the impact and value of public health science vary, often reflecting stakeholder perspectives. They frequently include a focus on tangible health benefits, concern about return on investment, interest in specific diseases, or prioritization of bibliometrics and scientometrics.[2,3] Retrospective metrics alone are insufficient to guide strategic science; effective action requires a prospective approach. We believe strategic science begins with a public health goal in mind, systematically identifies and then builds an evidence base to inform practice and policy, and ultimately results in improvement in health and equity outcomes. To optimize public health impact, high-quality strategic science addresses scientific gaps that inform policy and guide practice.

A prioritized strategic science agenda can help guide use of limited public health scientific resources to fill the evidence gaps that will have the largest impact on population health. Many examples of the impact of strategic science exist,[4] ranging from counterbioterrorism efforts informed by the smallpox research agenda,[5] smoke-free policies that protect millions based on research documenting adverse effects of second-hand smoke exposure,[6] increased vaccine coverage following implementation research, coordinated evidence-based actions to reduce antimicrobial resistance informed by surveillance,[7] and millions of lives saved by HIV antiretroviral therapy resulting from applied research on effective delivery

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strategies. A strategic pursuit of public health science that provides direction, has delineated measurable goals, and provides opportunities for stakeholders and affected communities to engage is needed more than ever. Developing and implementing an effective strategy is crucial for a new public health era.

The COVID-19 pandemic has illuminated at least 6 key themes that are central to a science strategy for improving public health: health equity science; data science and modernization; communication science; policy analysis and translation; scientific, including laboratory, collaboration; and climate science. With a US domestic focus, for each of these 6 themes, we first summarize related COVID-19 lessons. Second, we discuss their implications to help inform a strategic public health science agenda for a new era (Box 1).

HEALTH EQUITY SCIENCE

Structural racism, long-standing injustices, and neglect of factors that cause health inequities in the United States have worsened the consequences of the COVID-19 pandemic and resulted in substantial disparities in COVID-19 incidence, hospitalization, and mortality. Social determinants of health (SDOH) and vital conditions such as employment settings lacking employee protections and insecure or crowded housing have impeded the use of mitigation measures like social distancing and mask wearing. These factors contributed to 1.4- to 1.8-times-higher COVID-19 incidence, 2- to 3-times-higher hospitalization, and 3- to 5-times-higher mortality rates among Black and Hispanic/Latino persons compared with White persons.[8] In addition to elevated environmental exposure risk, racial/ethnic minority populations have less access to health care and higher prevalence of uncontrolled chronic lung, heart, kidney, liver, and metabolic conditions associated with more severe COVID-19 outcomes.[9] Race and ethnicity data have been incomplete, particularly in the beginning of the epidemic, and SDOH data were not widely leveraged, leaving the effects of structural racism, environmental injustice, and other socioeconomic factors largely unexplored. In addition, adverse impacts of the pandemic on employment, education, and other determinants of health could widen future disparities as well because Black, Hispanic/Latino, older, rural, and underinsured populations were more likely to experience unemployment and education setbacks.[10,11]

Future strategic scientific work can advance health equity by both building on existing recommendations and identifying new effective program and policy interventions. Rigorous evaluations of clinical, community, environmental, and policy interventions that link social determinants with health outcomes and assess impact on health inequities are essential.[12] To expand the evidence base, evaluation of real-world impact and the effect of interlocking contextual systems will be important to supplement experimental efficacy studies.[12] Expanding use of validated methods to document SDOH and assess social and environmental factors will be fundamental to this work.[13] This work can also elucidate how failure to address health disparities leads to less-effective preparedness and how health disparities can be exacerbated during a crisis. Research is needed to identify ways in which better data from modernization and innovation can be used to accelerate health equity.[14] Given how SDOH, structural racism, and health disparities contributed to the impact of this pandemic, implementation science should inform preparedness approaches that recognize health equity as a core pillar of future pandemic preparedness efforts.

DATA SCIENCE AND MODERNIZATION

Existing surveillance and data systems have proven inadequate for COVID-19 response efforts. Public health data systems have been historically undersupported and were unable to acquire, share, and transmit data efficiently. The lack of systematic data collection and automated linkages between laboratory-derived data, clinical data, and case investigation data has impeded COVID-19 response speed. Outdated policies and regulatory processes inhibit data collection and sharing at local, state, national, and international levels. Interconnectivity across a vast array of public–private sector systems in the United States has been nascent, slowing utilization of electronic health records in response efforts. While contact tracing can be an important public health tool to interrupt disease transmission, its application for COVID-19, particularly in the initial months of the pandemic and during spike periods, was largely inadequate. Data science could have greatly improved contact-tracing efforts by providing real-time information to those exposed to reduce transmission. Finally, the public health workforce has had limited expertise and access to new tools, policies, and approaches to data visualization, methods, and analytics including epidemiological modeling and disease forecasting as a routine part of pandemic planning and response.[15]

As public health strives to keep pace with rapidly advancing technologic innovation, scientists are poised to

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BOX 1— COVID-19 Lessons and Implications for Strategic Public Health Science

Themes	COVID-19 Lessons	Public Health Science Opportunities
Health equity science	• COVID-19 magnified and widened health disparities and other inequities. • Incomplete data on race, ethnicity, and SDOH limited some analyses. • Race/ethnicity interacted with causal SDOH factors and historical inequities. • Historic neglect of factors that cause health disparities resulted in worse pandemic outcomes.	• Assess how addressing health disparities is part of pandemic preparedness. • Document SDOH, including how they intersect to magnify risk. • Build evidence on intervention effectiveness. • Generate health equity evidence needed by policymakers. • Research how data modernization and innovation can accelerate health equity.
Data science and modernization	• Public health data systems were unable to acquire, share, and transmit data efficiently. • Lack of systematic linkages among laboratory, clinical, and case investigation data impeded response speed. • Outdated policies and regulatory frameworks inhibited data sharing at local, state, national, and international levels. • Public health workforce expertise was insufficient for data linkages and new analytic methods. • Public- and private-sector partnerships were nascent, slowing progress.	• Accelerate modernization to make public health science current. • Expand methods for use of multisectoral data sources, including environmental and climate, community SDOH, geospatial, genomic, and biomarker data. • Evaluate new surveillance and outbreak signal approaches. • Equip public health workforce with data science, genomics, informatics, and analytic skills. • Provide scientific leadership using public health data.
Communication science	• A COVID-19 "infodemic" occurred together with more than 90 million Facebook misinformation warnings • Misinformation and disinformation undermined public health messaging and response efforts. • Public trust in scientific integrity was undermined during COVID-19.	• Evaluate approaches to counter misinformation, such as engaging online influencers. • Expand communication science; assess impact of new technologies and social media. • Strengthen communication strategy as part of research planning. • Evaluate effective methods to amplify research dissemination. • Accelerate pace of science dissemination.
Policy analysis and translation	• Need for universal access to free testing, treatment, and vaccination for COVID-19 was evident. • COVID-19 made intersection of health and other sectors visible, raising plethora of policy issues (e.g., employment, housing, transportation). • Policy barriers hindered consistent mitigation approaches across jurisdictions, (e.g., mask, restaurant, and business opening policies). • Clear, consistent messaging was needed across all levels of policymakers. • COVID-19's postacute health effects (cardiovascular, pulmonary, mental health, and neurologic) raised policy issues in other health care domains. • Telehealth expansion demonstrated both feasibility and need for attention to equitable access.	• Expand use of policy analyses to assess public health impacts. • Utilize strongest methods possible for public health policy research, including randomized and nonrandomized designs. • Leverage partnerships to accelerate dissemination and implementation of evidence-based policy options. • Assess core capacities, policies, and systems, and ethical frameworks needed for future preparedness and resource distribution during public health threats. • Assess incidence, duration, severity, and societal impact of long-term sequelae. • Evaluate approaches to address policy and resource barriers that ensure equitable access as telework expands.
Scientific collaboration	• SARS-CoV-2 sequence was published online in 72 h, setting precedent. • Proliferation of COVID-19 preprints and rapid publications accelerated pace of dissemination. • Community engagement was critical to build trust and mitigation adherence. • Data from multiple sectors and disciplines helped to identify risks and assess mitigation feasibility and effectiveness, including political science, behavioral science, and data science.	• Implement transdisciplinary and convergence research studies. • Pursue research innovation; develop novel methods, such as improving specimen collection or using host genomics to explain health outcomes and responses to treatments and vaccines. • Conduct community participatory research; use tools of collaborative implementation science to enhance public health outcomes. • Facilitate rapid sharing of applied laboratory advances.
Climate science	• Air pollution can aggravate underlying respiratory conditions that lead to more severe COVID-19 outcomes. • Extreme heat, fire, and severe weather complicated COVID-19 mitigation efforts. • New COVID-19 guidance was needed for climate-related emergency response. • Lockdowns and reduced mobility and travel rapidly improved air quality.	• Implement research focused on climate-vulnerable populations. • Leverage predictive analytics to forecast adverse climate effects and intervention needs. • Expand methods and routinely incorporate a climate lens into public health research. • Evaluate effectiveness and impact of interventions designed to mitigate climate change to build evidence base.

Note. SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SDOH = social determinants of health.

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benefit from advanced data analytic skills, including those for conducting natural language processing and leveraging machine learning and artificial intelligence. Strategic public health science coupled with innovative use of technology could help transform contact tracing methods for the future. Furthermore, development of, building consensus around, and utilization of new and nimble regulatory, legislative, and ethical frameworks for data collection, sharing, quality, and privacy are needed to reduce risks and maximize benefits associated with rapid modernization. Strategic public health science will require expanded scientific methods and analytic approaches for multisectoral data sources, including community SDOH, environmental and climate, genomic and bioinformatics, social media, and geospatial data. As transdisciplinary data scientists increasingly use public health data, public health scientific leadership is needed to establish core method, analytic, ethical, and policy approaches.

COMMUNICATION SCIENCE

The COVID-19 pandemic has called attention to the cultural, structural, and technological barriers that hamper dissemination and acceptance of accurate messages informed by science. Misinformation and disinformation have spread rapidly in social media. Facebook, for example, reported placing warning labels on more than 90 million pieces of content deemed COVID-19 misinformation.[16] COVID-19 misinformation undermined accurate public health messaging; greater exposure to misinformation was associated with lower compliance with mask wearing and social distancing guidelines.[17]

Disinformation, defined as deliberately misleading or biased information, has been used to intentionally fuel anti-science views and sentiments, particularly among targeted subpopulations.[18] In addition, the sheer volume of evidence-based information and the speed and frequency with which information evolved made consistent and effective risk communication more challenging and led the World Health Organization (WHO) to declare an "infodemic" around COVID-19 in May 2020.[19] The inconsistency of clear COVID-19 messaging across public-sector authorities at local, national, and global levels further undercut mitigation efforts.

Strategic science can leverage community engagement, behavioral economics, and communications science to study the impact of new technologies and strategies to counter misinformation and antiscience disinformation, including engagement of online influencers and trusted messengers to provide a steady flow of evidence-based information.[20] Research to identify effective interventions can assist both health organizations and social media platforms as they work to counter mis- and disinformation.[21] Planning for strategic dissemination, monitoring audience knowledge and sentiment, and countering misinformation are standard practices for all public health scientists to incorporate into daily practice. Coupled with proactive, consistent messaging that employs sound risk communication principles, strategic science can help rebuild trust in public health.[22–24]

POLICY ANALYSIS AND TRANSLATION

COVID-19 has illuminated the potential of policy as a public health tool and impediment. For example, policy decisions to reduce economic barriers for vaccination and testing increased uptake.[25] COVID-19 has also raised a plethora of multisectoral policy challenges that have an impact on transmission risk, including workplace safety, housing density, and transportation. Inconsistent mitigation policies have hindered the response across sectors and jurisdictions, including mask mandates and restaurant, bar, and other business operating policies. Furthermore, the public has often been confused by inconsistent communications about the importance of mitigation policies. COVID-19 has had numerous collateral and lasting impacts, both at the societal and individual level. Public- and private-sector entities will be confronted with potentially millions of people with long-term cardiovascular, pulmonary, mental health, and neurological sequelae,[26] raising policy needs across health care domains.[27] One success has been the rapid expansion of telehealth[28]; policies to ensure equitable access going forward will be needed.[29]

Assessment of the positive and negative impacts of policies and use of mathematical modeling to predict future impacts are key tools for scientific inquiry. A component of this work will be the identification of the core capacities, policies, and systems needed for preparedness. This includes advance assessment of the epidemiological and ethical implications of policy approaches to distribute resources during public health emergencies. Characterizing overall COVID-19 collateral impacts will be an important research area to inform broader health care policy, starting with assessment and monitoring of the incidence, duration, severity, and societal impact of long-term sequelae.

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Translational science, which includes both implementation and dissemination approaches and moves knowledge to action by ensuring effective and widespread use of evidence-based policies, can leverage policy analysis and implementation research to accelerate action.[30] For example, policy analysis can be used to identify effective mitigation interventions to support those experiencing long-term impacts, assess SDOH, and achieve widespread impact by applying findings through implementation and dissemination strategies. Success of this policy research will depend on utilization of the strongest designs possible, including both randomized and nonrandomized methods.[12]

SCIENTIFIC COLLABORATION

Within 72 hours of the Chinese and WHO announcement of a novel coronavirus, Chinese researchers shared the full sequence for SARS-CoV-2 online, spurring a global effort toward vaccine and therapeutics development.[31] UNESCO accelerated Open Science efforts with 122 nations[32]; the Open COVID Pledge engaged patent holders and the private sector[33]; and more than 150 scientific institutions and journals reaffirmed their commitment to share data and expand open access during the public health emergency.[34] Peer-review timelines have shortened dramatically for COVID-19 scientific information, with rapid review processes and preprint postings.[35] Dissemination of COVID-19–related information exploded; more than 16 000 scientific publications, including greater than 6000 on preprint servers, were posted in just 4 months. Online and digital technologies supported low-cost and timely remote scientific collaborations.[36] Collaborative scientific innovation on mRNA technology greatly accelerated vaccine development,[37] and scientists in multiple settings worked rapidly to build the evidence base on the effectiveness of masking for both source control and user protection. The pandemic accelerated scientific collaboration and promoted new norms around transparency and sharing.

Sustaining a culture of scientific collaboration positions public health science to be enriched with innovation and cross-sectoral expertise, including with sectors outside of health.[38] Concerted effort by scientists will be needed to implement transdisciplinary and convergence research[39]; advance applied laboratory science; conduct community participatory research; pursue research innovation and develop novel methods, such as transdisciplinary environmental health disparities research[40]; and host transparent genomics studies to explain health outcomes and vaccine response.[41] Creative public health practice and academic linkages as well as transdisciplinary team-based research approaches could help drive innovation going forward, including laboratory advancements.[42,43] Improved laboratory capacities are foundational to enhanced public health science, including not only laboratory quality and safety but also advancements in specimen collection, pathogen inactivation, transport, and rapid characterization; multipathogen and point-of-care assays; and biomarker-based diagnostics. Collaborative sequence-based pathogen surveillance reinforced by a global network of reference laboratories can more swiftly identify new and emerging pathogens. Scientists can improve processes for rapidly posting sequences and early findings to accelerate evidence generation for diagnostics, program implementation, and policy development. Modeling the costs and benefits of reducing chronic disease burden before the next infectious disease outbreak could inform a new paradigm for preparedness. Scientists are poised to continue greater collaboration, which could be enhanced with local, national, and global leadership.

CLIMATE SCIENCE

Health threats from climate change are well-documented,[44] and the interplay between COVID-19 and climate and environmental factors is multifaceted.[40] Environmental determinants of health, including deforestation and increasing human presence in wildlife habitats, have fueled both climate change and emergence of zoonotic infections.[45] Climate change, especially changes in temperature and precipitation, can result in changes in the distribution, seasonality, and prevalence of infectious diseases.[46] Air pollution can aggravate underlying respiratory conditions that lead to more severe COVID-19 outcomes.[47] Extreme weather events, including fires and storms, complicated COVID-19 mitigation efforts[48]; in turn, COVID-19 complicated responses to these disasters.[49] COVID-19 also complicated the ability of local health departments to run climate-relevant congregate facilities, such as cooling centers and disaster shelters.[50,51] Lockdowns and reduced mobility and travel improved air quality, but these positive impacts rapidly eroded as mobility increased again.[52] Our collective response to COVID-19 has been described as "a rapid learning experiment about how to cope with climate change."[53] Indeed, COVID-19 and climate change mitigation share similar policy challenges, including the

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importance of speedy and decisive action to avoid global financial and public health impact, the difficulties of gaining public support for stringent mitigation policies given politicization of the issues, and the need to address health disparities and counter misinformation.[54]

A strategic public health science agenda creates the opportunity to identify effective approaches for these shared policy challenges. Other key priorities include expanding research on the relationship between climate and health outcomes and emerging pandemic threats and improving surveillance for climate-sensitive pathogens and vectors that identify locations and populations at greatest risk. In addition, use of predictive analytics and forecasting can help build an evidence base for early warning systems and for interventions that effectively counter adverse climate effects, particularly for populations experiencing environmental injustice,[55] such as migrant and refugee populations.[56] Given that climate impacts span across public health, from environmental health to chronic and infectious disease and mental health, an interdisciplinary approach can support scientists to expand methods and demonstrate the value of new mandates to routinely incorporate a climate lens in public health research.[57,58]

A NEW ERA OF PUBLIC HEALTH STRATEGIC SCIENCE

The COVID-19 pandemic and its impacts continue to grow, fueling the imperative to create a new era of public health guided by strategic science. The 6 themes emerging from COVID-19 experience discussed here—health equity science, data science and modernization, communication science, policy analysis and translation, scientific collaboration, and climate science—can help formulate a strategic public health science agenda that accelerates achievement of future public health goals (Box 1). To succeed, public health science should be grounded in scientific integrity and supported by a larger, sustained, well-trained, and innovative workforce. Workforce expansion, diversification, and development will be needed at multiple levels, including for epidemiologists, data scientists, and leadership.[59] This enhanced public health workforce could help break the cycle of panic and neglect that has characterized public health attention and resources for decades.[60] Given the impact of COVID-19, it is possible that public health will remain prominent, especially as vaccination coverage expands, other efforts to reduce community transmission continue, and researchers learn more about COVID-19's long-term effects. Public health leader and scientists have an unprecedented opportunity to use strategic science to guide and implement a new era of improved and equitable public health. AJPH

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The authors have no potential or actual conflicts of interest with the content presented in this article.

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This activity did not involve human participant research, was reviewed by CDC, and was conducted consistent with applicable federal law and CDC policy (see, e.g., 45 CFR 46; 21 CFR 56; 42 USC §241(d); 5 USC §552a; 44 USC §3501 et seq.).

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SUPPLEMENT ARTICLE

Evidence, Experience, Expertise, and the US Coronavirus Disease 2019 Public Health Response

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The U.S. Centers for Disease Control and Prevention (CDC), state, tribal, and local health departments assess available and promising interventions and individual and population health outcomes when crafting public health recommendations. This supplement provides a snapshot of some of the science, experience, and expertise supporting the COVID-19 response.

Keywords. COVID-19; CDC; public health; guidelines; transmission.

The United States (US) response to the coronavirus disease 2019 (COVID-19) pandemic underscores the need for evidence-based approaches to public health and clinical interventions. Charged with providing public health guidance and responding wherever the need is urgent, the US Centers for Disease Control and Prevention (CDC) and state, tribal, local, and territorial health departments assess individual- and population-level health outcomes, available and promising interventions, and downstream consequences when crafting public health recommendations and interventions. Over the past year, this pandemic response has demonstrated that a transparent, collaborative, and science-based approach that adapts to complex and rapidly evolving conditions is and will continue to be critical to bringing an end to the pandemic.

Data-driven guidance begins with clear terminology characterizing the evidence. National reports have demonstrated that the numbers of COVID-19 cases involving hospitalization and death have directly correlated with overall reported severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections [1]. As we look forward, particularly with increased vaccine and treatment availability, SARS-CoV-2 infection will lead to varying clinical outcomes, and the correlation with severe COVID-19 disease will not be as straightforward. As US COVID-19 hospitalizations and deaths decrease, reported mild or asymptomatic SARS-CoV-2 infections might not decrease at the same pace in all communities. Adapting the current case definition of COVID-19 [2], which assigns the same importance to mildly symptomatic infection as severe disease, to the appropriate context, with more rigorous delineation between asymptomatic or mildly symptomatic viral infection and a severe clinical syndrome, can facilitate informed clinician–patient conversations, targeted clinical and epidemiologic studies, evidence-based recommendations and policy, and effective resource allocation. We should consistently understand this distinction in every setting and subpopulation where we apply evidence and experience. This is analogous to the evolution of new nomenclature and disease classification that occurred as more was understood about human immunodeficiency virus (HIV) infection being clinically distinct from AIDS or latent tuberculosis (TB) infection as distinct from TB disease. Precision in how we characterize the epidemiology of infections at the local level will be critical for sustaining control of transmission and accelerating recovery.

In this supplement, we provide a snapshot of some of the science, experience, and experts supporting the response. We touch on 5 major topics with these articles: clinical sequelae of SARS-CoV-2 infection, SARS-CoV-2 testing, COVID-19's interaction with other infectious diseases, COVID-19 and disproportionately affected persons, and SARS-CoV-2 transmission.

CLINICAL SEQUELAE OF SARS-COV-2 INFECTIONS

The impact on patients and healthcare burden of minimally symptomatic SARS-CoV-2 infection is unequivocally different from the burden of severe COVID-19. Chevinsky et al demonstrate that the timing and type of post–COVID-19 sequelae differ between hospitalized inpatients and outpatients compared to control patients without COVID-19 [3]. This cohort study of over 25,000 inpatients and over 40,000 outpatients diagnosed with COVID-19 and matched to control patients without COVID-19 through a 4-month follow-up period, using electronic health record data and propensity score matching, demonstrates differences in long-term outcomes in patients diagnosed with COVID-19 compared to control patients without COVID-19, stratified by setting at diagnosis.

In addition to setting and severity of SARS-CoV-2 infection at diagnosis, many underlying medical conditions affect progression

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to severe disease; pregnancy is one of the most common comorbid conditions in our population. Two studies in this supplement look exclusively at pregnant women with COVID-19. Using CDC's Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET), Galang et al found that among 7950 pregnant women identified with SARS-CoV-2 infection, certain risk factors, such as pregestational diabetes, age 25 years and older, and healthcare occupation, were associated with moderate-to-severe COVID-19 [4]. Using data from over 400,000 delivery hospitalizations, Ko et al expand upon these findings, showing that a documented COVID-19 diagnosis at delivery hospitalization was associated with increased risk for sepsis, shock, acute renal failure, thromboembolic disease, adverse cardiac events/outcomes, intensive care unit admission, preterm labor with preterm delivery, and death, independent of race or ethnicity [5].

The goal of preventing hospitalization and death for those at highest risk of acquiring SARS-CoV-2 infection and progressing to severe COVID-19 directly informed vaccination program planning efforts in the US, with Advisory Committee on Immunization Practices (ACIP) recommendations targeting early vaccination distribution to persons in long-term care facilities, persons aged ≥65 years, frontline essential workers, and persons aged 16–64 years with high-risk medical conditions [6]. Sami et al demonstrate that in a sample of hospitalized patients from 14 academic centers in the US, more than 90% met ≥1 of these risk factors for severe COVID-19 [7]. These findings support continued emphasis on promoting vaccination for persons with higher-risk medical conditions, even as vaccines are widely available.

SARS-COV-2 TESTING

Alongside vaccine rollout, this year also witnessed the launch of more detailed CDC recommendations for SARS-CoV-2 testing [8], and more widespread SARS-CoV-2 testing across a variety of settings. Testing brings both opportunity and complexity. Fox et al demonstrate how, prior to vaccine availability, testing facilitated implementation of shortened quarantine protocols on college campuses, and reduced time lost from classroom and other campus commitments [9]. These data provided support for CDC's initial recommendations to reduce quarantine duration using diagnostic testing [10]. College student and staff vaccination are changing the campus landscape even further. Recognizing the importance of maintaining essential public health services during the pandemic even prior to vaccine availability, Laws et al describe the Ugandan Ministry of Health supplementing prevention measures with SARS-CoV-2 universal testing and isolation of persons with positive tests to continue an in-person HIV public health training activity [11].

Testing alone, however, has not been sufficient to prevent SARS-CoV-2 outbreaks. Moreno et al describe more than 30 confirmed secondary cases that occurred within a university athletics program after the index patient attended a meeting while infectious, despite a negative antigen test on the day of the meeting [12]. Clearly now, vaccination, regardless of any testing strategy, is essential to reduce transmission.

Interpreting a positive or negative SARS-CoV-2 test result requires consideration of multiple contextual factors. Test type, body site of specimen collection, how and why the specimen is collected and vaccination status, are all important to consider. Shah et al's evaluation of the BinaxNOW antigen test in an unvaccinated community setting in Wisconsin, found 99% concordance on repeat testing despite different testers and readers, showing reproducibility and supporting use of this platform in broader sectors [13]. Choice of specimen for testing also matters. In the study by Gable et al evaluating less invasive specimen types, investigators compared matched oropharyngeal swabs, anterior nasal swabs (ANS), and saliva collected from each unvaccinated participant across the course of their infections [14]. Saliva yielded more reverse-transcription polymerase chain reaction (RT-PCR) positives at later time points, suggesting that saliva-based diagnostics may lead to more unnecessary infection control actions by identifying RT-PCR–positive individuals who are potentially no longer infectious. ANS yielded the most RT-PCR positives at earlier time points and culturable virus more often than oropharyngeal specimens, suggesting that test positivity with this specimen may be a better indicator of infectivity. Finally, with goals of increasing patient acceptance and conserving healthcare resources, Marx et al evaluated self-collected saliva or ANS for SARS-CoV-2, compared with clinician-collected nasopharyngeal swabs in Denver, Colorado [15]. Sensitivity for SARS-CoV-2 detection by rRT-PCR in self-collected specimens was higher among unvaccinated symptomatic participants than among those without symptoms (94% vs. 29% for saliva; 87% vs. 50% for ANS) in this study. These data suggest self-collection offers many practical advantages and may be most useful for unvaccinated symptomatic patients patients.

COVID-19'S INTERACTION WITH OTHER INFECTIOUS DISEASES

Widespread testing and the overwhelming presence of COVID-19 in medical systems has the potential to lead clinical and public health practitioners astray, particularly when other infectious diseases are present. Narita et al describe a few clear examples from Seattle, Washington, where patients with risk factors for TB were repeatedly tested only for SARS-CoV-2 upon presentation to care, many tests later to be diagnosed with late-stage, infectious TB, including 1 death from TB [16]. Conversely, Schrodt et al characterize a long-term-care facility outbreak where, based on initial rapid testing, there appeared to be concurrent outbreaks of influenza and SARS-CoV-2; however, the influenza tests were all later found to be false positives [17]. Use of a rapid antigen test for influenza distracted the facility from focusing solely on a SARS-CoV-2 outbreak. These articles highlight that even during a pandemic, infectious disease and public health

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expertise from the pre–COVID-19 era and careful consideration of the overall clinical context remain critical to appropriate interpretation of SARS-CoV-2 test results.

COVID-19 AND DISPROPORTIONATELY AFFECTED PERSONS

Many groups who have been marginalized depend on their employers to align with national or local guidance, and workplace-specific challenges may prevent prompt detection, intervention, and prevention of COVID-19 outbreaks [18]; this may foreshadow similar challenges for vaccination efforts. Beyond the direct impact of COVID-19 itself, other consequences of the pandemic have resulted in a disproportionate burden on persons at risk of other diseases. Based on National Emergency Medical Services Information System data describing 911 emergency medical services (EMS) activations in 2020, EMS activations as a percentage of total activations increased during the early pandemic period for cardiac arrest, on-scene death, and opioid-related events, remaining above baseline levels through the end of the year [19].

In response, there has been focused national attention on disproportionately affected persons in many aspects of the pandemic. Marks et al characterized the potential for Health Resources and Services Administration (HRSA) Health Center Program service delivery sites to deliver COVID-19 vaccines to up to 30 million patients. With the exception of non-Hispanic black and American Indian/Alaska Native persons, there were more health center influenza vaccinations among racial/ethnic minorities, particularly among Hispanics, in comparison with county racial/ethnic demographics [20]. In April 2021, HRSA and CDC invited all HRSA-funded health centers to participate in a direct COVID-19 vaccine allocation program (Ensuring Equity in COVID-19 Vaccine Distribution: Engaging Federally Qualified Health Centers, https://www.hrsa.gov/coronavirus/health-center-program). Furthermore, Wilson et al describe the implementation of the Infection Prevention and Control (IPC) Global Webinar Series to bring together subject-matter experts and IPC professionals to share guidance and implementation examples across healthcare communities who no longer, or previously did not, have access to traditional modes of knowledge dissemination [21].

SARS-COV-2 TRANSMISSION

Finally, in regards to both COVID-19 and other upper respiratory viral diseases, 2 studies provide support for CDC recommendations on mitigation measures essential for control of SARS-CoV-2 as well as other upper respiratory viral infections during periods of widespread community transmission. Carter et al describe multistate SARS-CoV-2 transmission among approximately 462 000 unvaccinated persons attending a variety of outdoor and indoor activities at a national motorcycle rally held in South Dakota in August 2020 [22]. COVID-19 was diagnosed in participants not only in South Dakota, but also in Minnesota, Montana, North Dakota, Nebraska, and Wyoming, confirming increased risk of widespread SARS-CoV-2 transmission from mass gatherings where unvaccinated attendees traveled from outside the local area.

Basic nonpharmaceutical interventions have implications for respiratory viruses beyond SARS-CoV-2. Rodgers et al describe findings from an analysis of emergency department visits reported to the National Syndromic Surveillance Program according to chief complaints and diagnosis codes, excluding visits with diagnosed SARS-CoV-2 infections [23]. For each week during 1 March–31 December 2020, percentage positivity for influenza virus, respiratory syncytial virus, human parainfluenza virus, adenoviruses, and human metapneumovirus were lower in 2020 than 2019, suggesting that nonpharmaceutical interventions to mitigate spread of SARS-CoV-2 likely also reduced transmission of other pathogens.

In conclusion, the US public health response has required a coalition of federal, state, and local public health officials as well as researchers, academics, pharmaceutical partners, and clinicians working tirelessly to apply evidence, experience, and expertise in the development, implementation, and evaluation of national COVID-19 recommendations. The studies in this supplement provide insights into some of the most important aspects of the pandemic—who is at highest risk for which severe outcomes, how we can accurately track SARS-CoV-2 infections while maintaining awareness of other concurrent or mimicking illnesses, and opportunities for public health and clinical medicine to bring expertise and experience together to combat one of the largest threats to health of the past century. While in the US, deaths from the pandemic have reached more than half a million in the past year, through steady vaccination rollout and consistent implementation of evidence-based interventions, we are finally passing from darkness into the dawn.

Notes

Potential conflicts of interest. The authors: No potential conflicts of interest.

Disclaimer. The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the CDC.

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All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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Health Department Weekly Email

July 16, 2021

cdc.gov/coronavirus

From: Polk, Jennifer (OS/ASPR/SIIM)
Subject: HHS COVID-19 Update - 3/31
Date: Thursday, April 1, 2021 7:53:48 AM

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Wednesday, March 31, 2021 8:26 PM
Subject: HHS COVID-19 Update - 3/31

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 31, 2021:

Highlights from the White House COVID-19 Response Team briefing:

Andy Slavitt:

- **Increasing Vaccination Sites:** The President committed to opening at least 12 more federally run mass vaccination sites, adding to the existing total of 25 sites. Three new sites will open next week in Memphis, Tennessee, Milwaukee, Wisconsin, and Greenbelt, Maryland, in addition to the two we announced on Monday in St. Louis, Missouri, and Gary, Indiana. Each of these sites is the first federally run mass vaccination site in its respective state, and each can administer 3,000 vaccinations a day.
- **Mask Mandates:** We need every governor, mayor, and local leader to maintain or reinstate mask mandates. And we need every American to do their part so that we can win this race and save lives.

Dr. Walensky:

- **Case Update:** CDC's most recent data show that the seven-day average of new cases is slightly less than 62,000 cases per day. We continue to see an increase, and this is almost a 12 percent increase from the seven-day period prior. Hospitalizations also continue to increase. The most recent seven-day average — about 4,900 admissions per day — is up from 4,600 admissions per day in the prior seven-day period. The seven-day average of deaths remains slightly above 900 deaths per day.
- **Inequities in COVID-19 Deaths:** COVID-19 deaths were highest for older adults and males, and were higher, as we previously saw, among American Indian and Alaska Natives, Hispanics, non-Hispanic Blacks, and non-Hispanic Native Hawaiian and Pacific Islander persons compared to non-Hispanic whites. In fact, among nearly all these ethnic and racial minority groups, the COVID-19-related deaths were more than double the death rate of non-Hispanic white persons. Based on the current state of the pandemic, these impacts have remained in 2021, where we continue to see that communities of color account for an outsize portion of these deaths.
- **Number of People Vaccinated:** This week, we will reach 100 million people who have received at least one dose of the COVID-19 vaccine in the United States — a remarkable feat in such a short period of time. Further, over 70 percent of people over age 65, our most vulnerable group, have received at least one vaccine dose. In addition to increasing the number of mass vaccination sites across the country with FEMA, expanding the Federal

Retail Pharmacy Program, and ensuring that all Americans have a vaccine site within five miles of their home, we are also activating mobile vaccination units and clinics. CDC is also excited to partner with the Administration for Community Living to support their efforts to get older, at-risk adults and those with disabilities vaccinated.

- **Guidance for Adult Day Service Centers:** CDC updated COVID-19 guidance for adult day service centers. These populations are at high risk for severe COVID-19 disease, and this guidance will help center administrators and staff protect themselves and adults receiving their services by promoting and engaging in preventive behaviors that reduce COVID-19 spread and help maintain healthy operations and environments of these facilities.
- **B.1.1.7 Variant:** We now have B.1.1.7 (U.K. variant) as 26 percent of the circulating variant across the United states, and it is the predominant strain in at least five regions of the United States. The variant is more transmissible – somewhere between 50 and 70 percent more transmissible than the wild-type strain. Therefore, to the extent that people are not practicing those standard mitigation strategies, we do think that more infections will result because of B.1.1.7. We believe that the current mitigation strategies of masking and distancing would work just as well against the current, the wild-type strain, as they do the B.1.1.7 strain.

Dr. Fauci:

- **Importance of Getting Vaccinated:** We are seeing now immune protection against COVID-19 variants when individuals are vaccinated against the wild-type strain, namely the common virus in society, on two mechanisms: the antibody response that has a spillover effect and the cross-reactivity. Vaccination is not only going to protect us against the common COVID-19 virus in society, but it has the potential, to a greater or lesser degree, to also protect against a range of variants. So, when vaccination becomes available, get vaccinated.

Vaccine Updates

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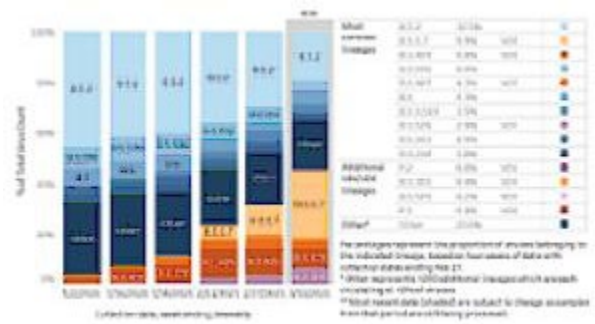

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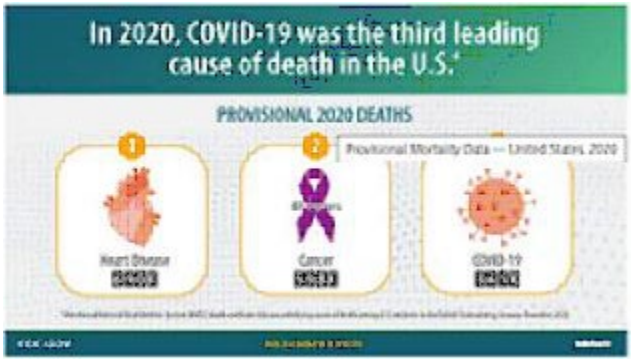

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Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA)
Subject: HHS COVID-19 Update - 3/31
Date: Wednesday, March 31, 2021 7:24:43 PM

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 31, 2021:

Highlights from the White House COVID-19 Response Team briefing:

Andy Slavitt:

- **Increasing Vaccination Sites:** The President committed to opening at least 12 more federally run mass vaccination sites, adding to the existing total of 25 sites. Three new sites will open next week in Memphis, Tennessee, Milwaukee, Wisconsin, and Greenbelt, Maryland, in addition to the two we announced on Monday in St. Louis, Missouri, and Gary, Indiana. Each of these sites is the first federally run mass vaccination site in its respective state, and each can administer 3,000 vaccinations a day.
- **Mask Mandates:** We need every governor, mayor, and local leader to maintain or reinstate mask mandates. And we need every American to do their part so that we can win this race and save lives.

Dr. Walensky:

- **Case Update:** CDC's most recent data show that the seven-day average of new cases is slightly less than 62,000 cases per day. We continue to see an increase, and this is almost a 12 percent increase from the seven-day period prior. Hospitalizations also continue to increase. The most recent seven-day average — about 4,900 admissions per day — is up from 4,600 admissions per day in the prior seven-day period. The seven-day average of deaths remains slightly above 900 deaths per day.
- **Inequities in COVID-19 Deaths:** COVID-19 deaths were highest for older adults and males, and were higher, as we previously saw, among American Indian and Alaska Natives, Hispanics, non-Hispanic Blacks, and non-Hispanic Native Hawaiian and Pacific Islander persons compared to non-Hispanic whites. In fact, among nearly all these ethnic and racial minority groups, the COVID-19-related deaths were more than double the death rate of non-Hispanic white persons. Based on the current state of the pandemic, these impacts have remained in 2021, where we continue to see that communities of color account for an outsize portion of these deaths.
- **Number of People Vaccinated:** This week, we will reach 100 million people who have received at least one dose of the COVID-19 vaccine in the United States — a remarkable feat in such a short period of time. Further, over 70 percent of people over age 65, our most vulnerable group, have received at least one vaccine dose. In addition to increasing the number of mass vaccination sites across the country with FEMA, expanding the Federal Retail Pharmacy Program, and ensuring that all Americans have a vaccine site within five miles of their home, we are also activating mobile vaccination units and clinics. CDC is also excited to partner with the Administration for Community Living to support their efforts to get older, at-risk adults and those with disabilities vaccinated.
- **Guidance for Adult Day Service Centers:** CDC updated COVID-19 guidance for adult day

service centers. These populations are at high risk for severe COVID-19 disease, and this guidance will help center administrators and staff protect themselves and adults receiving their services by promoting and engaging in preventive behaviors that reduce COVID-19 spread and help maintain healthy operations and environments of these facilities.

- **B.1.1.7 Variant:** We now have B.1.1.7 (U.K. variant) as 26 percent of the circulating variant across the United states, and it is the predominant strain in at least five regions of the United States. The variant is more transmissible – somewhere between 50 and 70 percent more transmissible than the wild-type strain. Therefore, to the extent that people are not practicing those standard mitigation strategies, we do think that more infections will result because of B.1.1.7. We believe that the current mitigation strategies of masking and distancing would work just as well against the current, the wild-type strain, as they do the B.1.1.7 strain.

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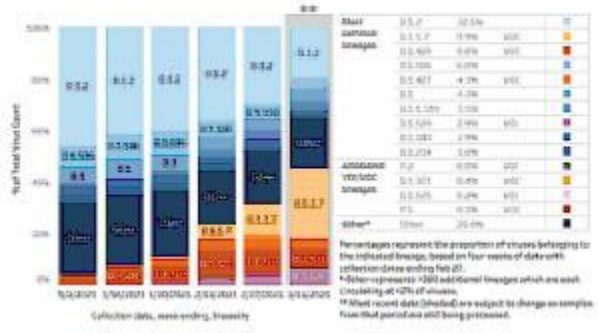

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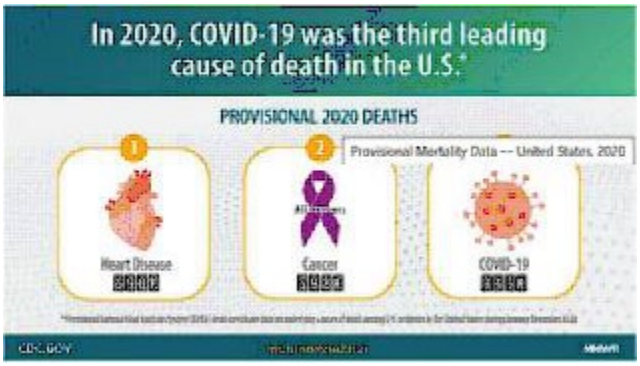

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Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA)
To: Baker, Michael (OS/IEA)
Subject: HHS COVID-19 Update - 4/19
Date: Monday, April 19, 2021 6:23:24 PM

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 19, 2021:

Renewal of Determination That a Public Health Emergency Exists: As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date (April 15, 2021) and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective April 21, 2021, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, that a public health emergency exists and has existed since January 27, 2020, nationwide.

Highlights from Friday and Monday's White House COVID-19 Response Team Briefing

Andy Slavitt

- **Vaccine Availability:** Over 80 percent of seniors have had at least their first shot. Fifty percent of adults in the U.S. have had at least one shot. We now have one thing on our mind: making sure that the other 50 percent know how easy it is to get a shot. If you still think it's too difficult your vaccine, here's what you need to know: the lack of supply, the shortage of locations, the confusing rules are all in the past. That cannot be said enough. There are thousands of more people ready to help you get vaccinated. There are now millions more vaccine doses available and waiting. There are now more than 60,000 safe and convenient places for you to get your shot.
- **Expanded Vaccine Eligibility:** If you are 16 or over, it is your turn to get vaccinated no matter where you live. There's a nine out of ten chance that you are located within five miles of your vaccine shot. For those of you who can't get to a vaccine site, we're helping community-based organizations connect vulnerable Americans with shots. And now, to get resources to healthcare providers serving at-risk populations and to promote equitable distribution of vaccines, today HHS is making $150 million available to community-based healthcare providers to strengthen their efforts to get shots in arms and care for patients with COVID-19.
- **Get Vaccinated:** Join the more than 130 million Americans who have already gotten at least one shot, that's half of all adults. Here's my direct plea to everyone listening: If you haven't already made an appointment to get vaccinated, make one right now. You are eligible. Then, reach out to your family, friends, and neighbors to make sure they can make an appointment too. See what help you can offer them to help those who might need extra assistance.
- **American Rescue Plan:** We are announcing a $1.7 billion investment to bolster the ability of the CDC and state and local public health departments to monitor, track, and defeat emerging threats — whether it's COVID-19 variants today or other viruses in the future — through a process known as genomic sequencing. This significant investment, which is made

possible due to the American Rescue Plan President Biden signed into law last month, is critical in our fight against the new and potentially dangerous variants of COVID-19. Right now, these variants account for nearly half of all COVID-19 cases in the United States, and we need more capacity in our public health system to identify and track these mutations. This funding will enable CDC and states to do more genomic sequencing as we activate the nation's great research capabilities to detect variants earlier and increase our visibility into emerging threats. This investment will give public health officials the chance to react more quickly to prevent and stop the spread. Today's investment also builds on the major investments in testing and genomic sequencing that we made earlier this year. That includes $10 billion of American Rescue Plan funding to support COVID-19 testing in schools, another $2.5 billion to help state and local public health agencies increase testing capacity in underserved and high-risk communities, and nearly $200 million to begin to increase genomic sequencing capacity that this investment comes on top of.

Dr. Walensky

- **Case Update:** Yesterday, CDC reported nearly 60,950 cases of COVID-19. Our seven-day average is up to over 67,440 per day. For context, one month ago, our seven-day average of cases was just over 53,000 per day. The seven-day average of hospital admissions is about 5,460. Sadly, the seven-day average of daily deaths are now increasing, with six consecutive days of increases, to about 695 deaths per day. Sunday, we again saw almost 700 deaths in a single day.
- **Vaccination Update:** So far, we have administered 209 million vaccine doses, with an average daily administration of more than 3 million doses. This brings us to 192.8 million doses in the first 100 days — 96 percent of our goal in 88 days. This means that almost 40 percent of the total population has received at least one dose of a COVID-19 vaccine, and one out of every four people is fully vaccinated. More than 65 percent of people age 65 and older and more than 25 percent of people are fully vaccinated.
- **Vaccine Effectiveness:** First, among nearly 4,000 healthcare personnel, first responders, and essential workers who received the Pfizer and Moderna vaccines, the risk of any infection, asymptomatic and symptomatic, was reduced by 90 percent after receiving the two recommended doses of the vaccine. This study was yet additional evidence that these vaccines are working. The efficacy we saw in clinical trials is now being shown in the real world. Second, last week, we released data on the number of so-called "breakthrough infections," of people who, despite being vaccinated, still tested positive for COVID-19 more than 14 days after they're getting their second vaccine dose. With any vaccine, we expect such rare cases. But so far, out of more than 84 million people who are fully vaccinated, we have only received reports of less than 6,000 breakthrough cases. Although this number is from 43 states and territories and likely an underestimate, it still makes a really important point: These vaccines are working. Of the nearly 6,000 cases, approximately 30 percent had no symptoms at all. Based on these data, here's the bottom line: Getting a vaccine will help protect you, it will help protect others, and it will help us end this pandemic.
- **Rising Cases and Variants:** Some of these increases are as a result of relaxed prevention efforts in states across the country, such as relaxed mask mandates or loosened restrictions on indoor restaurant seating. Another reason for these increases is the continued spread of highly transmissible variants — more than 50 to 70 percent more transmissible — which

makes the race to stop the transmission even more challenging and threatens to overwhelm our healthcare system again in parts of this country. CDC data show that the B117 variant — the variant originally identified in the United Kingdom — represents 44 percent of the virus circulating during the week of March 27th.

- **Johnson & Johnson Update:** After the press briefing on Wednesday (4/14), the Advisory Committee on Immunization Practices — or ACIP — met to discuss the six cases and provide recommendations. I want to thank the ACIP for their thoughtful discussion and their commitment to the science. The recommendation from this group of independent experts for a continued pause will allow additional time to review any additional cases that might come in, and for them to conduct a complete risk assessment and to evaluate the emerging science. ACIP will meet again this Friday, April 23rd, from 11:00 to 5:00 to provide further recommendations.

Dr. Fauci

- **Vaccine Efficacy in Clinical Trials:** This is work that has been done in tens of thousands of people in clinical trials, has been peer reviewed independently, and published in scientific journals. Pfizer and Moderna's efficacy are shown in the New England Journal of Medicine papers. The same holds true for J&J. All three are highly efficacious in clinical trials.
- **Vaccine Efficacy in Real-World Settings:** In over 23,000 employees at the University of Texas, the infection rate was miniscule among vaccinated employees: 0.05 percent. The CDC — looking, again, at the real-world effectiveness — showed that in almost 80,000 person-days with full immunization, 0.04 per 1,000 person-days.
- **Vaccine Safety:** We have an extraordinary capability to monitor safety, as an extremely rare adverse event of 6 individuals among 7,000 was picked up by the surveillance system. Those surveillance systems include ones that follow up on clinical trials, monitoring systems by the CDC, by the FDA, and other monitoring systems. When we say a vaccine is safe, you're talking about an exquisitely sensitive monitoring system.
- **NIH-sponsored Coronavirus Disease 2019 Treatment Guidelines Panel:** This is a panel of individuals co-chaired by Dr. Cliff Lane, who is the Deputy Director of NIAID, but also the Clinical Director of the Institute; Henry Masur, who is the Director of the Critical Care Medicine Unit at NIH; and Roy "Trip" Gulik, who is the Chief of Infectious Diseases at Weill Cornell Medicine in New York City. This panel was established to be able to work, literally in real time, updating guidelines for clinicians and healthcare providers throughout the country and the world on the latest information.

Dr. Murthy

- **American Indians and Alaska Natives:** According to a recent CDC report, American Indians and Alaska Natives were 3.5 times more likely to get COVID than a non-Hispanic, white population. Native people are also more than four times likely to be hospitalized as a result of COVID-19. Despite these challenges, our colleagues working in the Indian health system have heroically administered more than 1 million doses of COVID-19 vaccines. That is a remarkable achievement and a testament to their dedication. Today, the Biden administration is doubling down on this critical work with a — with a $4 billion investment from the American Rescue Plan to the Indian Health Service Tribal and urban Indian health programs. Specifically, these funds will support the following: expanded COVID-19

vaccinations, including mobile efforts, large-scale vaccination events, and public education and outreach campaigns; expanded testing, contact tracing, PPE access, and treatment; increased preventive health services for those at higher risk for COVID-19; and increased support for telehealth, the healthcare workforce, and the broader Indian healthcare system, which has been a hard hit during the pandemic due to lost reimbursements for care for both public and private insurance.

- **Increasing Access and Increasing Confidence:** The more people see those around and get vaccinated, particularly family and friends, the more comfortable they become with getting vaccinated themselves. The easier we make it to get vaccinated, the more people will get vaccinated, and that means more people around them would feel comfortable with getting vaccine themselves. That's why access and confidence go hand in hand, and so does safety. This brings me to the second topic. This week you've heard a lot from us about the pause with administering the Johnson & Johnson COVID-19 vaccine. These decisions are never simple, and this one was taken after a very careful assessment of the risks and benefits of calling for such a pause. However, the actions taken by CDC and the FDA this week should give Americans confidence that our safety system is working for them. For some members of the public, uncertainty about getting vaccinated stems from questions about how safe the vaccines are. This week is a reminder that safety is our top priority. Even when an extremely rare safety occurs, our scientific agencies will act with thoroughness and transparency so people can remain confident in the vaccines that are recommended to them.

Vaccine Updates

Vaccine Eligibility: CDC updated the following COVID-19 information pages to include that everyone 16 years of age and older is now eligible to get a COVID-19 vaccine: Vaccine FAQs, How Vaccines Get to You, Key Things to Know, and Vaccine Rollout Recommendations. CDC also updated the following information pages for specific communities to include the expanded eligibility of the COVID-19

vaccine: persons with disabilities, essential workers, healthcare personnel, older adults, and those high risk for severe illness. Get a COVID-19 vaccine as soon as you can. Moreover, CDC updated their general vaccination resources, including information on preparing for your vaccine.

Moderna Vaccine Update: The FDA updated their Moderna COVID-19 Vaccine Frequently Asked Questions page. On December 18, 2020, the U.S. Food and Drug Administration issued an emergency use authorization for the second vaccine for the prevention of coronavirus disease 2019 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows Moderna COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

Johnson & Johnson Update: On April 13, 2021, CDC and FDA recommended a pause in the use of Johnson & Johnson's Janssen COVID-19 Vaccine. Of the nearly 7 million doses administered so far in the United States, a small number of reports of a rare and severe type of blood clot have been reported in people after receiving the J&J/Janssen COVID-19 Vaccine. All reports occurred among women between the ages of 18 and 48, and symptoms occurred six to 13 days after vaccination. As of April 13, 2021, of the more than 180 million doses administered so far of the Pfizer-BioNTech or Moderna vaccines, no reports matching those associated with the J&J/Janssen vaccine have been received.

FEMA's J&J Update: In alignment with the recommendation from the CDC and FDA to pause the use of the Johnson & Johnson vaccine, FEMA immediately ceased administration of these doses at our federal community vaccination center pilot sites and mobile vaccine units. This pause will continue until further guidance is received from CDC and FDA. We are working with our state partners to determine the path forward and find alternative vaccine options for these sites.

FEMA Vaccination Sites: There are 31 active or temporarily closed federal community vaccination center pilot sites and 20 mobile pop-up sites in 22 states. Additionally, there are 10 mobile vaccination units deployed to eight states. These centers and units have administered more than 3.4 million vaccinations. Working with state governments FEMA will open additional federal community vaccination center pilot sites, which include federal support and supplemental vaccine allocation: this week, federal community vaccination center pilot sites are scheduled to open in Bessemer, Alabama; Tulsa, Oklahoma; and Central Point, Oregon. Last week, FEMA transitioned management

of the federal community vaccination center pilot sites in Los Angeles and Oakland to the state. FEMA continues to support both sites with federal personnel. Additionally, FEMA has obligated more than $936 million to support the state's vaccination efforts. These sites administered more than 671,000 shots since they opened on Feb. 16. FEMA mobile vaccination units have begun operations. These vehicles can bring vaccinations to hard-to-reach and high-risk populations who cannot access services from fixed sites. Ten mobile vaccination units are currently deployed to Connecticut, Maine, Maryland, Nebraska, Nevada, New Mexico, Oregon and South Dakota.

DoD Response to J&J Pause: In a press briefing on Friday, Pentagon Press Secretary John F. Kirby stated that while the DoD intended to use the Johnson & Johnson vaccine to support overseas personnel and their families, the vaccine distribution planners on our COVID task force developed a plan to reallocate doses of the Moderna vaccine to our overseas commands. Each service will now direct a total of approximately 30,000 additional doses of Moderna throughout the month of May. That's around roughly 10,000 per week, beginning May 10th, to overseas locations in European Command, Indo-Pacific Command and Central Command. This will help keep the vaccination efforts right on pace to provide initial doses to over 70 percent of our overseas personnel and their families by the end of May.

COVID-19 Illness After Vaccination: CDC released information regarding what you should know about the possibility of COVID-19 illness after vaccination. COVID-19 vaccines are effective. However, a small percentage of people who are fully vaccinated will still get COVID-19 if they are exposed to the virus that causes it. These are called "vaccine breakthrough cases." This means that while people who have been vaccinated are much less likely to get sick, it may still happen. Experts continue to study how common these cases are.

CDC Weekly Review: On Friday, CDC released their weekly review on the COVID-19 pandemic, including updated numbers of reported cases, SARA-CoV-2 variants, testing, vaccinations, hospitalizations, and deaths. Nationally, COVID-19-related emergency department visits as well as both hospital admissions and current hospitalizations have risen among patients ages 18 to 64 years in recent weeks. The good news is that emergency department visits and hospitalizations among people ages 65 years and older have decreased, likely demonstrating the important role vaccination plays in protecting against COVID-19. As access to vaccines for all Americans increases, we have reason to be hopeful. However, until more of the U.S. population is fully vaccinated, consistent use of prevention strategies, such as universal and correct use of masks, social distancing, and hand washing, will help to limit the spread of SARS-CoV-2, the virus that causes COVID-19. Even if you have been fully vaccinated against COVID-19, you should keep taking these everyday precautions in public places. For more information, view the CDC's data on vaccinations, vaccination demographics, and vaccination trends.

Operational Considerations for Jurisdictions Planning to Operate COVID-19 Vaccination Clinics: CDC released guidance for jurisdictions planning to operate COVID-19 vaccinations clinics. Safe and effective COVID-19 vaccines have been developed and authorized and are being manufactured. Jurisdictions are presently vaccinating people in their target populations. Currently, vaccine is available in growing quantities, with even more vaccine slated to become available soon. Most jurisdictions can provide access to vaccination using a combination of usual vaccination providers

(pharmacies and medical providers/community health centers) and a limited number of public health clinics. Many jurisdictions are planning for and operating multiple, temporary, large- and small-scale vaccination sites, both fixed location and mobile, as strategies to vaccinate more of the population rapidly. The Federal Emergency Management Agency (FEMA) is working with jurisdictions to establish Community Vaccination Centers (CVCs). These CVCs can be established as fixed facilities, drive-through facilities, or as mobile vaccination clinics based on a jurisdiction's needs.

ACIP Jurisdictions Estimated Worker Population: CDC updated their information from the Advisory Committee on Immunization Practices (ACIP) regarding vaccination data among different worker populations.

Testing and Treatment

FDA Revokes EUA for Monoclonal Antibody Bamlanivimab: On Friday, the FDA revoked the emergency use authorization (EUA) that allowed for the investigational monoclonal antibody therapy bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. Based on its ongoing analysis of emerging scientific data, specifically the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone resulting in the increased risk for treatment failure, the FDA has determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. Therefore, the agency determined that the criteria for issuance of an authorization are no longer met and has revoked the EUA. Instead of administering Bamlanivimab alone, health care providers should consider using the other authorized monoclonal antibody therapies expected to retain activity against the viral variants: Casirivimab and imdevimab, administered together, and Bamlanivimab and etesevimab, administered together.

FDA Testing Update: As of Friday, 363 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 266 molecular tests and sample collection devices, 75 antibody and other immune response tests, and 22 antigen tests. There are 46 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home tests, four over-the-counter (OTC) at-home antigen tests, and two OTC molecular tests. The FDA has authorized 7 antigen tests and 2 molecular tests for serial screening programs. The FDA has also authorized 457 revisions to EUA authorizations.

Funding

$150 Million from ARP to Support Community-Based Health Care Providers: HHS announced the availability of nearly $150 million to community-based health care providers to aid their response to COVID-19. These funds will support approximately 100 Health Center Program look-alikes to respond to and mitigate the spread of COVID-19, strengthen vaccination efforts, and enhance health care services and infrastructure in communities across the country. Health center look-alikes (LALs) are community-based health care providers that provide essential primary care services to underserved communities and vulnerable populations but are not Health Center Program grantees. This funding

will be made available through the Health Resources and Services Administration (HRSA) and is part of President Biden's commitment to ensuring equity in the nation's COVID-19 response and vaccination efforts.

Biden Administration Announces $1.7 Billion Investment to Fight COVID-19 Variants: In order to improve the detection, monitoring, and mitigation of COVID-19 variants, the Biden Administration is rapidly investing $1.7 billion from the American Rescue Plan to help states and other jurisdictions more effectively fight these mutations. An essential component of the response to the emerging COVID-19 variants is increasing the country's genomic sequencing — the process by which COVID DNA is decoded and potentially deadly mutations in the virus are detected. With this funding, allocated through the Centers for Disease Control and Prevention (CDC), will help the CDC, states, and other jurisdictions more effectively detect and track variants by scaling genomic sequencing efforts. With the information from sequencing, the CDC and state and local public health leaders can implement known prevention measures to stop the spread.

Biden Administration Invests $4 Billion in ARP Funding to Combat COVID-19 in Indian Country: As part of President Biden's continued efforts to ensure the pandemic response reaches all people and all communities, the Biden Administration is announcing it will invest more than $4 billion to combat COVID-19 in Indian Country. The funding, from the American Rescue Plan, will expand COVID-19 vaccinations, testing, and treatment; increase preventive health services to American Indians and Alaska Natives at higher risk for COVID-19; expand hospitals' and health clinics' ability to serve their communities during the pandemic and beyond; and provide the Indian Health Service (IHS), tribal health programs, and urban Indian health programs with needed funding to make up for lost reimbursements experienced during the pandemic.

FEMA Funeral Assistance Funding: As of today, FEMA has received more than 101,000 funeral assistance applications. Applicants may apply by calling 844-684-6333 (TTY: 800-462-7585) from 9 a.m. to 9 p.m. ET, Monday through Friday. Multilingual services are available. Callers who use a relay

service, videophone or captioned telephones should provide their specific number assigned to that service. It is important that FEMA is able to contact applicants. Please note, phone calls from FEMA may come from an unidentified number. FEMA will not contact anyone until they have called FEMA or have applied for assistance.

Reopening Guidance

Personal and Social Activities: CDC updated their information on engaging in personal and social activities. COVID-19 cases, hospitalizations, and deaths are extremely high across the United States. To decrease your chance of getting and spreading COVID-19, CDC recommends that you do not gather with people who do not live with you at this time. Attending events and gatherings increases your risk of getting and spreading COVID-19. Stay home to protect yourself and others from COVID-19.

Travel Health Notices: CDC updated their travel health notices to provide current risk assessment levels for COVID-19 in different countries.

Considerations for Casinos and Gaming Operations: As some casinos and gaming operations resume in some areas of the United States, CDC offers the following considerations for ways in which casino and gaming operators can help protect staff and customers and slow the spread of COVID-19. Casinos and gaming operations can determine, in collaboration with local, state, territorial, federal, or tribal health officials, whether and how to implement these considerations, making adjustments to meet the needs and circumstances of the local community. Implementation should be guided by what is feasible, practical, acceptable, and tailored to the needs of each community. For more information on bars and restaurants within casinos, please see CDC's Considerations for Restaurants and Bars. These considerations are meant to supplement—not replace—any local, state, territorial, federal, or tribal safety laws, rules, or regulations with which businesses must comply.

Community-Based Organizations: CDC updated their guidance for community-based organizations (CBOs). As some CBOs begin to resume or increase their level of activities, CDC offers considerations for ways these organizations can help protect individuals and communities and slow the spread of coronavirus disease 2019 (COVID-19). COVID-19 cases, hospitalizations, and deaths are extremely high across the United States. To decrease your chance of getting and spreading COVID-19, CDC recommends that you do not gather with people who do not live with you at this time. Attending events and gatherings increases your risk of getting and spreading COVID-19. Stay home to protect yourself and others from COVID-19.

Considerations for Institutions of Higher Education: CDC updated their guidance for institutions of higher education (IHEs). As some IHEs prepare to re-open or keep open in-person learning in the United States, IHEs are faced with the challenge of keeping students, faculty, staff, and volunteers safe due to the coronavirus disease 2019 (COVID-19) pandemic. CDC offers the following considerations for ways that IHEs can help protect students and employees (e.g., faculty, staff, and administrators) and slow the spread of COVID-19. This document refers only to risks related to COVID-19. IHEs may consider implementing several strategies to maintain healthy environments.

Information for Specific Populations

USDA Activities to Contain the COVID-19 Pandemic: The United States Department of Agriculture (USDA) updated their fact sheet on activities to contain the COVID-19 pandemic. USDA has deployed 1,064 disaster, public health specialists to assist with federal response.

Guidance for Large or Extended Families Living in the Same Home: CDC released guidance for large or extended families living in the same home. If you or someone in your household is at increased risk for severe illness from COVID-19, then all family members should act as if they are at increased risk. This can be difficult if space is limited for large or extended families living together. While avoiding close contact with others and isolating someone who is sick can feel lonely, these actions are necessary to reduce the spread of COVID-19 and protect yourself and your household.

DoD Force Health Protection Guidance: On Friday, the Department of Defense released the memorandum for Force Health Protection Guidance (Supplement 20) – Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic. This memorandum applies to official and unofficial travel and proves updated pre- and post-travel guidance for purposes of force health protection (FHP) for Service members, DoD family members, DoD civilian employees, and DoD contractor personnel, as well as fully vaccinated individuals.

Staffing Resources: CDC updated their staffing resources and guidance to strengthen the public health workforce. CDC updated their information regarding the number of CDC COVID-19 response staff deployed across America.

Cleaning, Disinfecting, and Ventilation: CDC updated their resources for cleaning, disinfecting, and ventilation, including an updated toolkit for school administrators on cleaning, disinfection, and hand hygiene. Reducing the risk of exposure to SARS-CoV-2, the virus that causes COVID-19, by cleaning and disinfection is an integral part of opening schools that will require careful planning.

Childhood Vaccination Toolkit for Clinicians: CDC released a toolkit for clinicians on getting children caught up on receiving recommended vaccinations. COVID-19 disrupted both in-person learning and routine well-child visits for many children over the last year. As a result, too many children have fallen behind on receiving recommended vaccines. Children need to get caught up now so that they are protected as they go back to in-person learning and summer camps. Healthcare providers can identify families whose children have missed doses and contact them to schedule appointments. Providers can also let families know what precautions are in place for safe delivery of in-person services.

Health Departments and Public Safety Partners: CDC updated their information for health departments and public health partners to help educate communities and promote COVID-19 vaccination.

Manufacturing Workers & Employers: CDC and the Occupational Safety and Health Administration (OSHA) updated their guidance for manufacturing workers and employers.

Acute Care Delivery at Home Tip Sheet: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released a tip sheet providing an overview of characteristics of various types of acute care delivery at home programs to help healthcare providers better understand this care model. Some healthcare providers and systems have been providing hospital-level care in patient's homes for years; others have implemented acute care delivery at home models in response to overcrowding at hospitals due to COVID-19.

COVID-19 and Healthcare Professional Stress and Resilience: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released Issue 12 of The Exchange, which examines the impact of COVID-19 on healthcare professionals. The issue focuses on three categories: understanding acute and chronic stressors in the healthcare worker population, identifying at-risk employees, and promising practices in building resilience.

COVID-19 Healthcare Delivery Impacts: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) updated their tip sheet to help healthcare system planners prepare to mitigate potential healthcare delivery impacts.

Strategies to Help Combat the Coronavirus Blues: The COVID-19 Schools Task Force, FEMA Region VII, and HHS Region 7 released a document summarizing the contents of the Mind Over Matter Resource Guide. This guide can be used to support messaging for college and university campus communities to help combat COVID-19 fatigue and promote general wellness, both during and after the pandemic.

Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19: On April 2, 2021, the CDC released a declaration determining that the eviction of tenants could be detrimental to public health control measures to slow the spread of COVID-19. View the posted order, as well as eviction protection declaration forms in English and Spanish. Please visit HUD's COVID-19 Emergency Information for Housing Counselors for additional resources and information.

United States Coast Guard Vaccine FAQs: The United States Coast Guard updated their Frequently Asked Questions page about the vaccine, and specific questions related to Coast Guard administered vaccines.

Older Adults: CDC updated their information for older adults, who are at a greater risk of hospitalization or dying if diagnosed with COVID-19. The risk for severe illness with COVID-19 increases with age, with older adults at highest risk. If you have a family member or friend who lives in a nursing home, assisted living facility, or other type of senior living or retirement community, you may be concerned about COVID-19. To protect friends and family members who live in these communities, CDC has issued updated recommendations for visitations at post-acute facilities. These recommendations align with the Centers for Medicare and Medicaid Services (CMS) guidance for visitations under various circumstances.

Caring for Someone Sick: CDC updated their guidance for caregivers in non-healthcare settings. Cleaning with a household cleaner that contains soap or detergent reduces the amount of germs on

surfaces and objects and decreases risk of infection from surfaces. In most situations, cleaning alone removes most virus particles on surfaces.

People at Increased Risk: CDC updated their resources available for people at increased risk, and for other people who need to take extra precautions.

Non-Emergency Transportation for Tribal Communities: CDC updated their guidance on non-emergency transportation for tribal communities. Tribal community members may need to regularly share personal vehicles with members outside of their own households. They may also need to use personal vehicles to transport people who are visibly sick. In addition, tribal organizations may provide medical transportation to their community members using non-emergency vehicles (cars or vans, for example). CDC outlines precautions that can be considered to minimize risk of spreading COVID-19 when sharing personal vehicles.

Implementing Screening and Treatment of Unhealthy Alcohol Use During COVID-19: The Agency for Healthcare Research and Quality (AHRQ) posted an article on implementing screening and treatment of unhealthy alcohol use during COVID-19. Since the onset of the COVID-19 pandemic in March 2020, alcohol sales have increased dramatically in many States across the country and rates of unhealthy alcohol use are rising in parallel. Unhealthy alcohol use, which refers to the full spectrum of alcohol misuse from risky or hazardous drinking to alcohol use disorder, is associated with adverse consequences, including poorer physical and mental health outcomes as well as negative socioeconomic effects. AHRQ's EvidenceNow: Managing Unhealthy Alcohol Use Initiative represents an important opportunity to help clinicians support many patients receive the appropriate diagnosis, counseling, and treatment for unhealthy alcohol use by implementing the best patient-centered outcomes research findings available to improve health.

Sprayers Safety Precautions: CDC updated their information regarding how to select cleaners, disinfectants, and application methods for use in facilities, businesses, and public indoor spaces to ensure that you can clean and disinfect safely and effectively. In most situations, cleaning surfaces (using soap or detergent) is enough to reduce SAR-CoV-2, the virus that causes COVID-19. Clean surfaces before disinfecting.

CMS Updates

Encouraging Latino Consumers to Enroll in Health Insurance Coverage: Today, HHS Secretary Xavier Becerra announced commitments from national organizations to support Latino outreach and enrollment efforts during the current Special Enrollment Period (SEP) made available on HealthCare.gov by President Biden due to the COVID-19 Public Health Emergency (English | Spanish). As part of the Latino Week of Action April 18 - 24, these organizations and HHS will share information with Latino consumers and use social media to encourage them to enroll in affordable, quality health plans through HealthCare.gov. Access to affordable health coverage and care is particularly important for Latinos in the US because 22% of non-elderly Latinos are uninsured, a rate almost 2.5 times that of White Americans. During this week and beyond, HHS and many organizations will send targeted messages, participate in earned media opportunities, and amplify the SEP through social media channels to raise awareness about the coverage options available

through HealthCare.gov for the Latino community. The Centers for Medicare & Medicaid Services (CMS) has also launched an outreach and an educational campaign, which includes broadcast and digital advertising and educates through email and text messages in both Spanish and English.

PPE

Guidance for Wearing Masks: CDC updated their guidance for wearing masks. Masks are a simple barrier to help prevent your respiratory droplets from reaching others. Studies show that masks reduce the spray of droplets when worn over the nose and mouth. CDC also updated their information on the different types of masks. CDC recommends that N95 respirators should be prioritized for protection against COVID-19 in healthcare settings. Essential workers and workers who routinely wore respirators before the pandemic should continue wearing N95 respirators. As N95s become available they can be worn in non-healthcare settings.

Research

Large Clinical Trial to Study Repurposed Drugs to Treat COVID-19 Symptoms: The NIH will fund a large, randomized, placebo-controlled Phase 3 clinical trial to test several existing prescription and over-the-counter medications for people to self-administer to treat symptoms of COVID-19. Part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public–private partnership, the ACTIV-6 trial aims to provide evidence-based treatment options for the majority of adult patients with COVID-19 who have mild-to-moderate symptoms and are not sick enough to be hospitalized. NIH will provide an initial investment of $155 million in funding for the trial.

Experimental Antiviral for COVID-19 Effective in Hamster Study: The experimental antiviral drug MK-4482 significantly decreased levels of virus and disease damage in the lungs of hamsters treated for SARS-CoV-2 infection, according to a new study from NIH scientists. SARS-CoV-2 is the virus that causes COVID-19. MK-4482, delivered orally, is now in human clinical trials. Remdesivir, an antiviral drug already approved by the U.S. Food and Drug Administration for use against COVID-19, must be provided intravenously, making its use primarily limited to clinical settings. In their study, published in the journal *Nature Communications*, the scientists found MK-4482 treatment effective when provided up to 12 hours before or 12 hours after infecting the hamsters with SARS-CoV-2. These data suggest that MK-4482 treatment potentially could mitigate high-risk exposures to SARS-CoV-2 and might be used to treat established SARS-CoV-2 infection alone or possibly in combination with other agents.

Public Health Investigations of COVID-19 Vaccine Breakthrough Cases: CDC released a case investigation protocol on public health investigations of COVID-19 vaccine breakthrough cases. The U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for three COVID-19 vaccines. In large, randomized controlled trials, each vaccine was safe and efficacious for preventing symptomatic, laboratory-confirmed COVID-19 disease. There were no statistically significant differences in efficacy by age, gender, race, or comorbidities. Despite the high level of efficacy, a small number of breakthrough cases occurred. The phase 3 studies have not yet identified risk factors for vaccine breakthrough cases; however, approximately 44,000 people received the FDA-authorized vaccines during the clinical trials and follow-up is ongoing. This protocol can be used

to guide public health investigations of COVID-19 vaccine breakthrough cases. We aim to capture both symptomatic and asymptomatic infections. Characterization of vaccine breakthrough cases could provide the first indication that a vaccine is less effective in certain demographic groups or that vaccine-induced immunity is waning, and booster doses may be needed. Clustering of cases among vaccinated persons by time, geographic area, or lot could help identify an issue in manufacturing, shipping, handling, or administration. Evaluating SARS-CoV-2 strains that cause vaccine breakthrough cases provides one way to monitor for variant strains that could result in lower vaccine efficacy.

COVID-19 and the Changing Healthcare Delivery Landscape: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released a study highlighting the impact of COVID-19 on healthcare delivery. The study examines supply chain, patients delaying emergency care, the delay of elective procedures, and financial impacts to the healthcare system.

COVID-19 Science Update: CDC released their weekly COVID-19 Science Update. This week's issue includes, but is not limited to, research on the following: the association of sociodemographic factors and blood group type with risk of COVID-19, increased household secondary attack rates with variants of concern**,** and the epidemiologic evidence for airborne transmission of SARS-CoV-2 during church singing.

Hospitalization and Death by Race/Ethnicity: CDC updated their information on hospitalization and death rates by race/ethnicity. Race and ethnicity are risk markers for other underlying conditions that affect health including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: HHS IEA (OS/IEA)
To: HHS IEA (OS/IEA)
Subject: HHS COVID-19 Update - 8/5
Date: Thursday, August 5, 2021 9:08:37 PM

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for August 5, 2021:

Highlights from President Biden's August 3rd Remarks on Fighting the COVID-19 Pandemic

- **Delta Variant and Transmissibility:** President Biden stated that because the Delta variant is highly transmissible, it is causing a new wave of cases, accounting for over 80% of cases in the United States today, with a likelihood of an increase in cases in the future. Biden states that the predicted increase is "a largely preventable tragedy that will get worse before it gets better."
- **COVID-19 and Vaccines:** Biden stated that the best way to protect yourself from COVID-19 is to get vaccinated; if vaccinated, it is highly unlikely to get COVID-19 and, if you contract the virus, you will likely experience mild symptoms if any. The data shows that the vast majority of cases, hospitalizations, and deaths due to COVID-19 are from the unvaccinated population. Biden commented, "The best line of defense against the virus is the vaccine… We have a pandemic of the unvaccinated."
- **Data of Increased Vaccination:** Biden reported a 55 percent increase in the average number of new people getting vaccinated every day in the past two weeks, and the highest seven-day total in a month. The eight states with the highest current case rates have seen a doubling of the number of people newly vaccinated each day. Biden declared that "we have to continue our aggressive efforts to vaccinate the unvaccinated."
- **Federal Steps to Incentivize Vaccination:** Biden outlined steps taken by his administration and other government-affiliated organizations to increase vaccinations. Places that have offered $100 to get vaccinated have seen an uptick of 25 percent of daily vaccination rates. Biden reiterated his plan to reimburse small- and medium-sized businesses who give paid time off to their employees to get vaccinated, to work with the Pentagon on adding COVID-19 to required vaccines for troops, and to require healthcare workers in the Department of Veterans Affairs to be vaccinated. Biden stated that these restrictions are "tough, unpopular steps to keep people safe and our economy strong."
- **States' Lack of Action on COVID:** President Biden stated that many states' harmful laws on mask mandates is disappointing and harmful; seven states have both banned mask mandates statewide and in schools while many students are not yet eligible to be vaccinated. The president cited these measures and accompanying low vaccination rates as the cause of the rise of cases, citing Florida and Texas as accounting for a third of all new cases. Biden declared that "COVID-19 is a national challenge, and we must come together — we have to come together — all of us together, as a country, to solve it."
- **Vaccination Abroad:** Biden stated that a global attack on the virus is in the United States' national interest. New, potentially more dangerous variants (such as the Delta variant) can mutate outside of the United States and threaten the country if a global approach is not taken. Biden highlighted American action in global vaccination, announcing that he will

purchase and donate 500 million doses from Pfizer; he also stated that the U.S. has domestically manufactured 110 million doses for global vaccination. Biden reiterated that he's "been very clear-eyed that we need to attack this virus globally, not just at home, because it's in America's self-interest to do so."

Highlights from the White House COVID-19 Response Team Briefing

Jeff Zients

- **Update on Progress in the Fight Against COVID:** Mr. Zients highlighted how, driven by the Delta variant, cases are continuing to rise, especially among the unvaccinated. Zients states that over the past seven days, seven states — among the leaders in unvaccinated percentage — accounted for half of the new cases and hospitalizations despite holding less than a quarter of US population; vaccines are the best way to protect against COVID. Vaccinations are on the rise; the past 24 hours served as the greatest number of vaccinations in a single day since July 3 and the daily average of vaccinations has increased for the fourth week in a row. Zients said that "clearly Americans are seeing the impact of being unvaccinated and unprotected and they respond by doing their part, rolling up their sleeve, and getting vaccinated."
- **Action on Vaccination Requirements:** Mr. Zients reiterated President Biden's call for federal workers and contractors to get vaccinated and notes the further requests for similar requirements in the private sector. Zients stated that over 650 colleges and universities are requiring students and staff on campus to be vaccinated and nationwide, over 100 hospitals and healthcare systems are requiring healthcare professionals to be vaccinated. "America's businesses, large and small, universities and medical schools, and many other institutions are stepping up on vaccination requirements and our message is quite simple: we support these vaccination requirements to protect workers, communities, and the country," Zients said.
- **COVID-19 Surge Response Teams:** Mr. Zients stated that the COVID-19 Surge Response Teams are in 16 states and addressing each state's specific needs, whether that is increased testing, mobile vaccination clinics, or hospital capacity. Zients noted the hundreds of federal employees deployed to the states that are assisting in combatting COVID. "Our whole of government response," Zients said, "will continue its relentless efforts to end this pandemic and deliver progress each and every day."

Dr. Walensky

- **COVID-19 Case Update:** Dr. Walensky stated that on August 3, the CDC reported 103,455 new cases of COVID with a 7-day average of about 89,463 cases per day, representing an increase of 43.3% from last week. Hospitalizations and deaths from this week compared to the last increased significantly; deaths rose 39.3 percent. Walensky stated that 83% of counties within the United States are experiencing moderate or high transmission. Those at high risk remain people who have not yet been vaccinated. Walensky said that "now is the time to get vaccinated. We know these vaccines are working and we know that they save lives."

Dr. Fauci

- **Vaccine Hesitancy and Concern Over Development Speed:** In response to Americans

worried about the speed of the development of the vaccine, Dr. Fauci outlined the various ways in which the vaccine is safe and not rushed: the investment of logistics and resources, the decades of prior research (both in platform technology and immunogen), the non-sequential investment in vaccine development, and the reuse of clinical trial sites originally built for HIV and influenza further sped the development. Fauci said that the vaccine "did not go too fast; it was a major investment both in the logistics, the resources, and the clinical and basic research."

Dr. Murthy

- **Vaccine Efficacy:** Dr. Murthy stated that the COVID-19 vaccines protect against the Delta variant, both at reducing the risk of infection and the severity if infected. Murthy said that "breakthrough infections of vaccinated people are the exception, not the rule."
- **Meeting of Living Surgeons General:** Yesterday, Dr. Murthy met with the living former surgeons general to discuss the vaccination effort with equity being at the forefront. The meeting covered health misinformation, ensuring that communities of color and rural areas are not left behind, and engaging with trusted community messengers. Murthy stated that "this gathering of surgeons general reflected the diversity of our nation, and it was emblematic of what we have to do together to defeat the virus."

Testing and Treatment

FDA Testing Updates: As of August 3, 398 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 279 molecular tests and sample collection devices, 87 antibody and other immune response tests and 32 antigen tests. There are 53 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, six antigen over-the-counter (OTC) at-home tests and two molecular OTC at-home tests. The FDA has authorized 13 antigen tests and eight molecular tests for serial screening programs. The FDA has also authorized 595 revisions to EUA authorizations.

Funding

FEMA COVID-19 Funeral Assistance Tops $888 Million: FEMA announced that COVID-19 funeral assistance has now increased to over $888 million to more than 135,000 people to assist with COVID-19-related funeral costs for deaths occurring on or after Jan. 20, 2020. The assistance, easing financial stress, comes from the Coronavirus Response and Relief Supplemental Appropriations Act of 2021 and the American Rescue Plan Act of 2021. Eligibility determinations are not driven by state/location; instead, they are based on when the applicant submits all required documentation.

Information for Specific Populations

CDC Issues Eviction Order in Areas of Substantial and High Transmission: CDC announced that Director Dr. Rochelle Walensky signed an order on August 3rd determining the evictions of tenants for failure to make rent or housing payments could be detrimental to public health control measures to slow the spread of SARS-CoV-2, the virus that causes COVID-19. This order will expire on October 3, 2021 and applies in United States counties experiencing substantial and high levels of community

transmission levels of SARS-CoV-2: This temporary protection from eviction in counties with heightened levels of community transmission exists in order to respond to recent, unexpected developments in the trajectory of the COVID-19 pandemic, including the rise of the Delta variant. It is intended to target specific areas of the country where cases are rapidly increasing, which likely would be exacerbated by mass evictions.

CDC Extends Order at the Southern and Northern Land Borders: The Centers for Disease Control and Prevention (CDC) has issued an order under Sections 362 and 365 of the Public Health Service Act, and associated implementing regulations, that temporarily suspends the introduction of certain noncitizens. The order is based on the Director's determination that introduction of such noncitizens, regardless of their country of origin, migrating through Canada and Mexico into the United States creates a serious danger of the introduction of COVID-19 into the United States, and the danger is so increased by the introduction of such noncitizens that a temporary suspension is necessary to protect the public health. Unaccompanied noncitizen children already excepted under a July 16, 2021, order, remain excepted from the order's coverage.

Readout of the Sixth Covid-19 Health Equity Task Force Meeting: HHS released a readout on Friday, July 30's, sixth COVID-19 Health Equity Task Force meeting to consider interim recommendations addressing future pandemic preparedness. Task Force Members discussed and voted favorably on interim recommendations, including but not limited to exploring strategies that meet local and regional staffing needs during pandemic response, expanding adequate and evidence-based healthcare access and funding infrastructure to treat patients in congregate settings, establishing and adjusting national standards as well as strategically target funding for water, sewage, and air quality to where it's needed, based on data from reliable equity indicators.

What to Consider When Planning to Operate a COVID-19 Vaccine Clinic: CDC released information regarding what to consider when planning to operate a COVID-19 vaccine clinic. The informational sheet provides guidance to conduct a gap analysis to determine specific geographic areas and specific populations that may benefit from additional sites to improve access to vaccination, work with community leaders and trusted members of the community to help with the success of vaccination clinics, and assess the optimal time to activate a vaccination site and consider the benefits of focused vaccination efforts. The page also page also provides a checklist of best practices for vaccination clinics held at satellite, temporary, or off-site locations.

Know What to Expect at Your Child's K- 12 School or Child Care Program: CDC released information for parents on what to expect for K-12 school or childcare programs. The page provides information for factors that a child's school or care program may consider, prevention strategies for these programs, and vaccination and masking.

CMS Updates

Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Rates Final Rule (CMS-1752-F): CMS announced that, on August 2, 2021, it issued the final rule for fiscal year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS). The final rule

updates Medicare payment policies and rates for operating and capital-related costs of acute care hospitals and for certain hospitals and hospital units excluded from the IPPS for FY 2022. The policies in this IPPS and LTCH PPS final rule build on key priorities to close health care equity gaps and support greater access to life-saving diagnostics and therapies during the COVID-19 public health emergency (PHE) and beyond. To continue to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments and to minimize any potential payment disruption immediately following the end of the PHE, CMS is extending the New COVID-19 Treatment Add-on Payment for eligible COVID-19 products through the end of the fiscal year in which the PHE ends.

Research

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings: CDC released an *MMWR* on the outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings in Barnstable County, Massachusetts in July, 2021. This report was released as an *MMWR* Early Release on July 30. Variants of SARS-CoV-2 continue to emerge. The B.1.617.2 (Delta) variant is highly transmissible. In July 2021, following multiple large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; 346 (74%) occurred in fully vaccinated persons. Testing identified the Delta variant in 90% of specimens from 133 patients. Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not. Jurisdictions might consider expanded prevention strategies, including universal masking in indoor public settings, particularly for large public gatherings that include travelers from many areas with differing levels of SARS-CoV-2 transmission. CDC Director Rachelle Walensky, MD, MPH, released an accompanying statement on the MMWR.

COVID-19 Vaccine Safety in Adolescents Aged 12–17: CDC released an *MMWR* on COVID-19 vaccine safety in adolescents aged 12–17 in the United States from December 14, 2020 - July 16, 2021. This report was released as an *MMWR* Early Release on July 30. In preauthorization trials of the Pfizer-BioNTech COVID-19 vaccine, adolescents aged 12–17 years reported local and systemic mild and moderate reactions. Myocarditis has been observed after vaccination with mRNA vaccines in post authorization monitoring. Local and systemic reactions after vaccination with Pfizer-BioNTech vaccine were commonly reported by adolescents aged 12–17 years to U.S. vaccine safety monitoring systems, especially after dose 2. A small proportion of these reactions are consistent with myocarditis. Mild local and systemic reactions are common among adolescents following Pfizer-BioNTech vaccine, and serious adverse events are rare. The Advisory Committee on Immunization Practices conducted a risk-benefit assessment and continues to recommend the Pfizer-BioNTech COVID-19 vaccine for all persons aged ≥12 years.

Full-dose Blood Thinners Reduce the Need for Organ Support in Moderately Ill COVID-19 Patients, but Not in Critically Ill Patients: NIH released a report on full-dose blood thinners reducing the need for organ support in moderately ill COVID-19 patients, but not critically ill patients. In April 2020, hospitalized COVID-19 patients received either a low or full dose of heparin, a blood thinner, for up to 14 days after enrollment. By December 2020, interim results indicated that full-dose anticoagulation did not reduce the need for organ support and may even cause harm in critically ill

patients. However, one month later, interim results indicated that full doses of heparin likely benefited moderately ill patients. The full study can be viewed here.

Long-Term Study of Brain Development Records Pandemic Life: NIH released a report on the analysis of adolescent brains to examine the long-term health impacts caused by the COVID-19 pandemic and shutdowns. Through surveys and tests, the study, from Adolescent Brain Cognitive Development (ABCD) Study and funded by NIH, is capturing the impact of the COVID-19 pandemic on children using an MRI.

Case Forecasts: This week's national ensemble predicts that 350,000 to 1,800,000 new cases will likely be reported in the week ending August 28, 2021. Over the last several weeks, more reported cases have fallen outside of the forecasted prediction intervals than expected. This suggests that current forecast prediction intervals may not capture the full range of uncertainty. Because of this, case forecasts for the coming weeks should be interpreted with caution. View previous case forecasts.

Hospitalization Forecasts: This week's national ensemble predicts that the number of new daily confirmed COVID-19 hospital admissions will likely increase over the next 4 weeks, with 6,700 to 24,000 new confirmed COVID-19 hospital admissions likely reported on August 30, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of daily confirmed COVID-19 hospital admissions will likely increase in 38 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported hospital admissions are uncertain or predicted to remain stable in the other states and territories. View previous hospitalization forecasts.

Death Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 deaths will likely increase over the next 4 weeks, with 2,300 to 9,100 new deaths likely reported in the week ending August 28, 2021. The national ensemble predicts that a total of 624,000 to 642,000 COVID-19 deaths will be reported by this date. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of newly reported deaths per week will likely increase in 17 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported deaths are uncertain or predicted to remain stable in the other states and territories. View previous death forecasts.

Top Military Medical Doctor Predicts Coronavirus Longevity: DoD released a report on the analysis of COVID-19 longevity according to director of Defense Health Agency, Army Lt. Gen. Ronald J. Place. Place stated his belief that COVID-19 and other such coronaviruses likely will stay in the environment and continue to mutate. Vaccines serve as the way to protect oneself from this lingering threat.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: Weaver, Richard L COL USARMY NG MSARNG (USA)

To: Thompson, Brian L CIV USAF 81 TW (USA); Barrett, Colleen E CIV USN CBC GULFPORT MS (USA); Schneider, Nathan A CAPT USN SUPSHIP GULFCOAST MS (USA); Carter, Travis L CAPT USCG GULF COAST (USA); Burnett, William H SES USN COMNAVMETOCCOM SSC (USA); Howe, Bradley K COL USARMY NG MSARNG (USA); McCormick, Berry L Col USAF MS CRTC (USA); Watson, Britt A Col USAF 186 ARW (USA); Cole, Lynn E Col USAF 172 AW (USA); "Schlosser, Teresa A COL USARMY CEPOF (USA)"; Mccullouch, Murry Brent COL USARMY NG MSARNG (USA); Jody.m.smith2.mil; Thomas, Christopher M LTC USARMY NG MSARNG (USA); "Hilliard, Robert A COL USARMY CEMVK (USA)"; "Hinkebein, Andrew (Wicker)"; Ratcliffe, Andrew M III LTC USARMY NG MSARNG (USA); Austin, Lawrence B LTC USARMY NG MSARNG (USA); Dingler, Christopher Wayne 1SG USARMY NG MSARNG (USA); Hester, Colby D CPT USARMY NG MSARNG (USA); Hargett, Joe D COL USARMY NG MSARNG (USA); Smith, Cynthia Lea (Cindy) Col USAF 172 AW (USA); Williams, Stanley T CSM USARMY NG MSARNG (USA); "Craig Sumrall"; "DuVerger, Frank R III LTC USARMY CEMVK (USA)"; "Gargiulo, Michele"; "Laura Hipp"; "AnneHall Brashier"; Craig, Jim; Dobbs, Thomas E; McIngvale, James W CTR (USA); "Andrew McMillin"; Welborn, Jeffrey H Col USAF (USA); Reedy, Millard G IV COL USARMY NG MSARNG (USA); Shaffer, Perish Undrea MAJ USARMY NG MSANG (USA); Tillman, Tommy F Jr Col USAF 172 AW (USA); Moore, Timothy B (Brent) CAPT USN NAS MERIDIAN MS (USA); Blackwell, Heather W Col USAF US STRATCOM (USA); 14 FTW/CAT Organizational Mailbox; Powell, Jeffrey S (Jeff) CAPT USN CBC GULFPORT MS (USA)

Subject: ICC COVID 19 and weather update

Date: Thursday, October 8, 2020 7:38:21 AM

Attachments: DUB 10.08.2020.pdf

[redacted]

V/R

Rick

Daily Update Brief

24 Hour State Warning Point Report

PREPARING FOR TOMORROW'S DISASTERS TODAY

10/8/2020 4:54:54 AM

SEOC Status – **SEOC Level 2 (Partial Activation)**

MS-DOH-21-1816-A-000877

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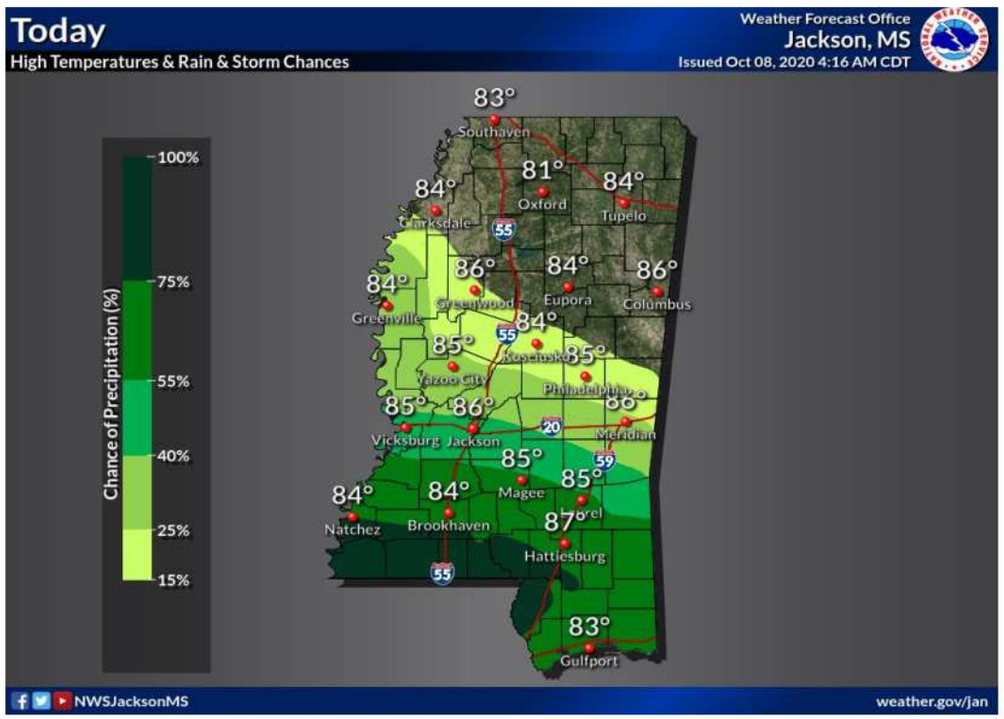
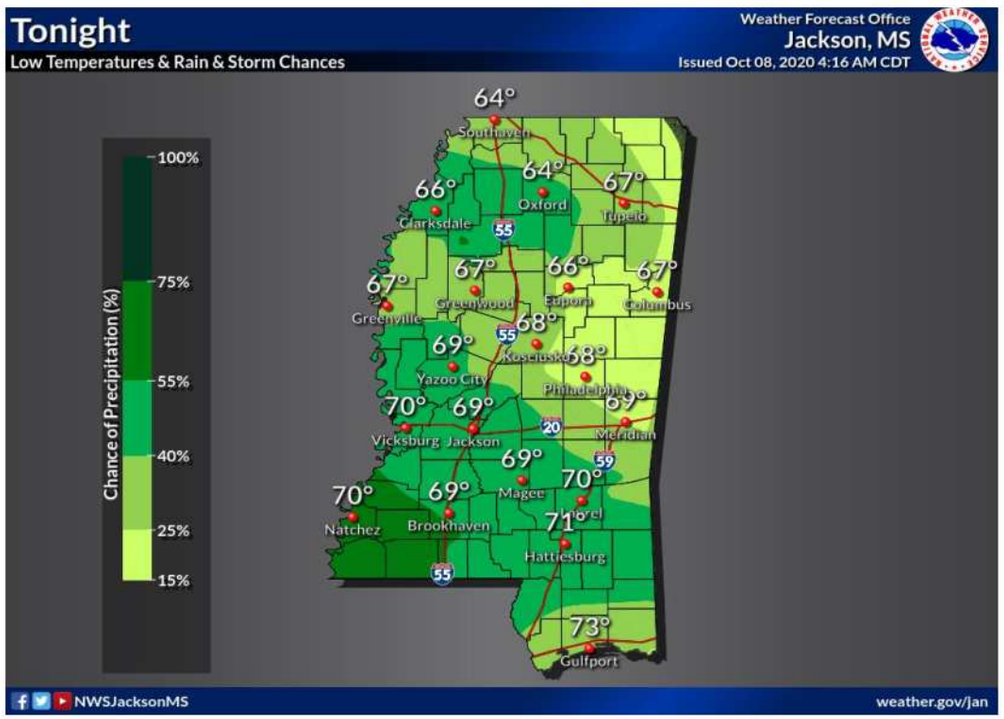
Daily Update Brief

As of 10/8/2020 4:54 AM

Weather - Next 24 hours (See NWS for the latest information)





NORTH:
TODAY... PARTLY SUNNY. HIGHS IN THE LOWER TO MID 80S.
TONIGHT... CLOUDY. CHANCE OF SHOWERS. LOWS IN THE MID 60S.
FRIDAY... CLOUDY. SHOWERS LIKELY. HIGHS IN THE MID 70S.
FRIDAY NIGHT... SHOWERS LIKELY. LOWS IN THE MID TO UPPER 60S

CENTRAL:
TODAY...CHANCE SHOWERS AND TSTORMS IN THE AFTERNOON.
TONIGHT...CLOUDY. CHANCE OF SHOWERS. LOWS IN THE UPPER 60S.
FRIDAY... CLOUDY. CHANCE OF SHOWERS. HIGHS IN THE UPPER 70S.
FRIDAY NIGHT... SHOWERS LIKELY. LOWS NEAR 70.

SOUTH:
TODAY...CHANCE OF SHOWERS AND TSTORMS. HIGHS IN MID 80S.
TONIGHT... CHANCE OF EVENING AND OVERNIGHT SHOWERS.
FRIDAY... CHANCE OF SHOWERS. HIGHS IN THE LOWER 80S.
FRIDAY NIGHT... BREEZY. SHOWERS LIKELY. LOWS IN THE LOW 70S.

MS-DOH-21-1816-A-000878

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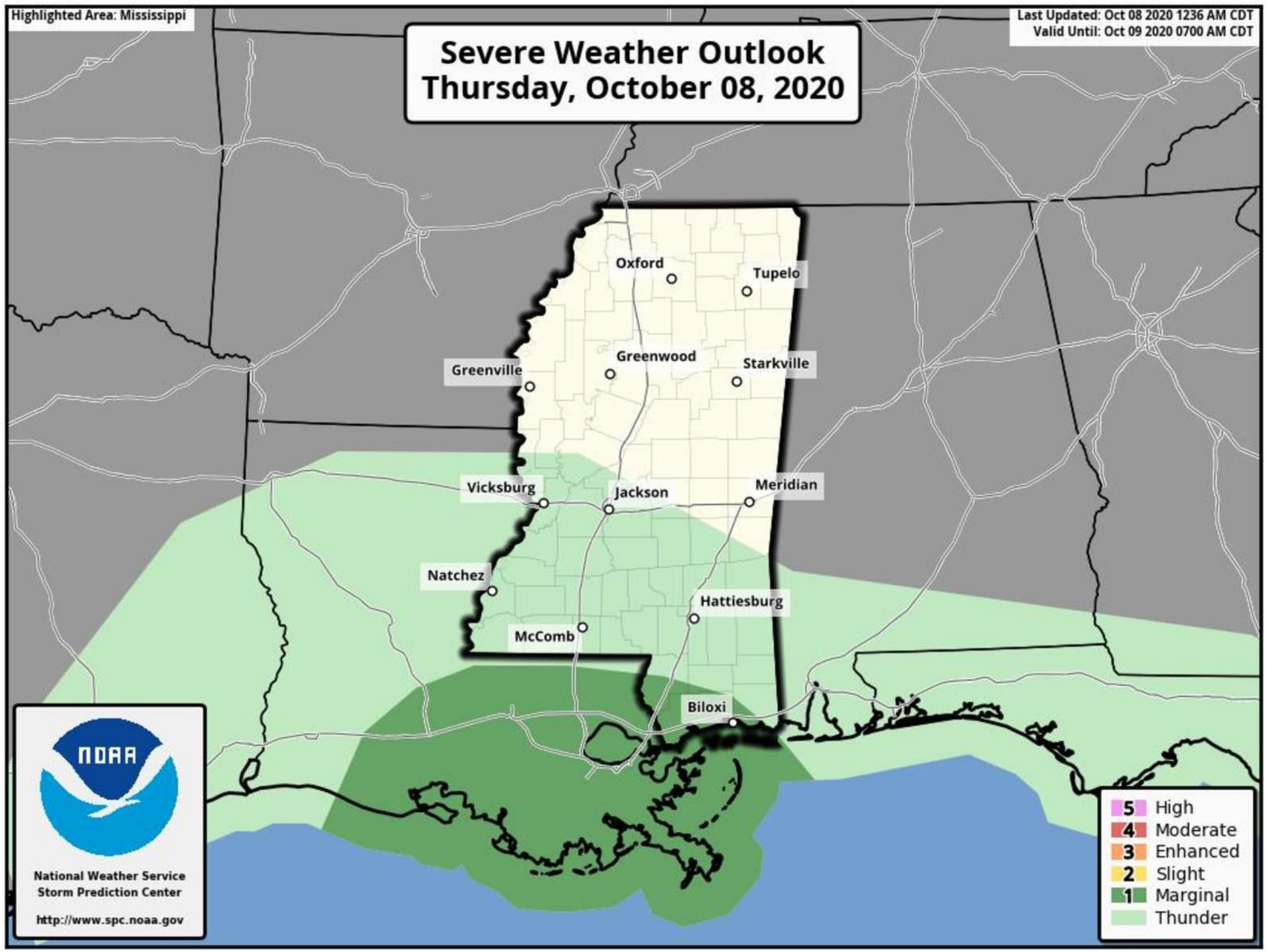
Daily Update Brief

As of 10/8/2020 4:54 AM

Weather – Day 1 SPC Severe Weather Outlook (See SPC for details)



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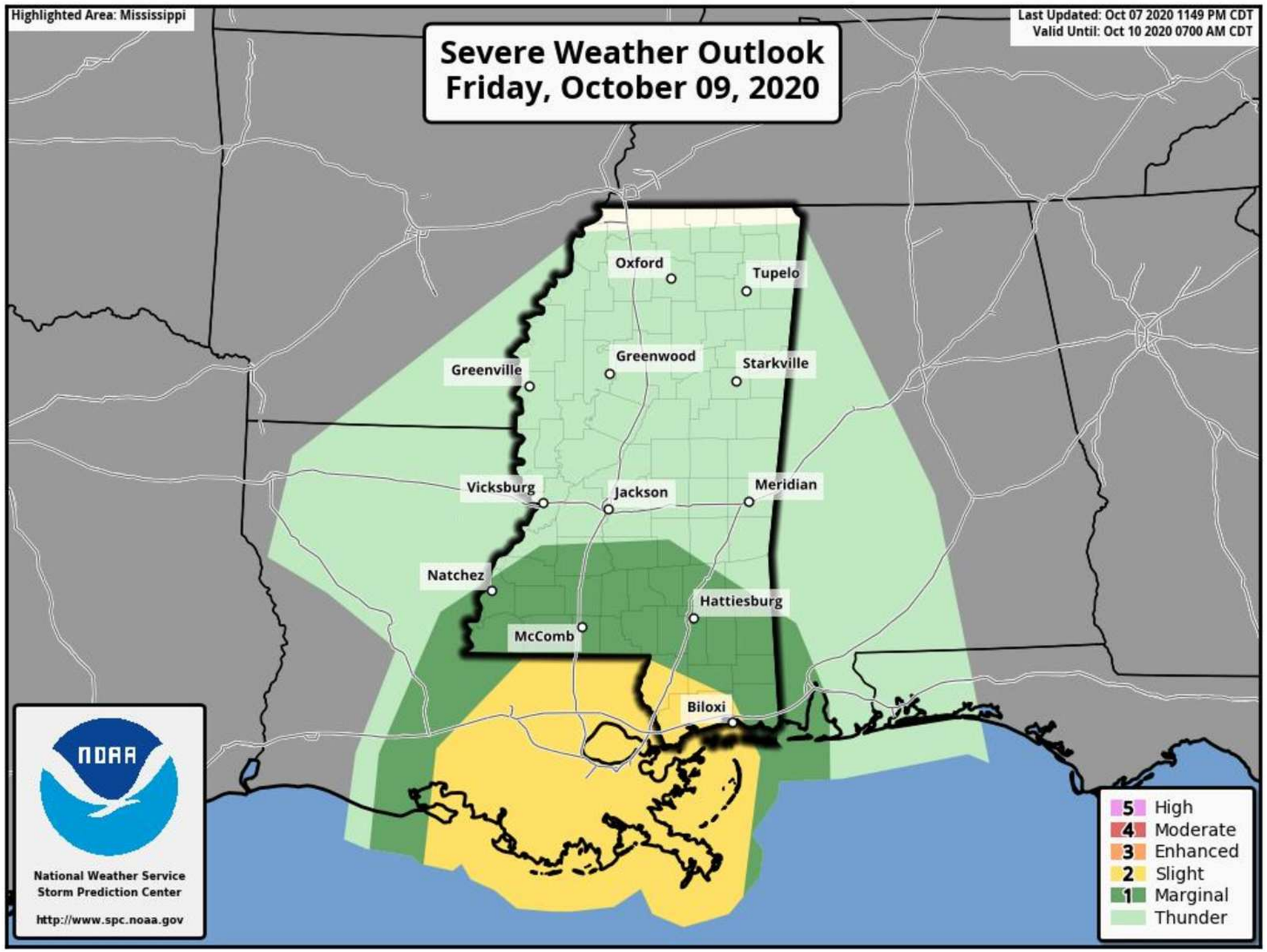
Daily Update Brief

As of 10/8/2020 4:54 AM

Weather – Day 2 SPC Severe Weather Outlook (See SPC for details)



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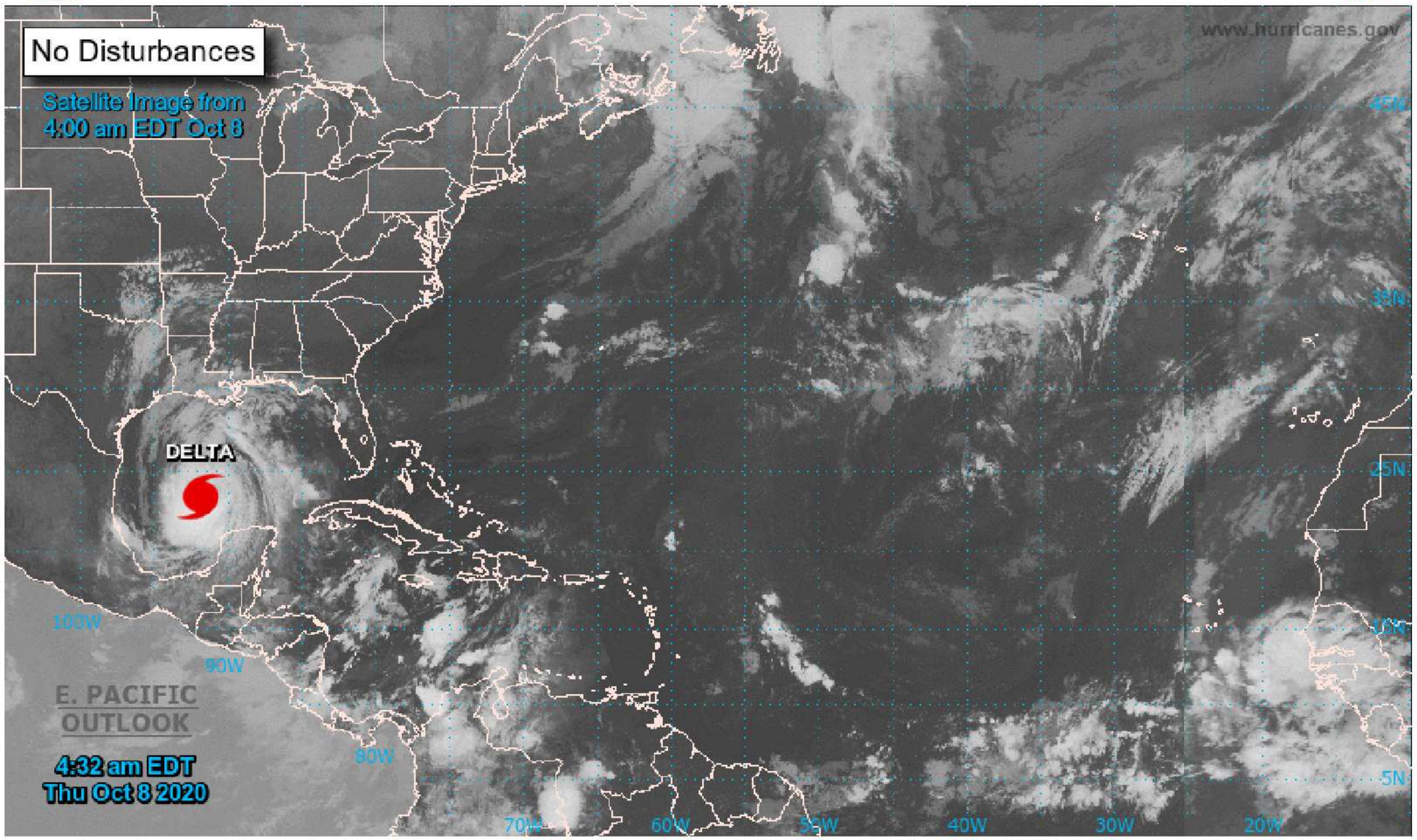
Daily Update Brief

As of 10/8/2020 4:54 AM

Tropical – Two-Day Outlook (See NHC for the latest information)

Two-Day Graphical Tropical Weather Outlook

National Hurricane Center Miami, Florida



Current Disturbances and Two-Day Cyclone Formation Chance: < 40% 40-60% > 60%

Tropical or Sub-Tropical Cyclone: Depression Storm Hurricane

Post-Tropical Cyclone or Remnants

MS-DOH-21-1816-A-000881

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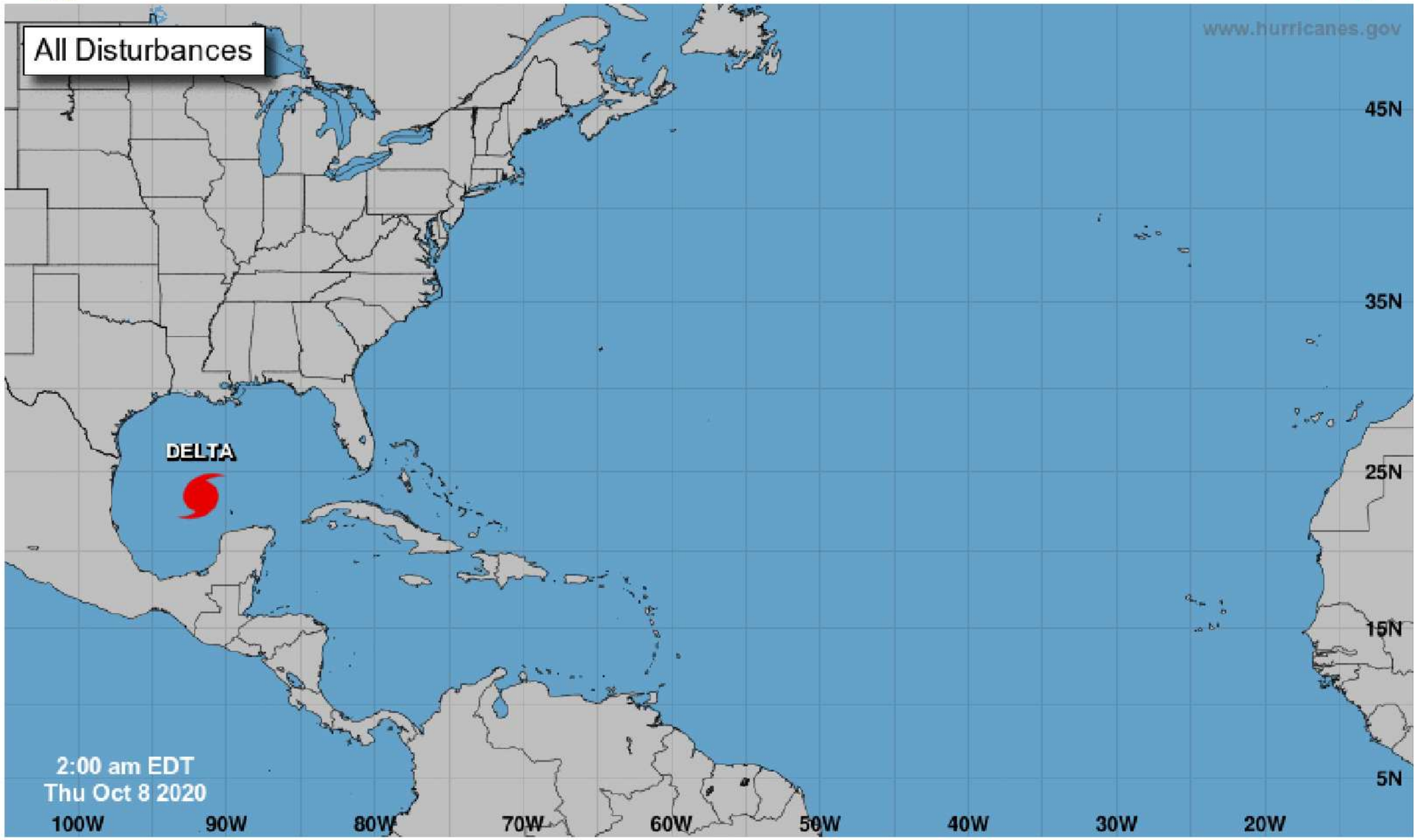
Daily Update Brief

As of 10/8/2020 4:54 AM

Tropical – Five-Day Outlook (See NHC for the latest information)

Five-Day Graphical Tropical Weather Outlook

National Hurricane Center Miami, Florida



Current Disturbances and Five-Day Cyclone Formation Chance: < 40% 40-60% > 60%

Tropical or Sub-Tropical Cyclone: Depression Storm Hurricane

Post-Tropical Cyclone or Remnants

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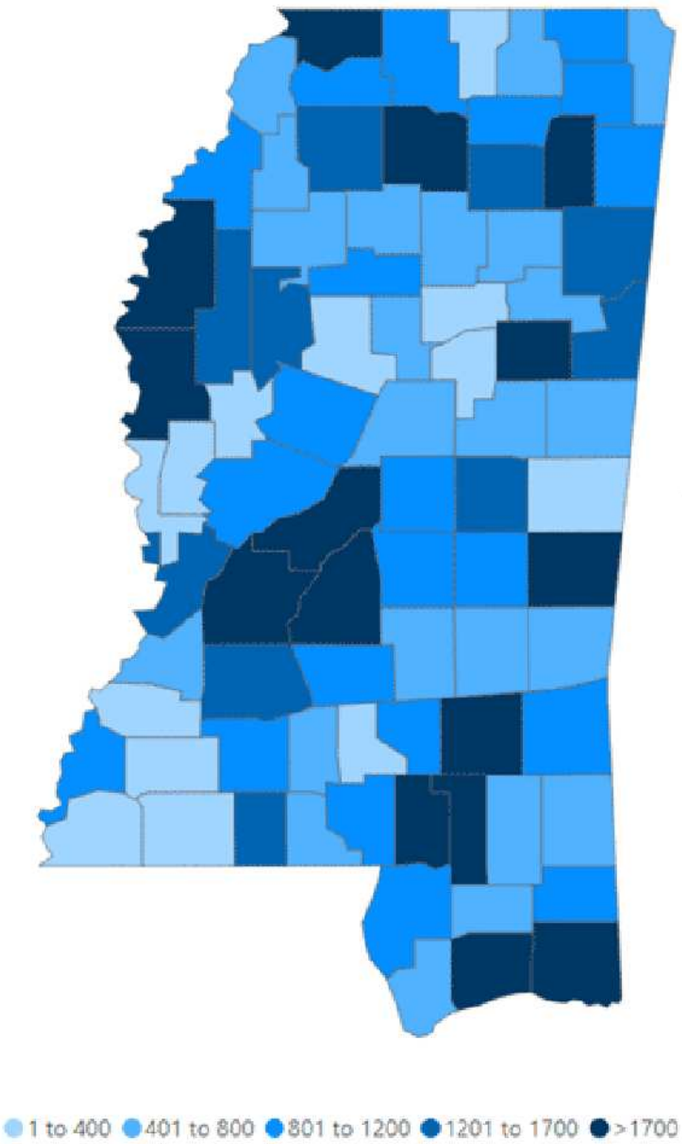
MS-DOH-21-1816-A-000882

Daily Update Brief

As of 10/8/2020 4:54 AM

Coronavirus Disease 2019 (COVID-19)

Mississippi COVID-19
Cases and Deaths by Race with Ethnicity
as of 6 pm CT, October 6, 2020



Total Cases

102,241

	American Indian or Alaska Native	Asian	Black	White	Other	Unknown
Non Hispanic	517	288	31,751	29,275	1,162	448
Hispanic	19	12	134	895	1,782	162
Unknown Ethnicity	785	85	7,746	8,224	4,737	14,219

Total Deaths

3,051

	American Indian or Alaska Native	Asian	Black	White	Other	Unknown
Non Hispanic	66	3	1,261	1,218	16	3
Hispanic	1	0	5	19	13	1
Unknown Ethnicity	20	4	149	184	24	64

The MSDH has established a COVID-19 Hotline for the general public:
877-978-6453
7 Days a week – 7:00am until 7:00pm

Local COVID-19 testing:
We now have a list of local COVID-19 testing providers for you to contact if you have symptoms:
View local testing providers »

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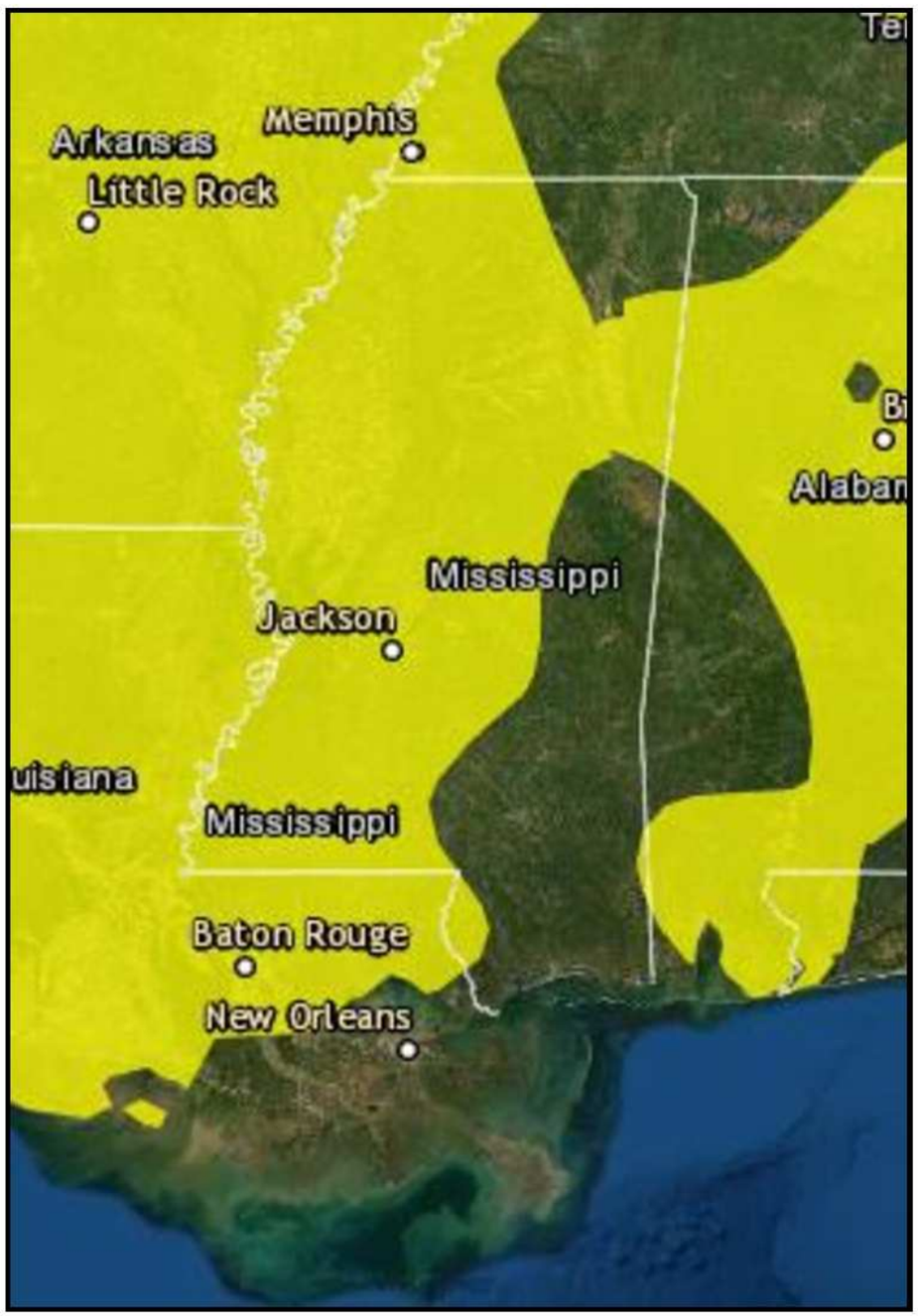
Daily Update Brief

As of 10/8/2020 4:54 AM

Map of Air Quality *(See Interactive Map Airnow for details)*



U.S. Air Quality Index

- Good (0-50)
- Moderate (51-100)
- Unhealthy for Sensitive Groups (101-150)
- Unhealthy (151-200)
- Very Unhealthy (201-300)
- Hazardous (301-500)
- No Data

Note: Values above 500 are considered Beyond the AQI. Follow recommendations for the Hazardous category. Additional information on reducing exposure to extremely high levels of particle pollution is available here.

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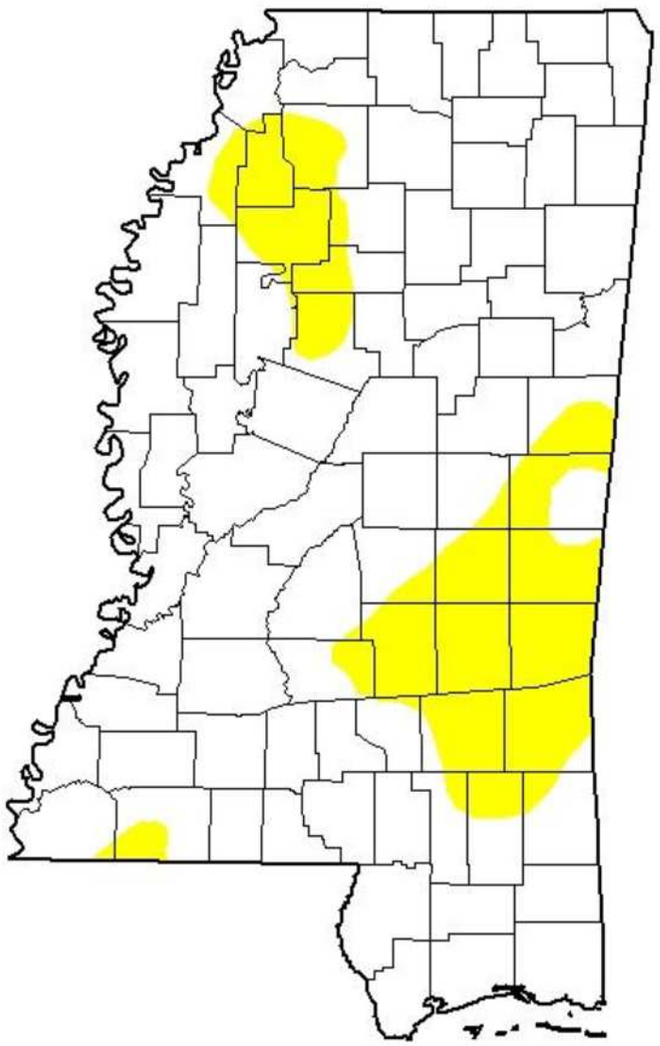
Daily Update Brief

As of 10/8/2020 4:54 AM

Map Released: Thursday, October 1, 2020

U.S. Drought Monitor
Mississippi



September 29, 2020

(Released Thursday, Oct. 1, 2020)

Valid 8 a.m. EDT

Drought Conditions (Percent Area)

	None	D0-D4	D1-D4	D2-D4	D3-D4	D4
Current	81.73	18.27	0.00	0.00	0.00	0.00
Last Week 09-22-2020	63.88	36.12	3.31	0.00	0.00	0.00
3 Months Ago 06-30-2020	98.32	1.68	0.00	0.00	0.00	0.00
Start of Calendar Year 12-31-2019	95.94	4.06	0.27	0.00	0.00	0.00
Start of Water Year 10-01-2019	2.22	97.78	9.03	0.00	0.00	0.00
One Year Ago 10-01-2019	2.22	97.78	9.03	0.00	0.00	0.00

Intensity:

- None
- D0 Abnormally Dry
- D1 Moderate Drought
- D2 Severe Drought
- D3 Extreme Drought
- D4 Exceptional Drought

The Drought Monitor focuses on broad-scale conditions. Local conditions may vary. For more information on the Drought Monitor, go to https://droughtmonitor.unl.edu/About.aspx

Author:

Brad Rippey

U.S. Department of Agriculture

droughtmonitor.unl.edu

There Are Currently No Active County Burn Bans

A burn ban means no outdoor burning of ANY KIND.

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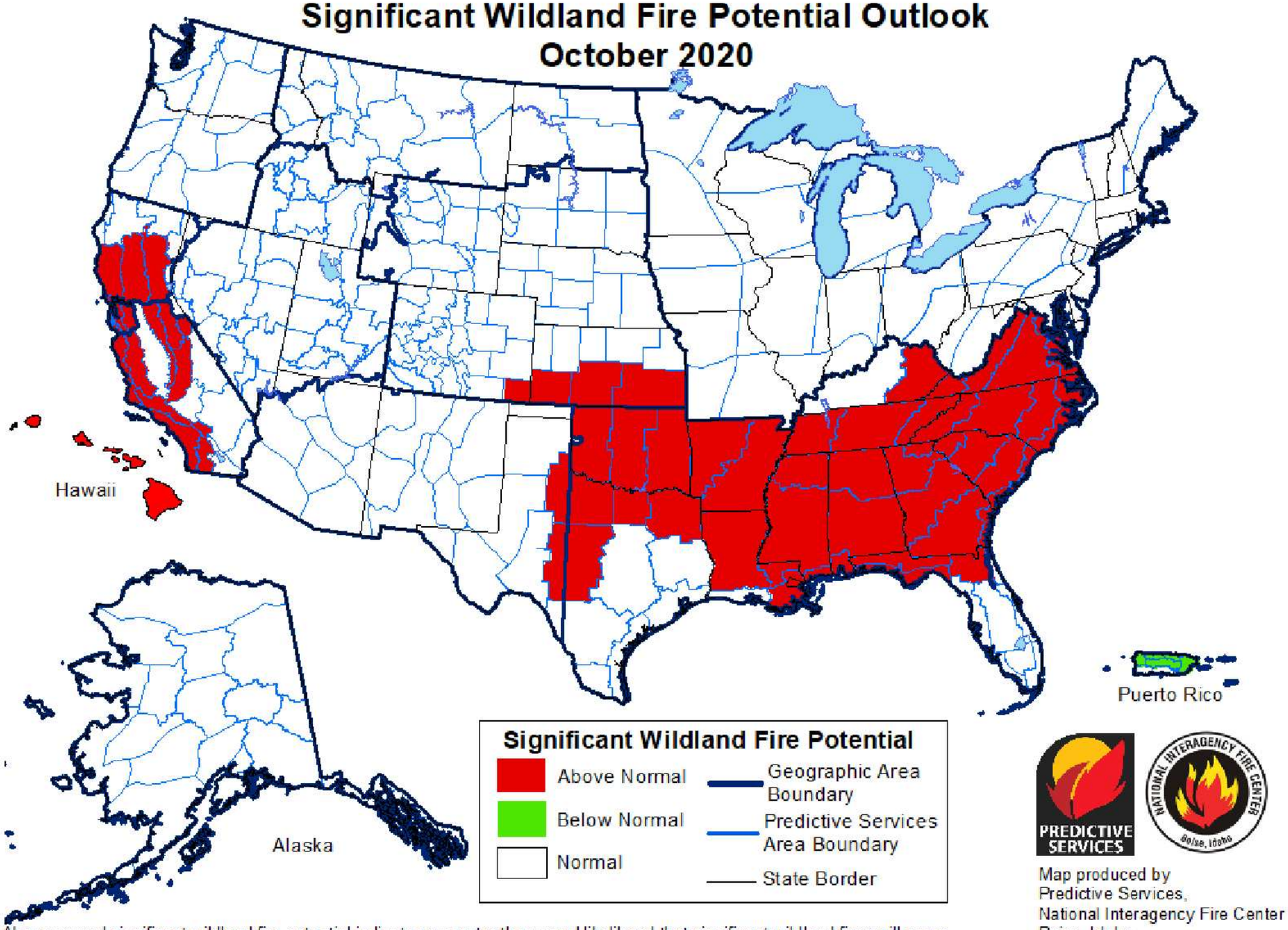
MS-DOH-21-1816-A-000885

Daily Update Brief

As of 10/8/2020 4:54 AM

Significant Wildland Fire Potential Outlook
October 2020



Above normal significant wildland fire potential indicates a greater than usual likelihood that significant wildland fires will occur.
Significant wildland fires should be expected at typical times and intervals during normal significant wildland fire potential conditions.
Significant wildland fires are still possible but less likely than usual during forecasted below normal periods.

Map produced by
Predictive Services,
National Interagency Fire Center
Boise, Idaho
Issued September 1, 2020
Next issuance October 1, 2020

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Daily Update Brief

As of 10/8/2020 4:54 AM

Mississippi News of Interest

Mississippi governor declares state of emergency ahead of Hurricane Delta

Mississippi Gov. Tate Reeves declared a state of emergency Wednesday as Hurricane Delta threatens the Gulf Coast. Delta made landfall near Puerto Morelos Mexico as a strong category 2 storm Wednesday morning.

Clinton Public School District COVID-19 cases at 17 since start of school

Clinton Public School District leaders reported two Eastside Elementary students, from the same household, have tested positive this week for COVID-19.

Mississippi State Fair kicks off with COVID-19 precautions in place

There is a lot of scrutiny about safety at the fairgrounds with so many moving parts and a pandemic to boot.Health inspectors were out Tuesday inspecting food vendors, who will be required to wear masks during the Mississippi State Fair, …

Red Cross deploying ahead of Hurricane Delta

The Mississippi Red Cross is sending volunteers to Mobile, Alabama, ahead of Hurricane Delta. Mobile is the staging area for the Alabama Mississippi regional response to Hurricane Delta.

Canton Flea Market vendors ready their wares

The Canton Flea Market is Thursday, but there will be several changes because of the COVID-19 pandemic. Hundreds of vendors spent Wednesday setting up shop for the event. Social distancing will be enforced and masks are required.

Masks will not be required for the November election in Mississippi

There will be no mask mandates at the polls when you vote November 3rd. Though PPE supplies have been sent to precincts around the state, it can be offered to voters but not mandated.

Mississippi Forestry Commission personnel and equipment respond to western wildfires

According to the Mississippi Forestry Commission (MFC), several personnel and pieces of equipment were deployed to assist states experiencing wildfires. “Everyone is well aware of the wildfires raging in California, Colorado, and Oregon.

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Daily Update Brief

As of 10/8/2020 4:54 AM

Emergency Management News

Hurricane Delta lashes Mexico's Yucatan, then heads for US

Hurricane Delta emerged into the Gulf of Mexico on Wednesday and headed toward Louisiana after making landfall just south of the Mexican resort of Cancun, toppling trees and cutting power to residents of the Yucatan peninsula's resort-studded coast.

Delta to re-strengthen Thursday; major impacts for Louisiana, some for South Mississippi

Hurricane Delta is expected to re-strengthen to a major Hurricane Thursday before making landfall Friday evening along the Louisiana coastline. While the most significant impacts appear to be in Louisiana, South Mississippi could see some impacts.

COVID-19 cases spike almost one week after state mask mandate ends

Less than a week after Mississippi became the first state nationwide to let its mask mandate expire, the Mississippi State Department of Health reports a surge in coronavirus cases not seen in seven weeks.

Adams County braces for possible impact from Hurricane Delta

The Adams County Emergency Management is making resources for neighbors ahead of Hurricane Delta. Sandbags are available at the Foster Mound Fire Department. Parts of Adams County experienced damage from Hurricane Laura, and leaders want…

Trump doctor: President symptom-free 24 hours

President Donald Trump's physician says the president had been symptom-free for 24 hours and his vital signs have remained stable and in normal range. Dr. Sean Conley, in a memo, also wrote that Trump, who was diagnosed with COVID-19 five days…

EDM Wednesday Briefing: Hurricane Delta Forecast to Grow in Size

Emergency and disaster management briefing for October 7, 2020: Hurricane Delta makes landfall in Mexico as a Category 2 storm; the NHC is expecting Delta to rapidly intensify again as it re-emerges into the very warm waters of

COVID-19 Business Adjustments Are Changing Fire Safety

For society, 2020 has been a very different year, due to the coronavirus. In March, much of the economy shut down, which restricted people being able to go into businesses.

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Daily Update Brief

As of 10/8/2020 4:54 AM

Significant MEMA Future Events

Date(s)	Event	Location
06-09OCT20	G300 – Virtual Training	MEMA Virtual
06-15OCT20	Top 10 Mistakes Training	FEMA Virtual
27-28OCT20	G400 – Virtual Training	MEMA Virtual
03-06NOV20	G300 – Virtual Training	MEMA Virtual
09-10NOV20	G358 – Evac/Re-Entry Virtual Training	MEMA Virtual
19-20NOV20	G400 – Virtual Training	MEMA Virtual
01-30DEC29	Request Only Training	MEMA

To sign up for or inquire about training opportunities, please contact MEMA's Training Bureau at 601-933-6370

MS-DOH-21-1816-A-000889

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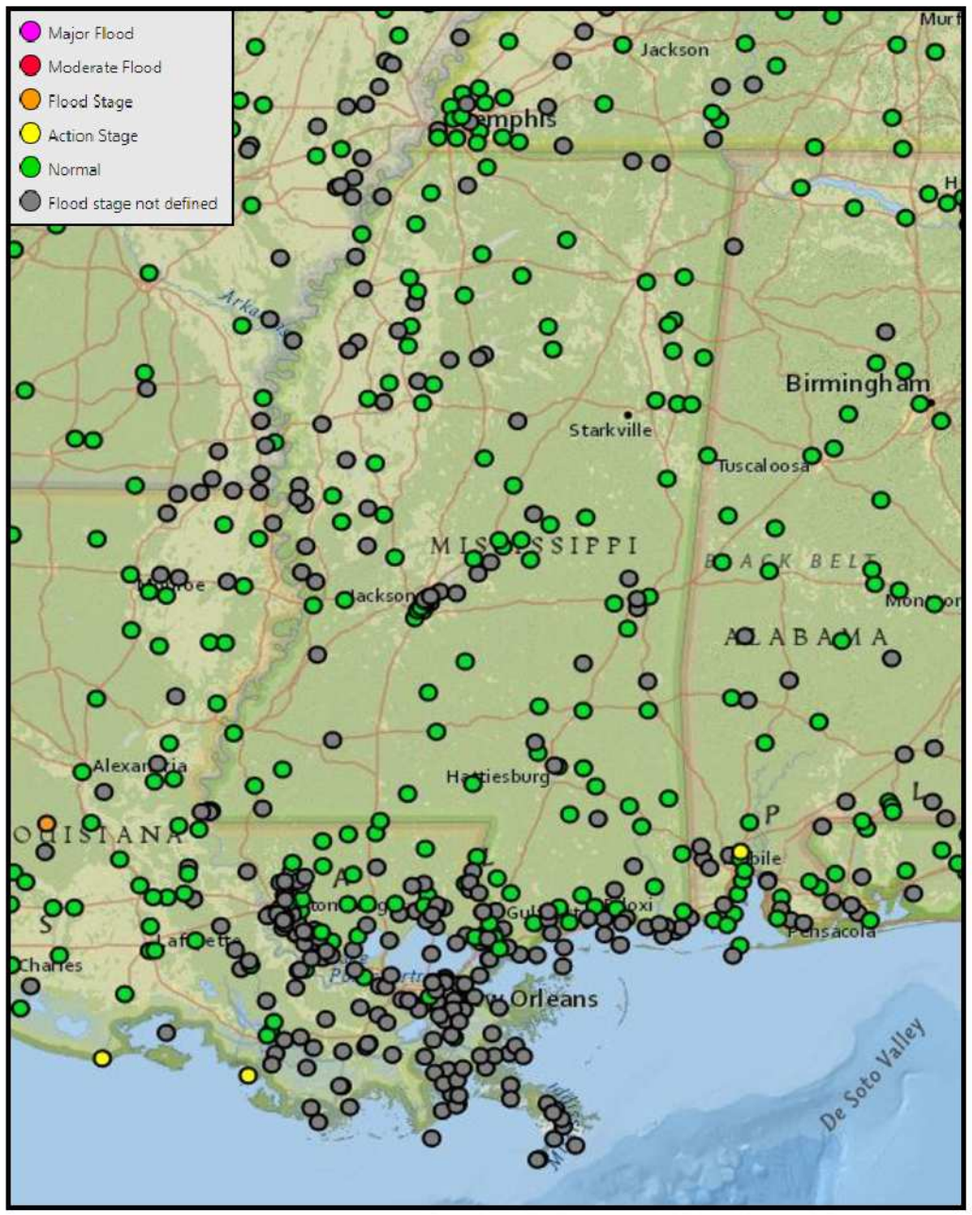
Daily Update Brief

As of 10/8/2020 4:54 AM

NWS Enhanced Data Display

Observed River Gauges and Forecasted to Flood

NWS – Observed River Gauges



NWS – Near or Above Flood Stage

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MS-DOH-21-1816-A-000890

Daily Update Brief

As of 10/8/2020 4:54 AM

New Madrid Seismic Data – 30 Day, Magnitude 2.5+ Update

M 2.6 - 6 km E of Maynard, Arkansas
2020-10-07 15:41:39 (UTC) 36.431°N 90.827°W
6.4 km depth

M 2.6 - 6 km ENE of Maynard, Arkansas
2020-10-07 12:18:55 (UTC) 36.431°N 90.827°W
12.4 km depth

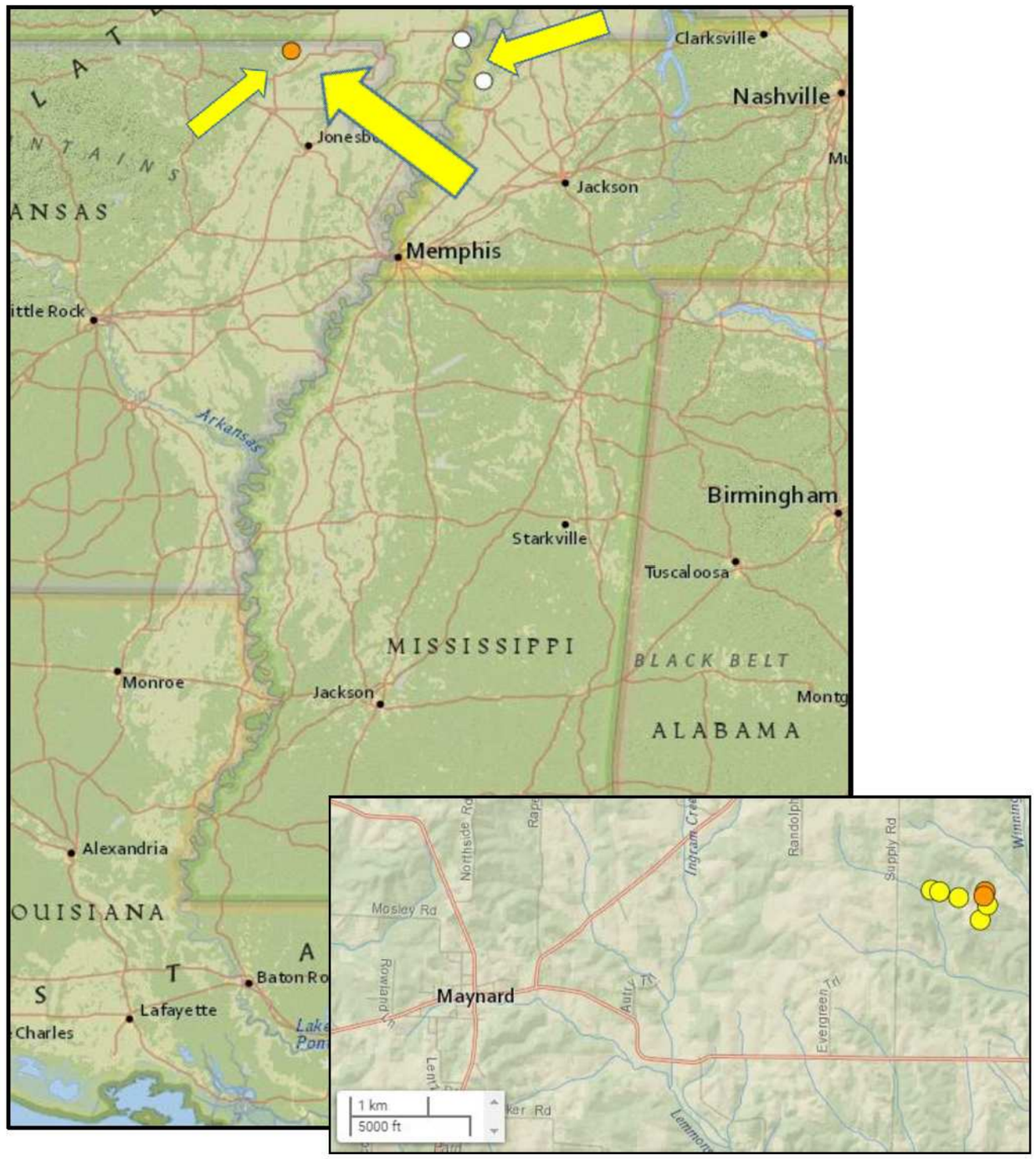
M 2.6 - 6 km E of Maynard, Arkansas
2020-10-06 23:52:19 (UTC 36.430°N 90.826°W
8.0 km depth

M 2.6 - 5 km ENE of Maynard, Arkansas
2020-10-06 14:11:31 (UTC) 36.431°N 90.833°W
12.8 km depth

M 2.5 - 5 km ENE of Maynard, Arkansas
2020-10-06 04:20:18 (UTC) 36.432°N 90.834°W
9.3 km depth

M 2.6 - 6 km ENE of Maynard, Arkansas
2020-10-05 23:18:04 (UTC) 36.431°N 90.830°W
8.2 km depth

M 2.5 – 6km E of Maynard, Arkansas
2020-10-05 22:07:18 (UTC) 36.428°N 90.827°W
10.5 km depth



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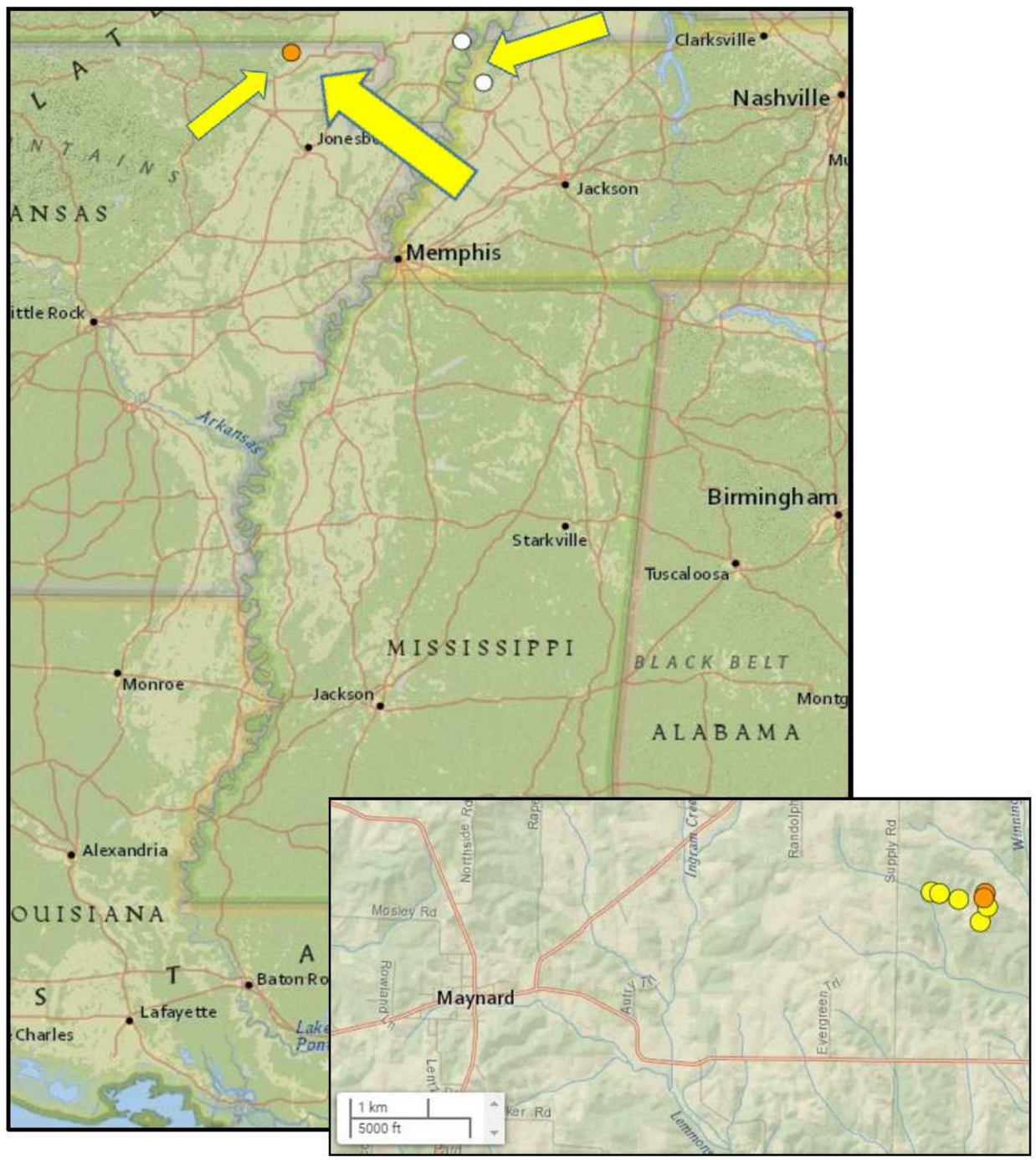
Daily Update Brief

As of 10/8/2020 4:54 AM

New Madrid Seismic Data – 30 Day, Magnitude 2.5+ Update

M 2.5 - 6 km ESE of Ridgely, Tennessee
2020-09-26 23:15:11 (UTC) 36.244°N 89.418°W
7.1 km depth

M 2.6 - 3 km ESE of Marston, Missouri
2020-09-22 00:30:07 (UTC) 36.501°N 89.577°W
5.3 km depth



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Daily Update Brief

As of 10/8/2020 4:54 AM

Prepare for Flooding Before it Happens

- Are you located in a flood plain?
- What is the fastest way to higher ground?
- What roads nearby are most likely to flood?

weather.gov/flood

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MS-DOH-21-1816-A-000893

Daily Update Brief

As of 10/8/2020 4:54 AM

Hurricane Delta will impact south Mississippi later this week. Now is the time to have a plan in place. Find hurricane evacuation routes, important contact info, radio coverage areas and more at GoMDOT.com/hurricanes.

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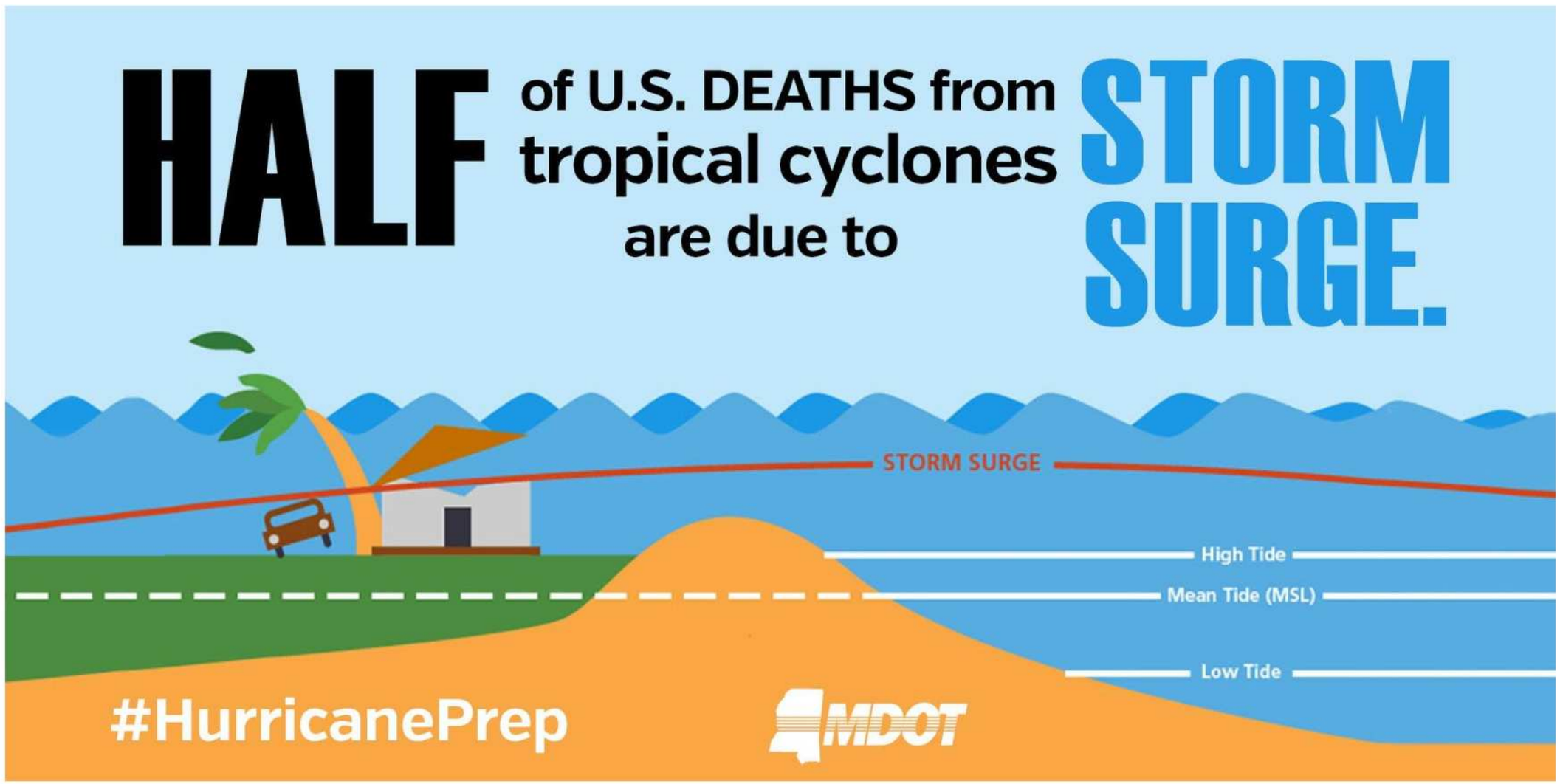
MS-DOH-21-1816-A-000894

Daily Update Brief

As of 10/8/2020 4:54 AM

Remember, never underestimate the potential impacts of these storms. Now is the time to have a plan in place. Download MDOT's free hurricane prep resources by visiting GoMDOT.com/hurricanes.



MS-DOH-21-1816-A-000895

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Daily Update Brief

As of 10/8/2020 4:54 AM

Delta Reminder:
During a power outage, ATMs & credit card machines will not work. Include extra cash (small bills) in your emergency kit...because you can pretty much count on power outages during hurricanes.
#HurricanePrep
#BePreparedNotScared

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MS-DOH-21-1816-A-000896

Daily Update Brief

As of 10/8/2020 4:54 AM

Remember to never drive through a flooded area. The road bed may be washed away and you may not know how deep the water is. #TurnAroundDontDrown

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Daily Update Brief

As of 10/8/2020 4:54 AM

Websites of Interest

MEMA: http://www.msema.org

MEMA Facebook: https://www.facebook.com/msemaorg

MEMA Twitter: https://twitter.com/msema

MEMA YouTube: https://www.youtube.com/user/MSEMAorg1

MEMA Snapchat: @msemergencymgmt

MEMA Situation Room (Adobe Connect): Daily Sitroom – https://share.dhs.gov/msema
EMAC Sitroom – https://share.dhs.gov/ms-emac

Federal Emergency Management Agency (FEMA): http://www.fema.gov

Emergency Management Institute (EMI): https://training.fema.gov/emi.aspx

Dept. of Homeland Security (DHS) : https://www.dhs.gov
https://www.dhs.gov/dhs-component-websites

Homeland Security Information Network (HSIN): https://www.dhs.gov/homeland-security-information-network-hsin

US Army Corps of Engineers – Vicksburg District: http://www.mvk.usace.army.mil

Mississippi Forestry Commission: http://www.mfc.ms.gov

Mississippi Department of Transportation – Traffic: https://www.mdottraffic.com

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From: Weaver, Richard L COL USARMY NG MSARNG (USA)

To: Thompson, Brian L CIV USAF 81 TW (USA); Barrett, Colleen E CIV USN CBC GULFPORT MS (USA); Schneider, Nathan A CAPT USN SUPSHIP GULFCOAST MS (USA); Carter, Travis L CAPT USCG GULF COAST (USA); Burnett, William H SES USN COMNAVMETOCCOM SSC (USA); Howe, Bradley K COL USARMY NG MSARNG (USA); "Schlosser, Teresa A COL USARMY CEPOF (USA)"; Mccullouch, Murry Brent COL USARMY NG MSARNG (USA); Jody.m.smith2.mil; Thomas, Christopher M LTC USARMY NG MSARNG (USA); "Hilliard, Robert A COL USARMY CEMVK (USA)"; "Hinkebein, Andrew (Wicker)"; Ratcliffe, Andrew M III LTC USARMY NG MSARNG (USA); Austin, Lawrence B LTC USARMY NG MSARNG (USA); Dingler, Christopher Wayne 1SG USARMY NG MSARNG (USA); Hester, Colby D CPT USARMY NG MSARNG (USA); Hargett, Joe D COL USARMY NG MSARNG (USA); Smith, Cynthia Lea (Cindy) Col USAF 172 AW (USA); Williams, Stanley T CSM USARMY NG MSARNG (USA); "Craig Sumrall"; "DuVerger, Frank R III LTC USARMY CEMVK (USA)"; "Gargiulo, Michele"; "Laura Hipp"; "AnneHall Brashier"; Craig, Jim; Dobbs, Thomas E; McIngvale, James W CTR (USA); "Andrew McMillin"; Welborn, Jeffrey H Col USAF (USA); Reedy, Millard G IV COL USARMY NG MSARNG (USA); Shaffer, Perish Undrea MAJ USARMY NG MSANG (USA); Moore, Timothy B (Brent) CAPT USN NAS MERIDIAN MS (USA); Blackwell, Heather W Col USAF US STRATCOM (USA); 14 FTW/CAT Organizational Mailbox; Powell, Jeffrey S (Jeff) CAPT USN CBC GULFPORT MS (USA); Tillman, Tommy F Jr Col USAF 172 AW (USA); Cole, Lynn E Col USAF 172 AW (USA); Watson, Britt A Col USAF 186 ARW (USA); McCormick, Berry L Col USAF MS CRTC (USA); Mantooth, Randall P LTC USARMY NG MSARNG (USA)

Subject: ICC COVID 19

Date: Monday, November 9, 2020 6:38:20 AM

Attachments: DUB 11.09.2020.pdf

[redacted]

V/R

Rick

Daily Update Brief

24 Hour State Warning Point Report

PREPARING FOR TOMORROW'S DISASTERS TODAY

11/9/2020 4:57:43 AM

SEOC Status – **SEOC Level 2 (Partial Activation)**

MS-DOH-21-1816-A-000900

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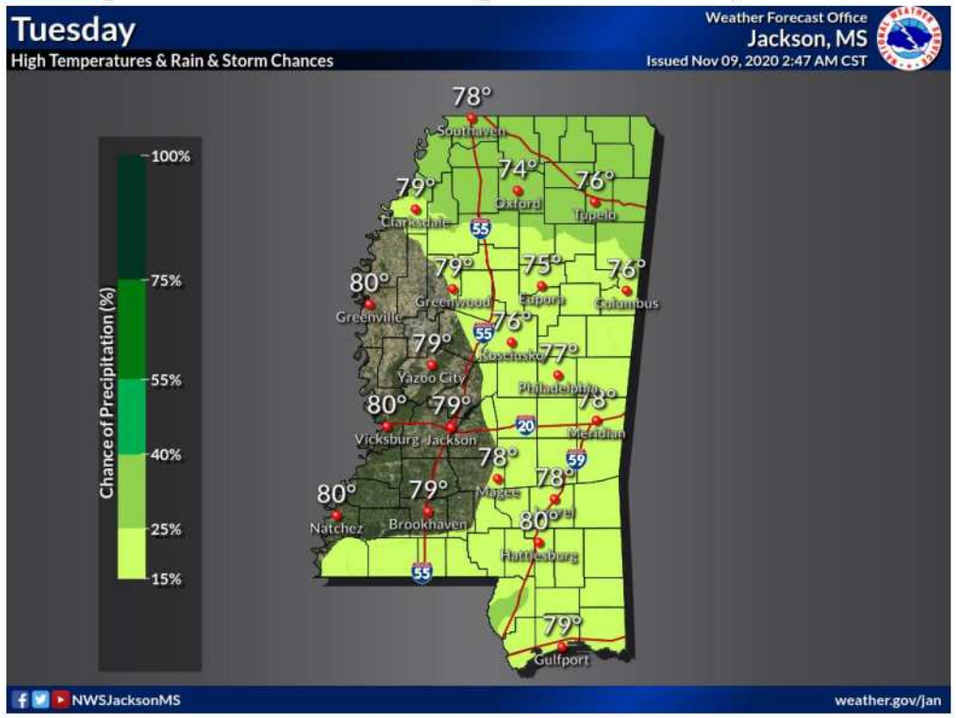
Daily Update Brief

As of 11/9/2020 4:57 AM

Weather - Next 24 hours (See NWS for the latest information)



NORTH:

TODAY...MOSTLY SUNNY. HIGHS IN THE UPPER 70S.
TONIGHT...PARTLY CLOUDY. LOWS IN THE LOWER TO MID 60S.
TUESDAY...PARTLY SUNNY. SLIGHT CHANCE OF SHOWERS
TUESDAY NIGHT...MOSTLY CLOUDY. SLIGHT CHANCE OF SHOWERS.

CENTRAL:

TODAY...MOSTLY SUNNY. HIGHS IN THE LOWER 80S.
TONIGHT...PARTLY CLOUDY. LOWS IN THE LOWER TO MID 60S.
TUESDAY...PARTLY SUNNY. SLIGHT CHANCE OF SHOWERS
TUESDAY NIGHT... MOSTLY CLOUDY. SLIGHT CHANCE OF SHOWERS.

SOUTH:

TODAY...MOSTLY SUNNY. HIGHS IN THE LOWER 80S.
TONIGHT...PARTLY CLOUDY IN THE EVENING
TUESDAY...PARTLY SUNNY. SLIGHT CHANCE OF SHOWERS
TUESDAY NIGHT...PARTLY CLOUDY IN THE EVENING

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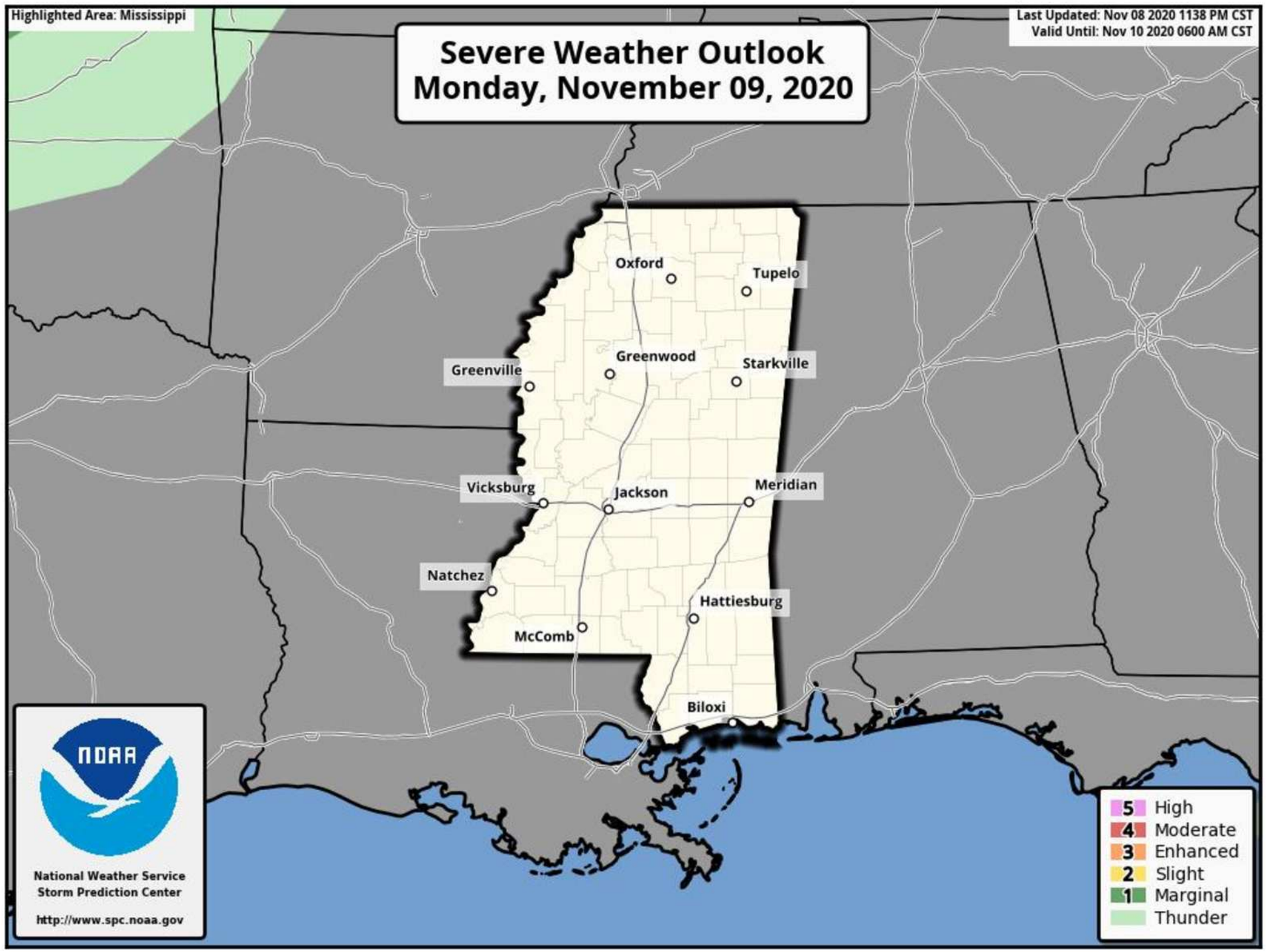
MS-DOH-21-1016-A-000901

Daily Update Brief

As of 11/9/2020 4:57 AM

Weather – Day 1 SPC Severe Weather Outlook (See SPC for details)



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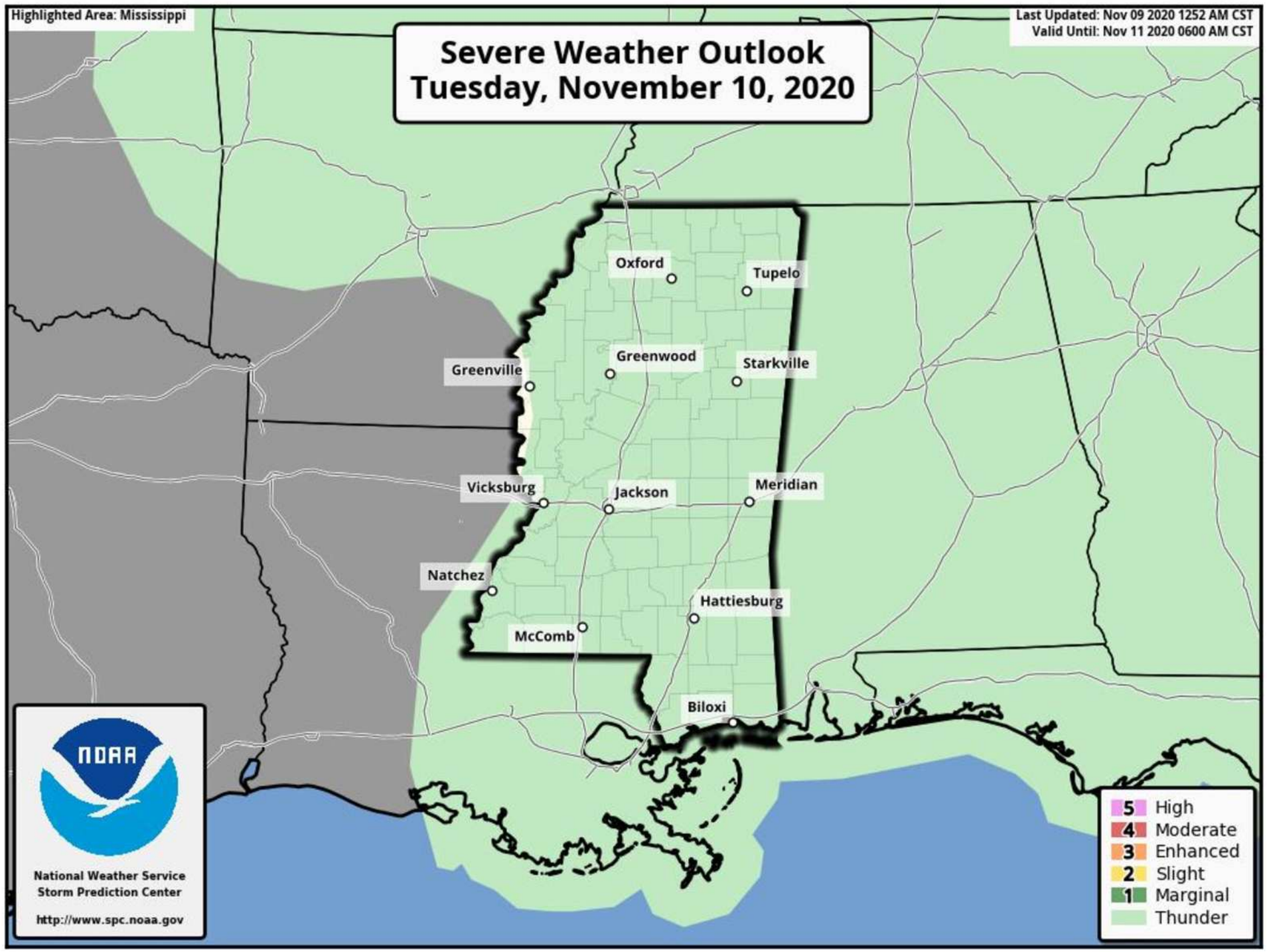
MS-DOH-21-1816-A-000902

Daily Update Brief

As of 11/9/2020 4:57 AM

Weather – Day 2 SPC Severe Weather Outlook (See SPC for details)



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MS-DOH-21-1816-A-000903

Daily Update Brief

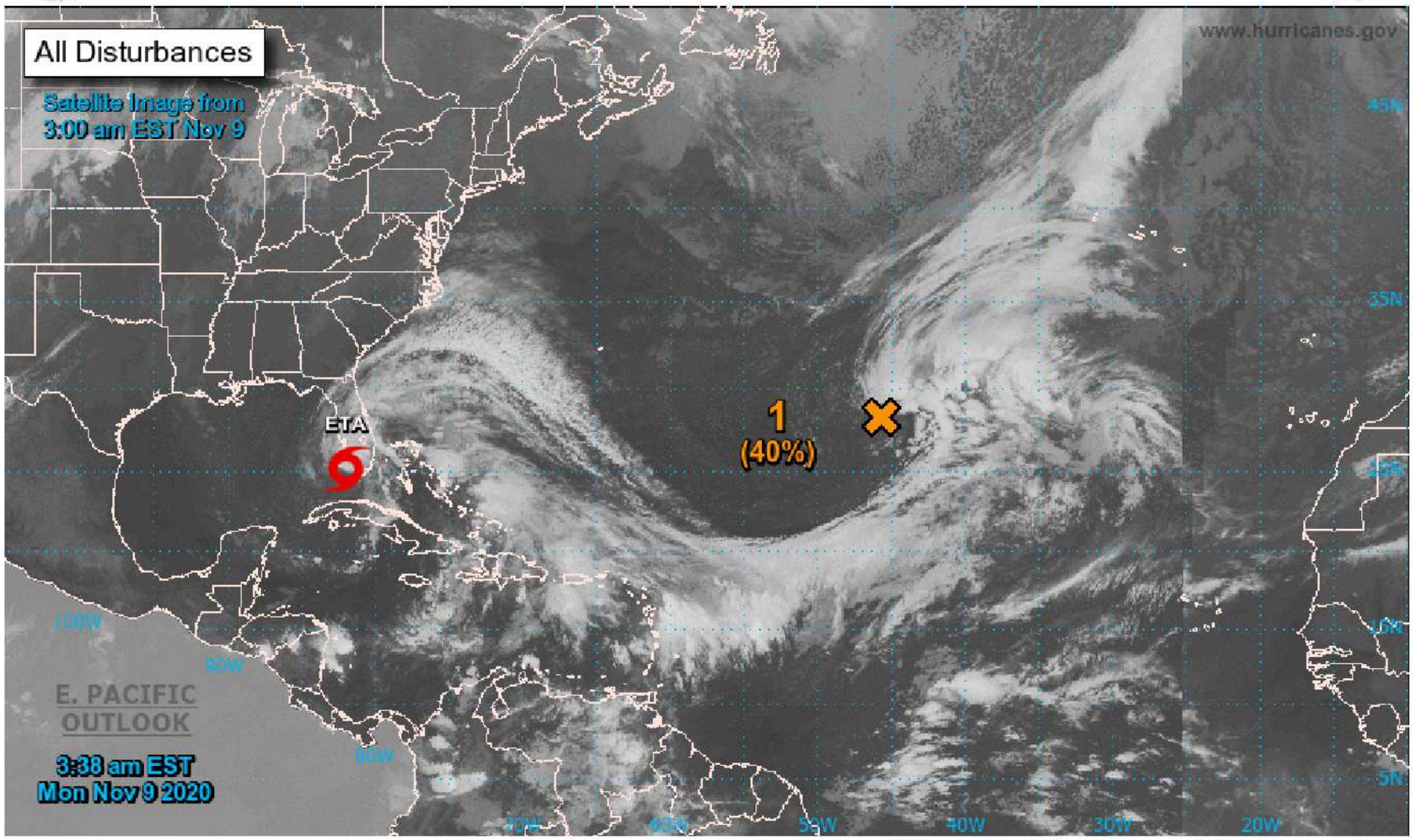
As of 11/9/2020 4:57 AM

Tropical – Two-Day Outlook *(See NHC for the latest information)*

Tropical Storm Eta Advisory Number 36
400 AM EST Mon Nov 09 2020

1. Heavy rainfall from Eta will continue across portions of Cuba, Jamaica, the Bahamas, and southern Florida and spread north into central Florida. Life-threatening flash flooding will be possible across inundated urban areas of southeast Florida today. Flash and urban flooding will also be possible for Cuba, Jamaica, the Bahamas and the remainder of southern Florida, along with potential minor river flooding in central Florida.
2. Tropical storm conditions will continue across portions of the Florida Keys, and south and central Florida today.
3. Water levels will gradually recede along portions of the southern coast of the Florida peninsula and Keys. Residents in these areas should follow any advice given by local officials.
4. Eta could approach the Florida Gulf Coast later this week as a tropical storm, and possibly bring impacts from rain, wind, and storm surge. Interests in this area should monitor the progress of Eta and updates to the forecast this week.

Two-Day Graphical Tropical Weather Outlook
National Hurricane Center Miami, Florida



Current Disturbances and Two-Day Cyclone Formation Chance: < 40% 40-60% > 60%
Tropical or Sub-Tropical Cyclone: Depression Storm Hurricane
Post-Tropical Cyclone or Remnants

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Daily Update Brief

As of 11/9/2020 4:57 AM

Tropical – Five-Day Outlook (See NHC for the latest information)

For the North Atlantic...Caribbean Sea and the Gulf of Mexico:

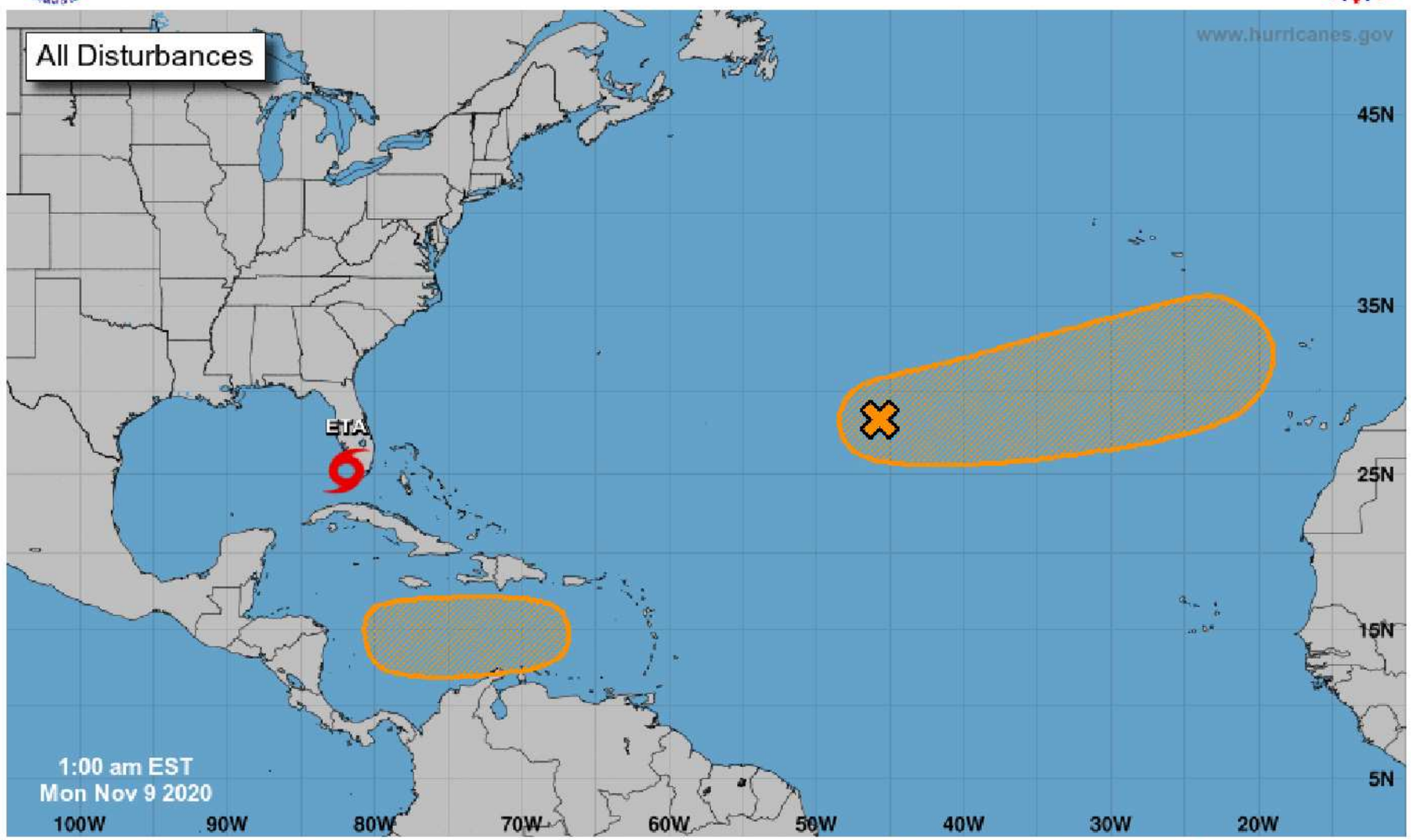
2. A tropical wave is forecast to move over the central Caribbean Sea, where an area of low pressure could form in a couple of days. Environmental conditions are forecast to be conducive for development, and a tropical depression could form late this week or over the weekend while the system moves slowly westward.

* Formation chance through 48 hours...low...near 0 percent.

* Formation chance through 5 days...medium...50 percent.

Five-Day Graphical Tropical Weather Outlook

National Hurricane Center Miami, Florida



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Tropical or Sub-Tropical Cyclone: Depression Storm Hurricane

Post-Tropical Cyclone or Remnants

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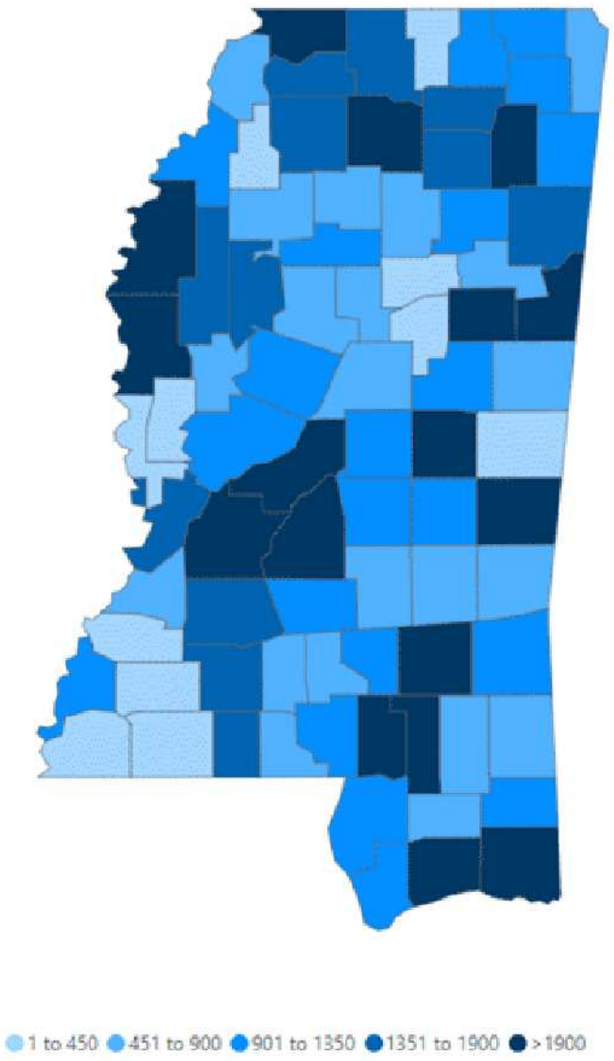
MS-DOH-21-1816-A-000905

Daily Update Brief

As of 11/9/2020 4:57 AM

Coronavirus Disease 2019 (COVID-19)

Mississippi COVID-19
Cases and Deaths by Race with Ethnicity
as of 6 pm CT, November 6, 2020



Total Cases

125,885

	American Indian or Alaska Native	Asian	Black	White	Other	Unknown
Non Hispanic	574	365	37,673	39,890	1,416	620
Hispanic	21	14	177	1,064	2,001	195
Unknown Ethnicity	803	100	8,615	10,225	5,066	17,066

Total Deaths

3,433

	American Indian or Alaska Native	Asian	Black	White	Other	Unknown
Non Hispanic	65	3	1,370	1,384	18	4
Hispanic	1	0	7	20	14	1
Unknown Ethnicity	21	5	177	233	29	81

The MSDH has established a COVID-19 Hotline for the general public:
877-978-6453
7 Days a week – 7:00am until 7:00pm

Local COVID-19 testing:
We now have a list of local COVID-19 testing providers for you to contact if you
have symptoms:
View local testing providers »

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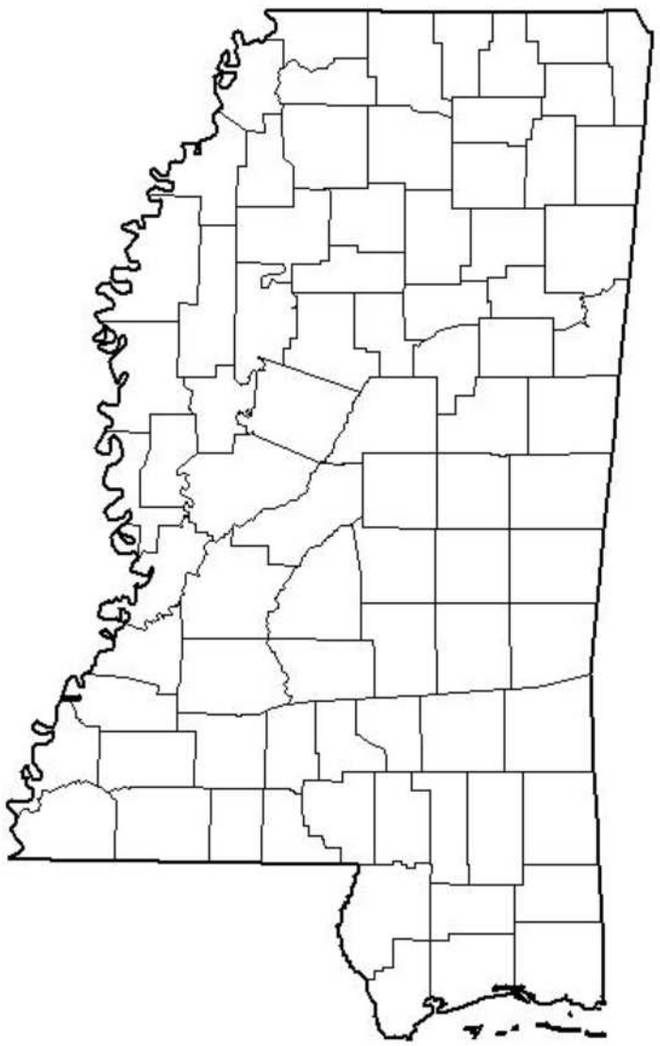
Daily Update Brief

As of 11/9/2020 4:57 AM

Map Released: Thursday, November 5, 2020

U.S. Drought Monitor

Mississippi



November 3, 2020

(Released Thursday, Nov. 5, 2020)

Valid 7 a.m. EST

Drought Conditions (Percent Area)

	None	D0-D4	D1-D4	D2-D4	D3-D4	D4
Current	100.00	0.00	0.00	0.00	0.00	0.00
Last Week *10-27-2020*	93.37	6.63	0.00	0.00	0.00	0.00
3 Months Ago *08-04-2020*	83.92	16.08	0.00	0.00	0.00	0.00
Start of Calendar Year *12-31-2019*	95.94	4.06	0.27	0.00	0.00	0.00
Start of Water Year *09-29-2020*	81.73	18.27	0.00	0.00	0.00	0.00
One Year Ago *11-05-2019*	98.39	1.61	0.22	0.00	0.00	0.00

Intensity:

- None
- D0 Abnormally Dry
- D1 Moderate Drought
- D2 Severe Drought
- D3 Extreme Drought
- D4 Exceptional Drought

The Drought Monitor focuses on broad-scale conditions. Local conditions may vary. For more information on the Drought Monitor, go to https://droughtmonitor.unl.edu/About.aspx

Author:

David Miskus

NOAA/NWS/NCEP/CPC

droughtmonitor.unl.edu

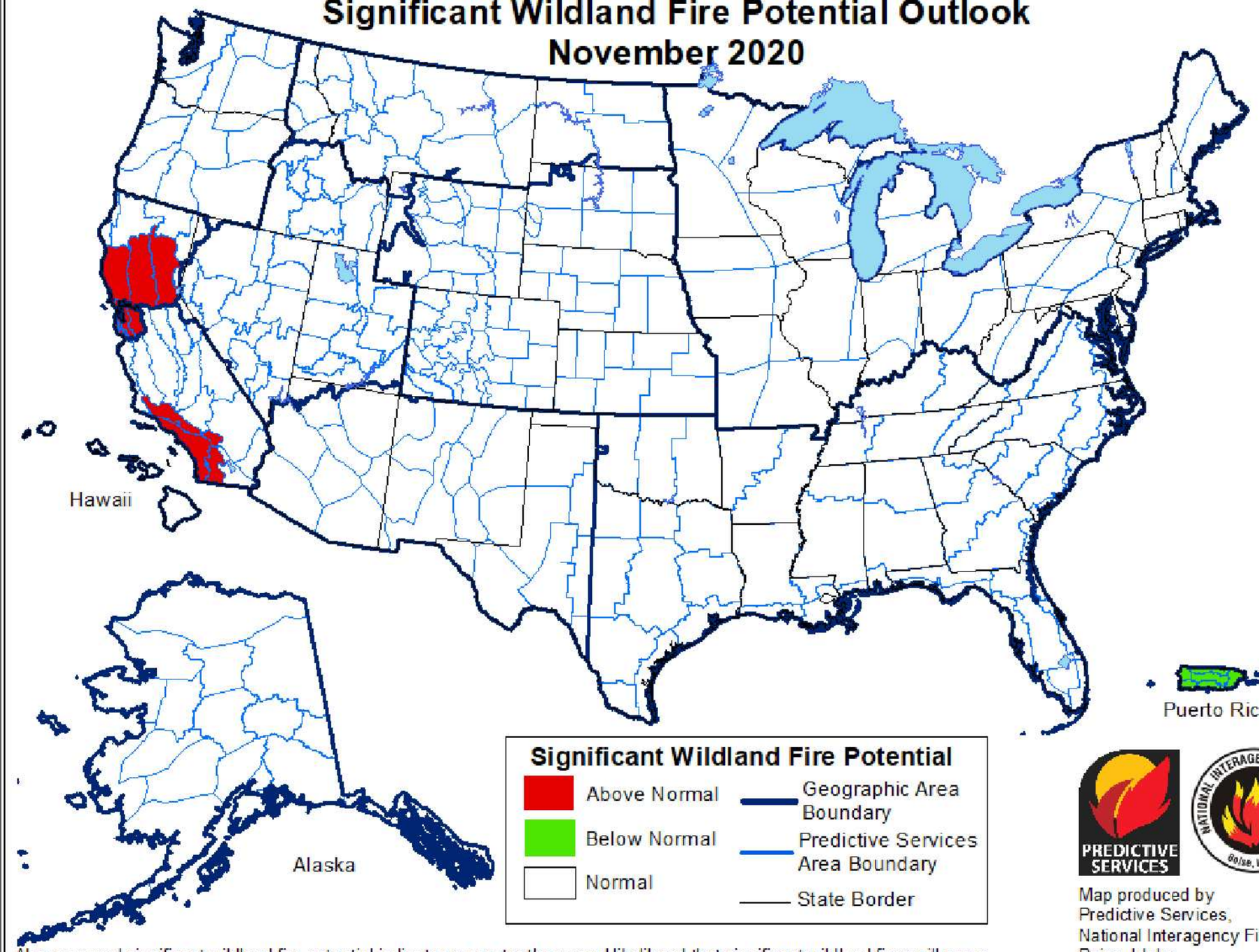
There Are Currently No Active County Burn Bans

A burn ban means no outdoor burning of ANY KIND.

Daily Update Brief

As of 11/9/2020 4:57 AM

Significant Wildland Fire Potential Outlook
November 2020



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Significant wildland fires should be expected at typical times and intervals during normal significant wildland fire potential conditions.
Significant wildland fires are still possible but less likely than usual during forecasted below normal periods.

Map produced by
Predictive Services,
National Interagency Fire Center
Boise, Idaho
Issued November 1, 2020
Next issuance December 1, 2020

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Daily Update Brief

As of 11/9/2020 4:57 AM

Mississippi News of Interest

Gulfport celebration for Biden-Harris more than just about a victory for Democrats

A celebration in downtown Gulfport on Sunday wasn't just about the historic victory by President-elect Joe Biden and Vice President-elect Kamala Harris. In fact, it could well have happened, even if the Democrats had lost the presidential election.

U.S. Senator Roger Wicker: Honoring America's Veterans

Each year on November 11th, our nation honors those who have served in the U.S. military. We show our appreciation through parades, ceremonies, and simple words of thanks. The opportunity to cast ballots in the recent election is one reason to be…

52nd Fall Street Festival brings much needed business to Picayune

Crowds of people took in the 52nd year of the Picayune Fall Street Festival while organizers praise the two-day event. The festival was a much-needed event after a very impactful year for South Mississippians.

Piney Woods School added to National Register of Historic Places

Piney Woods Country Life School, one of the nation's oldest independent Black boarding schools, has been listed in the National Register of Historic Places.

Voters narrowly approve keeping Confederate statue in place

A referendum on the monument was placed on the Nov. 3 ballot after the Forrest County Board of Supervisors couldn't agree on what to do with the monument in June, The Hattiesburg American reports.

Several leadership roles shuffled in Mississippi Senate

Several members of the Mississippi Senate are receiving new leadership roles, weeks ahead of the next legislative session that begins in January.

Aberdeen residents looks to revive old sports complex

People of Aberdeen volunteered their time on Saturday to rejuvenate the old sports complex on Sharpley Bottom Drive. Residents helped put together bleachers and clean up the area.

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Daily Update Brief

As of 11/9/2020 4:57 AM

Emergency Management News

Eta strikes Florida Keys; expected to become hurricane

Florida officials closed beaches, ports and COVID testing sites, shut down public transportation and urged residents to stay off the street. Florida officials closed beaches, ports and COVID testing sites, shut down public transportation and urged residents…

State-by-state face mask mandates vary but mostly require coverage in indoor public spaces

Because scientists and medical experts overwhelmingly recommend masks as an effective way to limit the spread of COVID19, I am placing the entire state of Utah under a mask mandate until further notice 128 Businesses must require employees to wear…

More COVID-19 hospitalizations among these workers

Construction workers are almost five times more likely to be hospitalized for the coronavirus compared to non-construction workers, according to a study from researchers with The University of Texas at Austin.

Election Security 2020: Why Did Things Go Right This Time?

In the weeks leading up to the 2020 presidential election, the U.S. government and technology companies took several steps to safeguard election security in cyberspace, focusing their efforts on disinformation and cyberattacks.

How to Follow CDC Holiday Party Advice

With the holiday season already well underway (at least when you look at the store shelves and displays), it is understandable that employers might want to give a little boost to morale by holding something like a traditional office Christmas party.

How to Prepare for Hurricane Dangers

OSHA requires firms with over 10 employees to adopt an emergency action plan. After many years of mild hurricane seasons, 2020 has proven to be extraordinarily active, resulting in widespread damage, deaths and injuries.

Proposed troop drawdown in Germany complicates plans to hand back military land

A directive from President Donald Trump to withdraw some 12,000 U.S. troops from Germany and move numerous units elsewhere in Europe or to the U.S. has further complicated the plan, which was first announced by the Pentagon in 2015.

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Daily Update Brief

As of 11/9/2020 4:57 AM

Significant MEMA Future Events

Date(s)	Event	Location
09NOV20	Procurement Under Grants Training 2hr	FEMA Virtual
10NOV20	Procurement Under Grants Training 1hr	FEMA Virtual
09-10NOV20	G358 – Evac/Re-Entry Virtual Training	MEMA Virtual
19-20NOV20	G400 – Virtual Training	MEMA Virtual
01-30DEC29	Request Only Training	MEMA

To sign up for or inquire about training opportunities, please contact MEMA's Training Bureau at 601-933-6370

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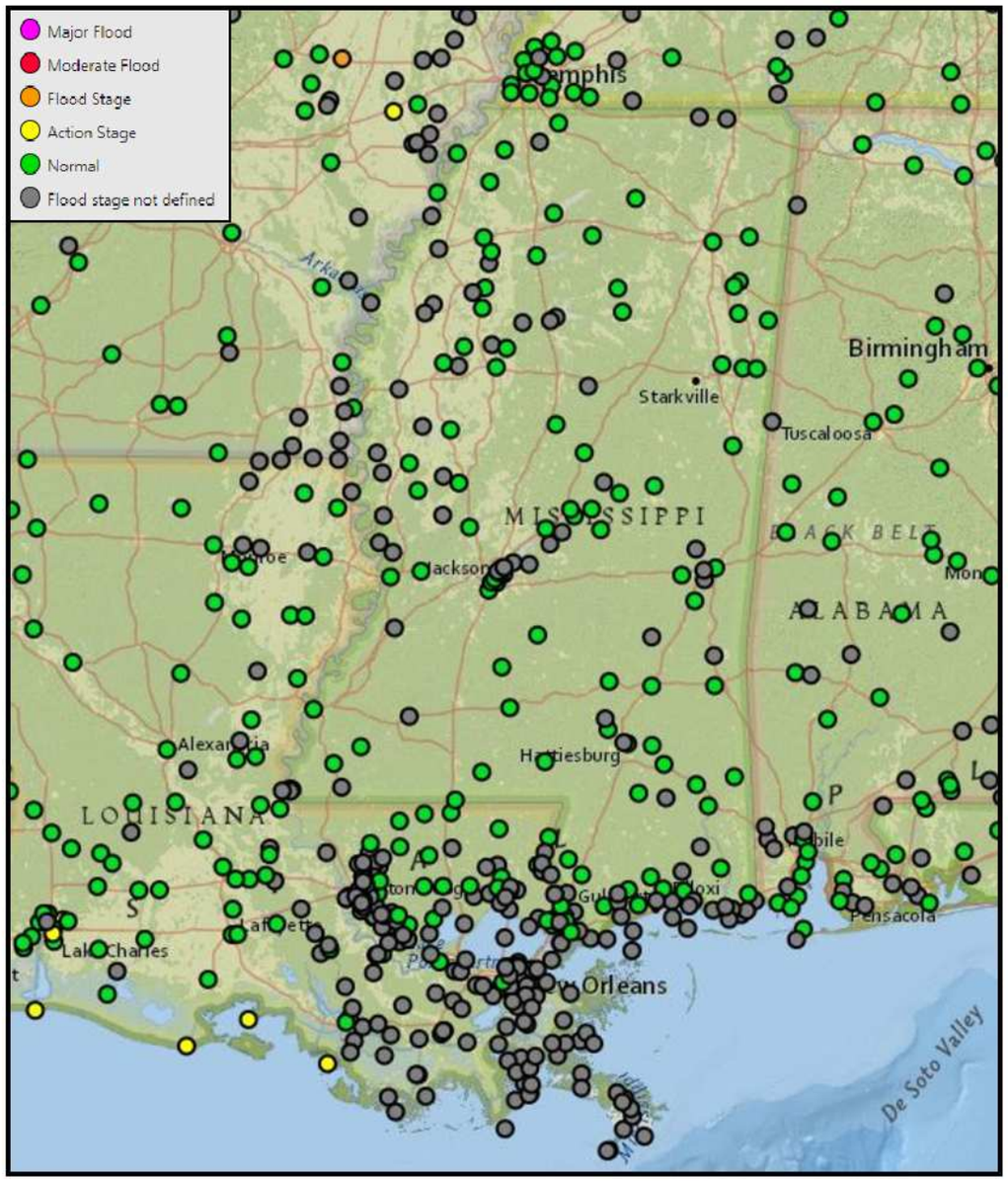
Daily Update Brief

As of 11/9/2020 4:57 AM

NWS Enhanced Data Display

Observed River Gauges and Forecasted to Flood

NWS – Observed River Gauges



NWS – Near or Above Flood Stage

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MS-DOH-21-1816-A-000912

Daily Update Brief

As of 11/9/2020 4:57 AM

New Madrid Seismic Data – 30 Day, Magnitude 2.5+ Update

M 2.5 - 5 km ENE of Maynard, Arkansas
2020-10-29 01:20:23 (UTC) 36.441°N 90.842°W
11.8 km

M 2.6 - 5 km NE of Maynard, Arkansas
2020-10-28 20:22:58 (UTC) 36.459°N 90.857°W
3.7 km

M 2.5 - 4 km NE of Maynard, Arkansas
2020-10-28 10:11:27 (UTC) 36.454°N 90.864°W
3.4 km

M 2.5 - 5 km ENE of Maynard, Arkansas
2020-10-27 00:02:18 (UTC) 36.439°N 90.842°W
7.9 km

M 2.6 - 6 km ENE of Maynard, Arkansas
2020-10-26 00:07:03 (UTC) 36.433°N 90.829°W
11.8 km

M 2.5 - 6 km E of Maynard, Arkansas
2020-10-13 21:48:14 (UTC) 36.430°N 90.828°W
10.1 km

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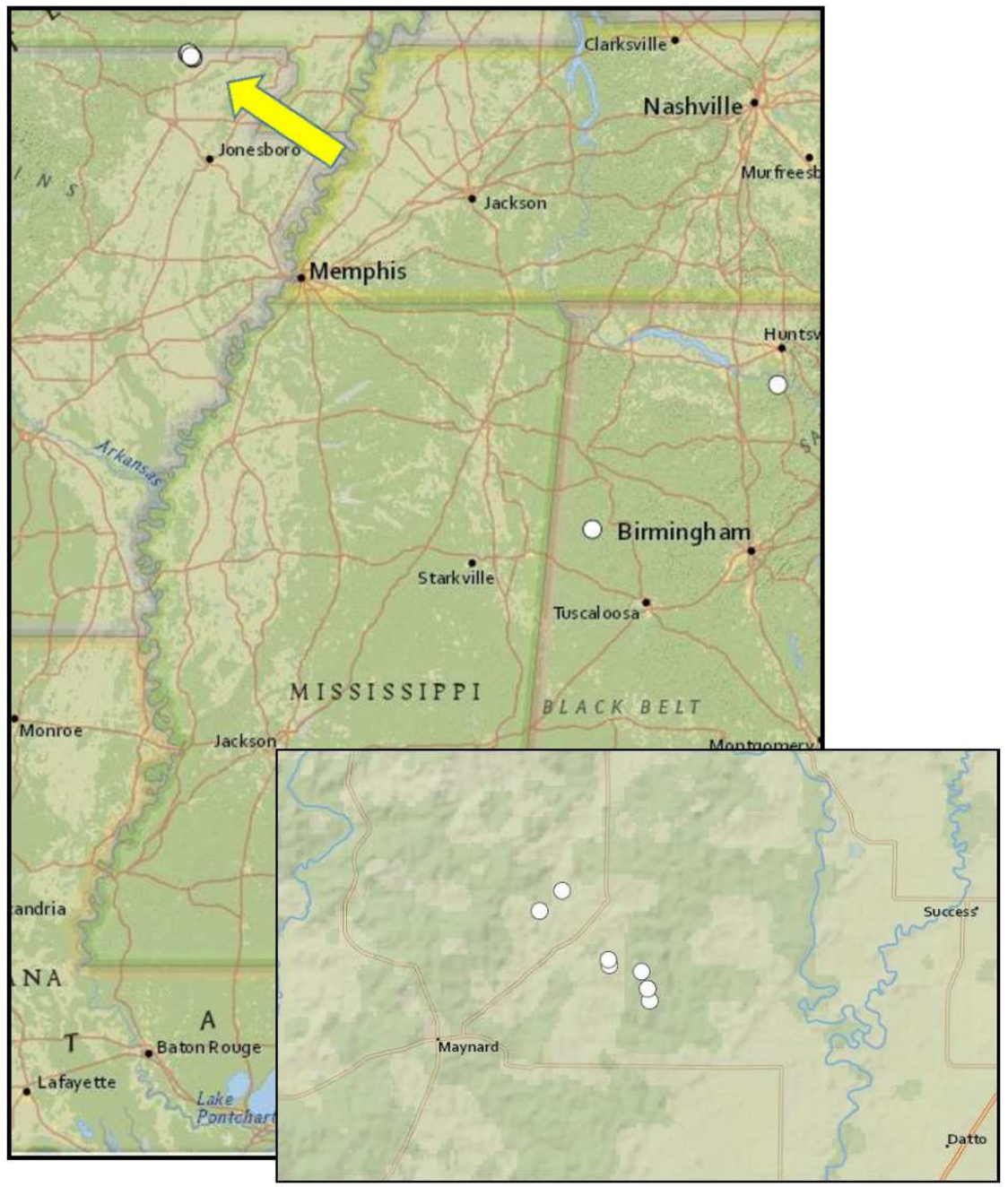
Daily Update Brief

As of 11/9/2020 4:57 AM

New Madrid Seismic Data – 30 Day, Magnitude 2.5+ Update

M 2.6 - 6 km ENE of Maynard, Arkansas
2020-10-12 01:35:46 (UTC) 36.438°N 90.831°W
9.9 km

M 2.6 - 6 km E of Maynard, Arkansas
2020-10-08 18:11:52 (UTC) 36.426°N 90.825°W
8.6 km



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Daily Update Brief

As of 11/9/2020 4:57 AM

Websites of Interest

MEMA: http://www.msema.org

MEMA Facebook: https://www.facebook.com/msemaorg facebook

MEMA Twitter: https://twitter.com/msema

MEMA YouTube: https://www.youtube.com/user/MSEMAorg1 YouTube

MEMA Snapchat: @msemergencymgmt

MEMA Situation Room (Adobe Connect): Daily Sitroom – https://share.dhs.gov/msema
EMAC Sitroom – https://share.dhs.gov/ms-emac

Federal Emergency Management Agency (FEMA): http://www.fema.gov

Emergency Management Institute (EMI): https://training.fema.gov/emi.aspx

Dept. of Homeland Security (DHS) : https://www.dhs.gov
https://www.dhs.gov/dhs-component-websites

Homeland Security Information Network (HSIN): https://www.dhs.gov/homeland-security-information-network-hsin

US Army Corps of Engineers – Vicksburg District: http://www.mvk.usace.army.mil

Mississippi Forestry Commission: http://www.mfc.ms.gov

Mississippi Department of Transportation – Traffic: https://www.mdottraffic.com

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From: Weaver, Richard L COL USARMY NG MSARNG (USA)

To: Thompson, Brian L CIV USAF 81 TW (USA); Barrett, Colleen E CIV USN CBC GULFPORT MS (USA); Schneider, Nathan A CAPT USN SUPSHIP GULFCOAST MS (USA); Carter, Travis L CAPT USCG GULF COAST (USA); Burnett, William H SES USN COMNAVMETOCCOM SSC (USA); Howe, Bradley K COL USARMY NG MSARNG (USA); "Schlosser, Teresa A COL USARMY CEPOF (USA)"; Mccullouch, Murry Brent COL USARMY NG MSARNG (USA); Jody.m.smith2.mil; Thomas, Christopher M LTC USARMY NG MSARNG (USA); "Hilliard, Robert A COL USARMY CEMVK (USA)"; "Hinkebein, Andrew (Wicker)"; Ratcliffe, Andrew M III LTC USARMY NG MSARNG (USA); Austin, Lawrence B LTC USARMY NG MSARNG (USA); Dingler, Christopher Wayne 1SG USARMY NG MSARNG (USA); Hester, Colby D CPT USARMY NG MSARNG (USA); Hargett, Joe D COL USARMY NG MSARNG (USA); Smith, Cynthia Lea (Cindy) Col USAF 172 AW (USA); Williams, Stanley T CSM USARMY NG MSARNG (USA); "Craig Sumrall"; "DuVerger, Frank R III LTC USARMY CEMVK (USA)"; "Gargiulo, Michele"; "Laura Hipp"; "AnneHall Brashier"; Craig, Jim; Dobbs, Thomas E; McIngvale, James W CTR (USA); "Andrew McMillin"; Welborn, Jeffrey H Col USAF (USA); Reedy, Millard G IV COL USARMY NG MSARNG (USA); Shaffer, Perish Undrea MAJ USARMY NG MSANG (USA); Moore, Timothy B (Brent) CAPT USN NAS MERIDIAN MS (USA); Blackwell, Heather W Col USAF US STRATCOM (USA); 14 FTW/CAT Organizational Mailbox; Powell, Jeffrey S (Jeff) CAPT USN CBC GULFPORT MS (USA); Tillman, Tommy F Jr Col USAF 172 AW (USA); Cole, Lynn E Col USAF 172 AW (USA); Watson, Britt A Col USAF 186 ARW (USA); McCormick, Berry L Col USAF MS CRTC (USA); Mantooth, Randall P LTC USARMY NG MSARNG (USA)

Subject: ICC COVID 19

Date: Tuesday, November 10, 2020 9:57:04 AM

Attachments: DUB 11.10.2020.pdf

[redacted]

Good morning to all

We will not have a call on this Friday (Nov. 13th) based on the ICC meeting on the 17th. If any questions please let me know and I will send out the final agenda Thursday.

V/R

Rick

Daily Update Brief

24 Hour State Warning Point Report

PREPARING FOR TOMORROW'S DISASTERS TODAY

11/10/2020 4:59:36 AM

SEOC Status – **SEOC Level 2 (Partial Activation)**

MS-DOH-21-1816-A-000917

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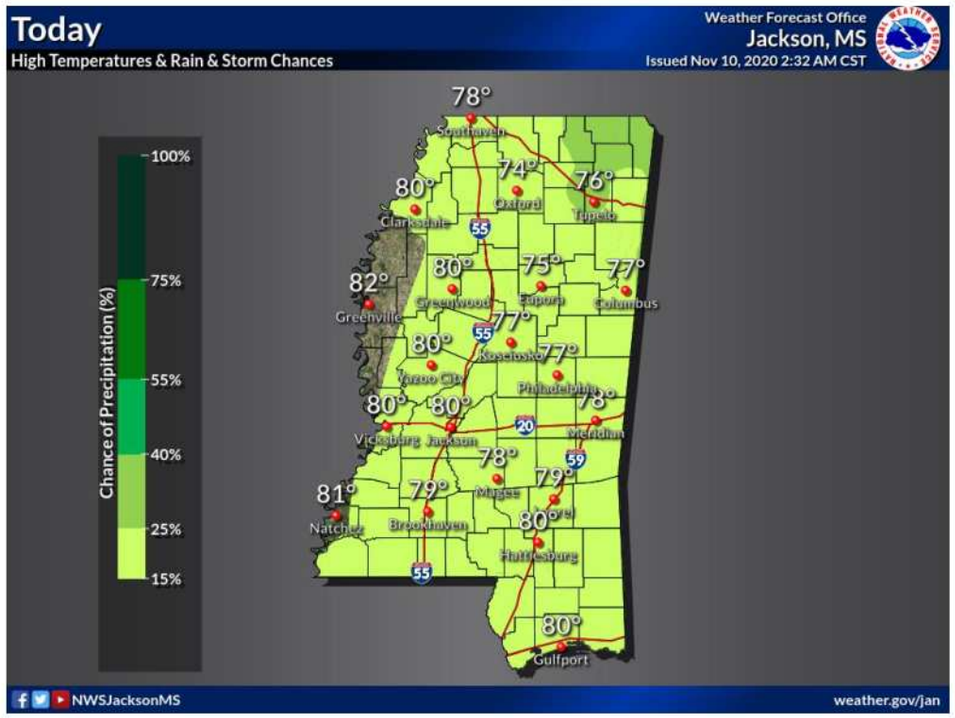
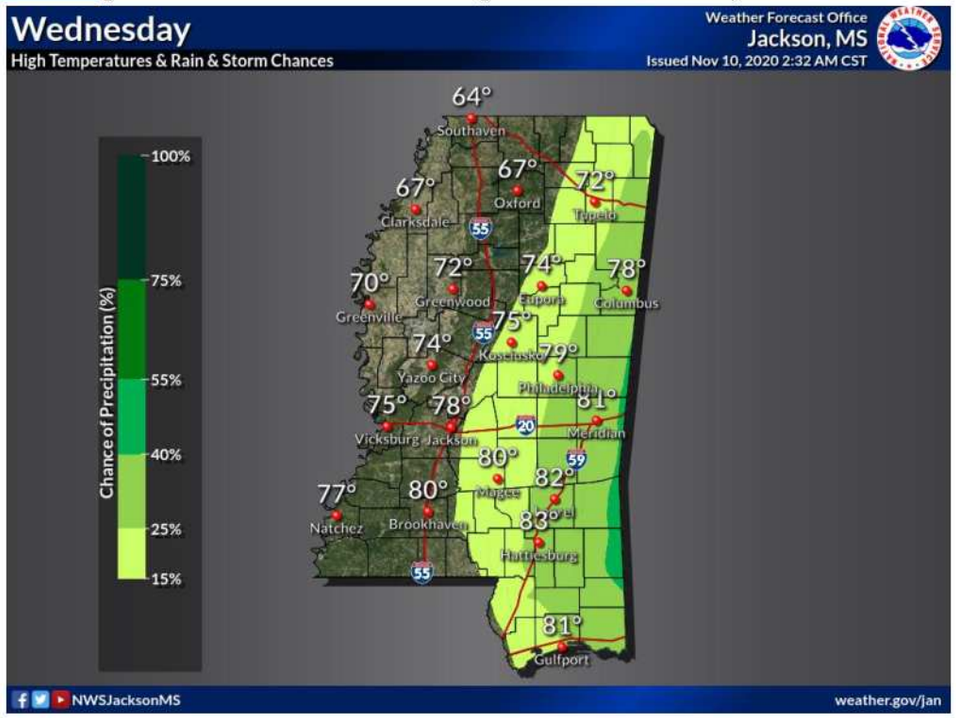
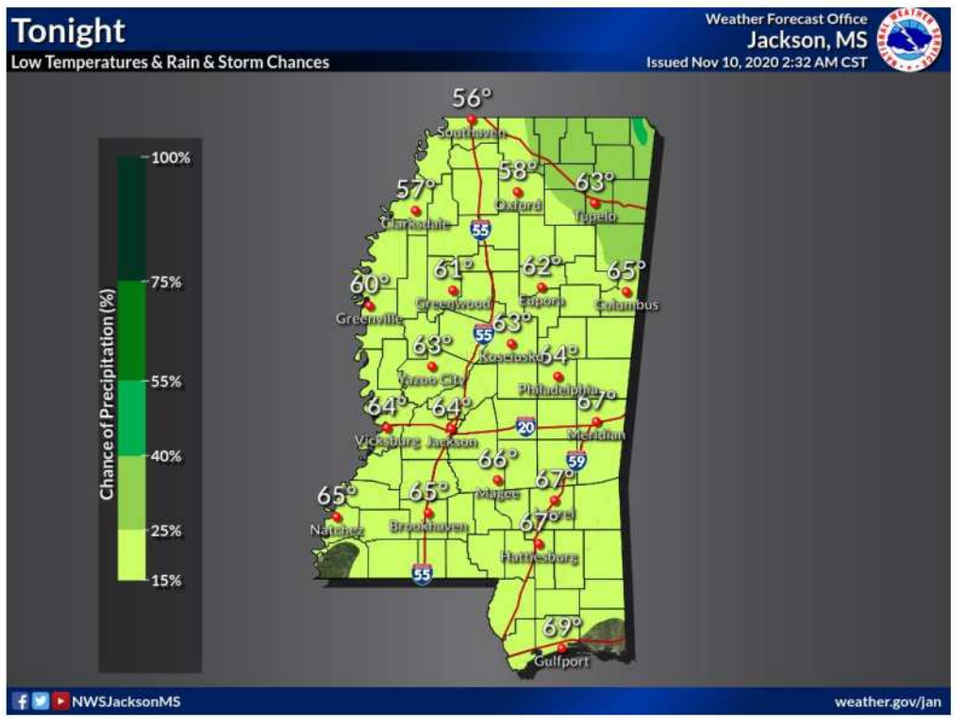
Daily Update Brief

As of 11/10/2020 4:59 AM

Weather - Next 24 hours (See NWS for the latest information)







NORTH:
TUESDAY...PARTLY SUNNY. SLIGHT CHANCE OF SHOWERS
TUESDAY NIGHT...MOSTLY CLOUDY. SLIGHT CHANCE OF SHOWERS.
VETERANS DAY...PARTLY SUNNY. SLIGHT CHANCE OF SHOWERS.
WEDNESDAY NIGHT...COOLER. PARTLY CLOUDY. LOWS NEAR 50.

CENTRAL:
TUESDAY...PARTLY SUNNY. SLIGHT CHANCE OF SHOWERS
TUESDAY NIGHT... MOSTLY CLOUDY. SLIGHT CHANCE OF SHOWERS.
VETERANS DAY...PARTLY SUNNY. SLIGHT CHANCE OF SHOWERS.
WEDNESDAY NIGHT...PARTLY CLOUDY. LOWS IN THE MID 50S.

SOUTH:
TUESDAY...PARTLY SUNNY. SLIGHT CHANCE OF SHOWERS
TUESDAY NIGHT...PARTLY CLOUDY IN THE EVENING
VETERANS DAY...MOSTLY SUNNY. SLIGHT CHANCE OF SHOWERS
WEDNESDAY NIGHT...PARTLY CLOUDY. LOWS IN THE 60s

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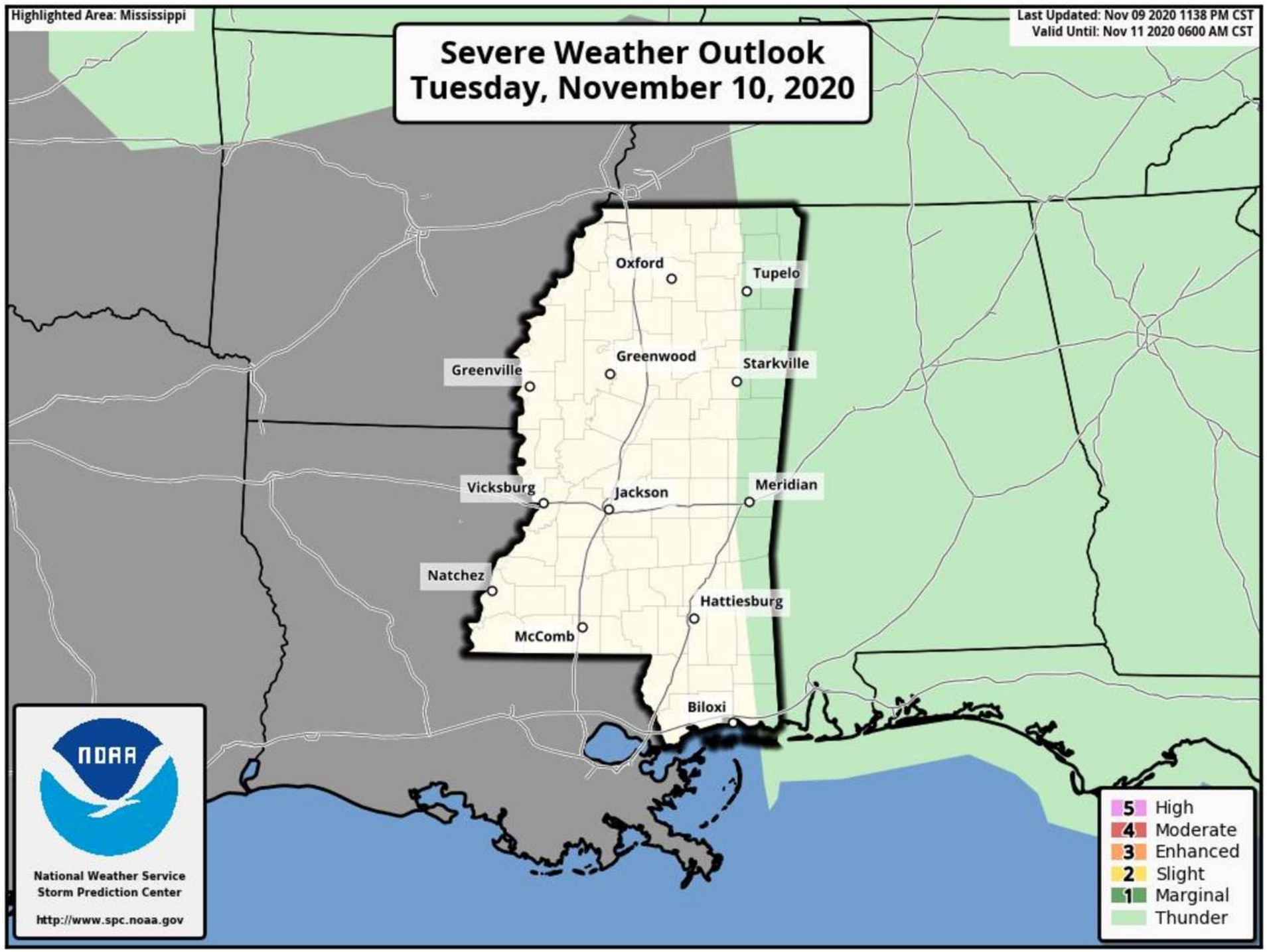
MS-DOH-21-1016-A-000918

Daily Update Brief

As of 11/10/2020 4:59 AM

Weather – Day 1 SPC Severe Weather Outlook (See SPC for details)



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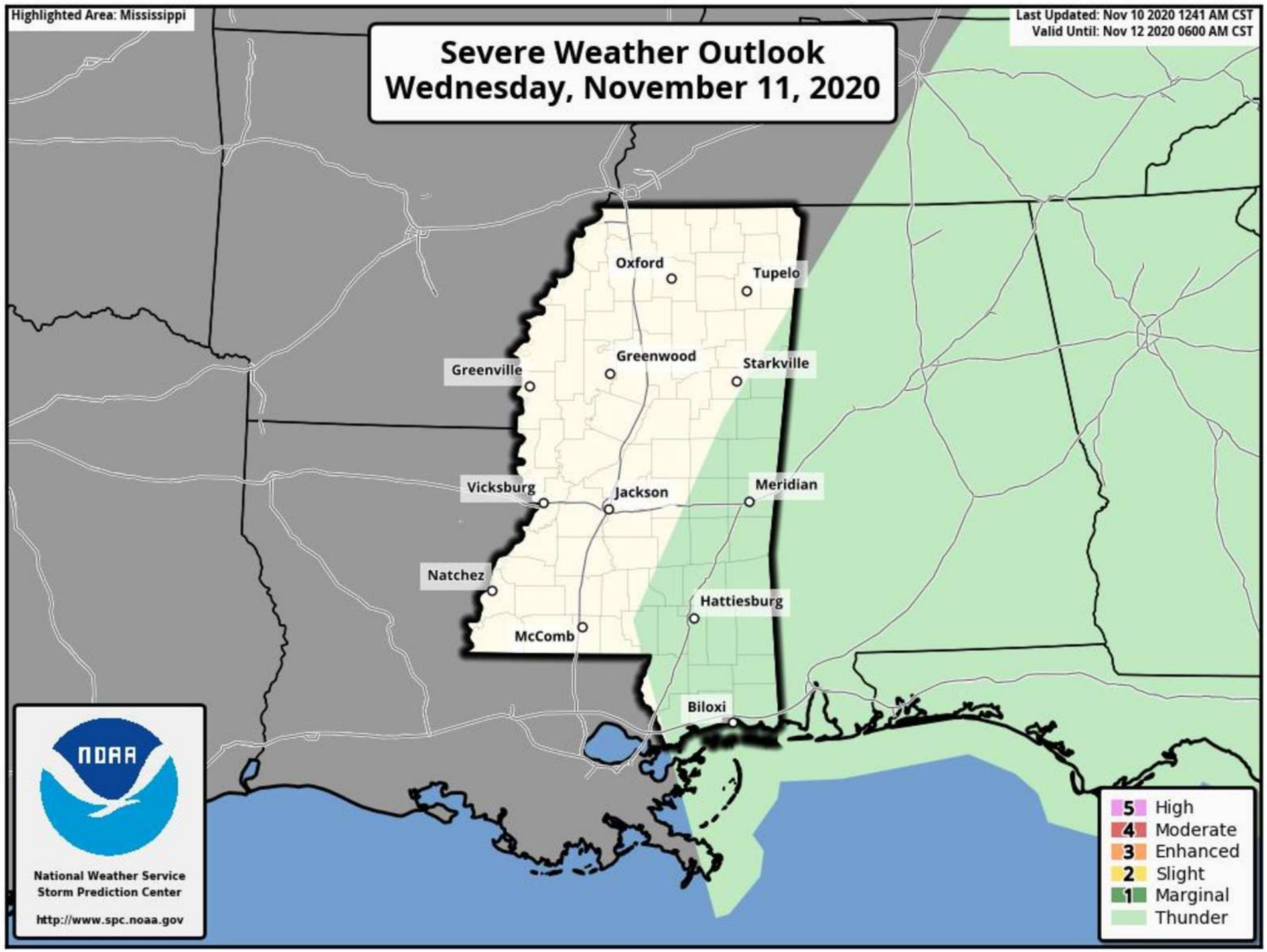
MS-DOH-21-1816-A-000919

Daily Update Brief

As of 11/10/2020 4:59 AM

Weather – Day 2 SPC Severe Weather Outlook (See SPC for details)



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MS-DOH-21-1816-A-000920

Daily Update Brief

As of 11/10/2020 4:59 AM

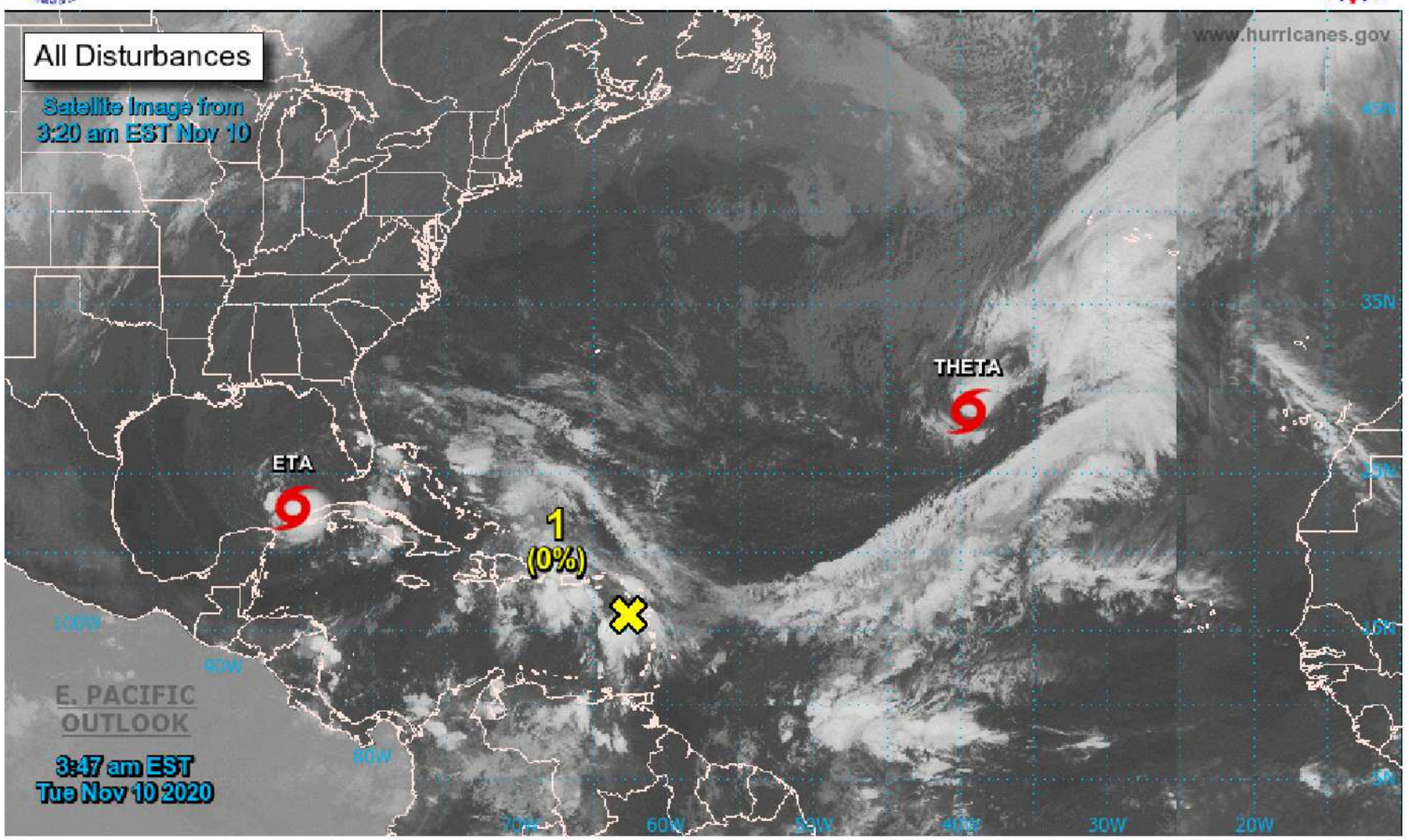
Tropical – Two-Day Outlook *(See NHC for the latest information)*

Tropical Storm Eta Advisory Number 40
300 AM CST Tue Nov 10 2020

1. Heavy rainfall from Eta will continue across portions of Cuba, the Bahamas, and southern Florida and spread north into central Florida. Additional flash and urban flooding, especially across previously inundated areas, will be possible in South Florida tonight. Flash and urban flooding will also be possible for Cuba, the Bahamas and the remainder of southern Florida over the next several days.

2. Eta could approach the Florida Gulf Coast later this week as a tropical storm, and possibly bring impacts from rain, wind, and storm surge. Interests in this area should continue to monitor the progress of Eta and updates to the forecast this week.

Two-Day Graphical Tropical Weather Outlook
National Hurricane Center Miami, Florida



Current Disturbances and Two-Day Cyclone Formation Chance: < 40% 40-60% > 60%
Tropical or Sub-Tropical Cyclone: Depression Storm Hurricane
Post-Tropical Cyclone or Remnants

MS-DOH-21-1816-A-000921

Daily Update Brief

As of 11/10/2020 4:59 AM

Tropical – Five-Day Outlook (See NHC for the latest information)

For the North Atlantic...Caribbean Sea and the Gulf of Mexico:

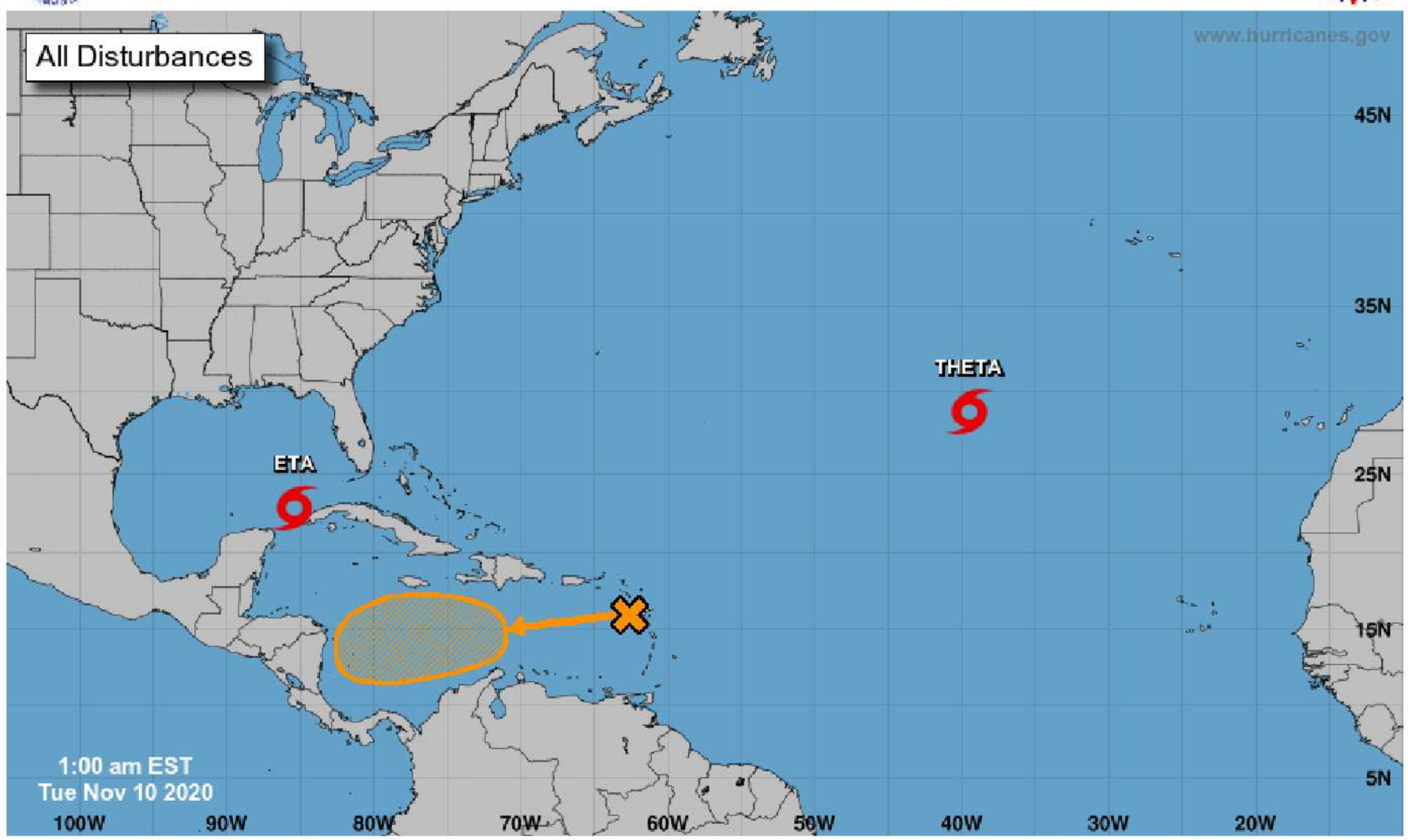
1. A tropical wave located over the eastern Caribbean Sea is producing disorganized showers and thunderstorms. This wave is expected to move westward into more conducive environmental conditions, and a tropical depression could form late this week or this weekend when the wave reaches the central or western Caribbean Sea.

* Formation chance through 48 hours...low...near 0 percent.

* Formation chance through 5 days...medium...60 percent.

Five-Day Graphical Tropical Weather Outlook

National Hurricane Center Miami, Florida



Current Disturbances and Five-Day Cyclone Formation Chance: < 40% 40-60% > 60%

Tropical or Sub-Tropical Cyclone: Depression Storm Hurricane

Post-Tropical Cyclone or Remnants

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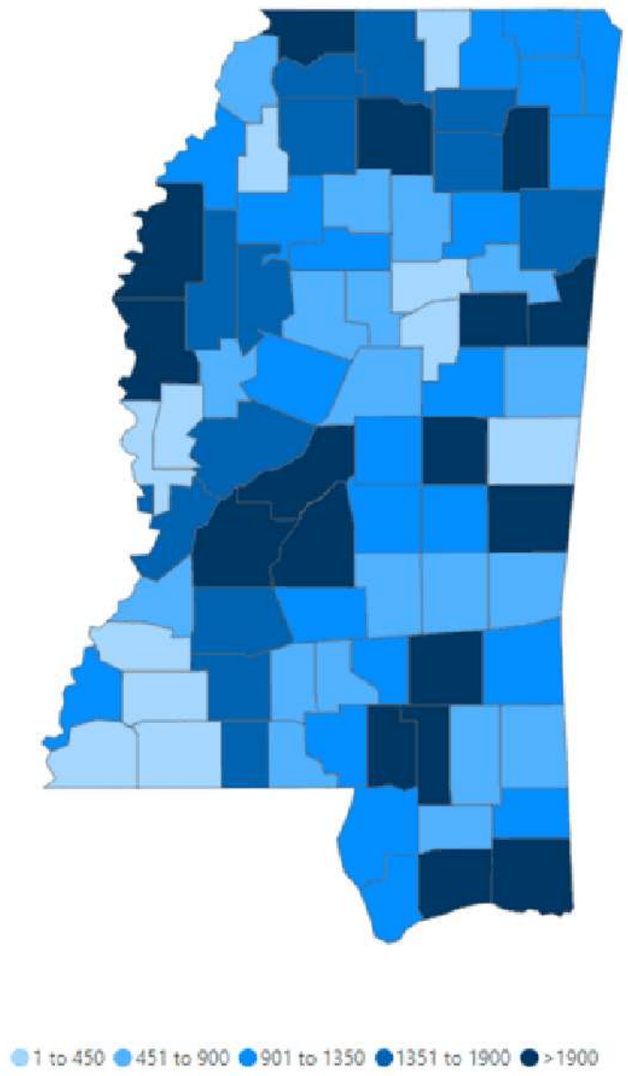
MS-DOH-21-1816-A-000922

Daily Update Brief

As of 11/10/2020 4:59 AM

Coronavirus Disease 2019 (COVID-19)

Mississippi COVID-19
Cases and Deaths by Race with Ethnicity
as of 6 pm CT, November 8, 2020



Total Cases

127,205

	American Indian or Alaska Native	Asian	Black	White	Other	Unknown
Non Hispanic	574	366	37,896	40,387	1,417	622
Hispanic	21	15	179	1,072	2,005	199
Unknown Ethnicity	803	103	8,703	10,343	5,087	17,413

Total Deaths

3,443

	American Indian or Alaska Native	Asian	Black	White	Other	Unknown
Non Hispanic	65	3	1,373	1,389	18	4
Hispanic	1	0	7	20	14	1
Unknown Ethnicity	21	5	179	233	29	81

The MSDH has established a COVID-19 Hotline for the general public:
877-978-6453
7 Days a week – 7:00am until 7:00pm

Local COVID-19 testing:
We now have a list of local COVID-19 testing providers for you to contact if you
have symptoms:
View local testing providers »

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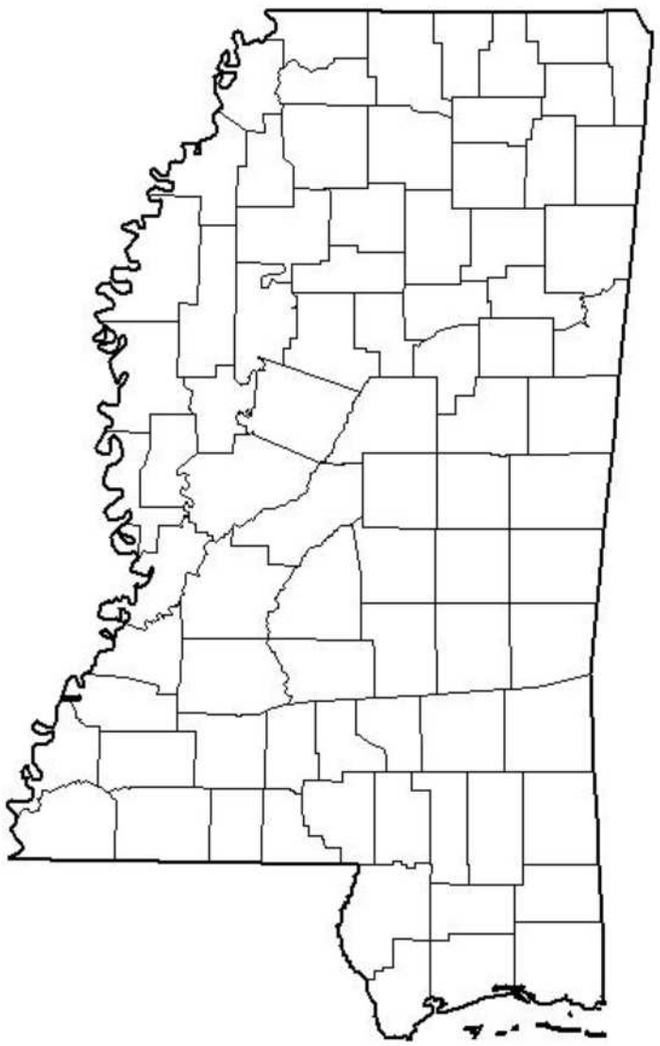
Daily Update Brief

As of 11/10/2020 4:59 AM

Map Released: Thursday, November 5, 2020

U.S. Drought Monitor

Mississippi



November 3, 2020

(Released Thursday, Nov. 5, 2020)

Valid 7 a.m. EST

Drought Conditions (Percent Area)

	None	D0-D4	D1-D4	D2-D4	D3-D4	D4
Current	100.00	0.00	0.00	0.00	0.00	0.00
Last Week *10-27-2020*	93.37	6.63	0.00	0.00	0.00	0.00
3 Months Ago *08-04-2020*	83.92	16.08	0.00	0.00	0.00	0.00
Start of Calendar Year *12-31-2019*	95.94	4.06	0.27	0.00	0.00	0.00
Start of Water Year *09-29-2020*	81.73	18.27	0.00	0.00	0.00	0.00
One Year Ago *11-05-2019*	98.39	1.61	0.22	0.00	0.00	0.00

Intensity:

- None
- D0 Abnormally Dry
- D1 Moderate Drought
- D2 Severe Drought
- D3 Extreme Drought
- D4 Exceptional Drought

The Drought Monitor focuses on broad-scale conditions. Local conditions may vary. For more information on the Drought Monitor, go to https://droughtmonitor.unl.edu/About.aspx

Author:

David Miskus
NOAA/NWS/NCEP/CPC

droughtmonitor.unl.edu

There Are Currently No Active County Burn Bans

A burn ban means no outdoor burning of ANY KIND.

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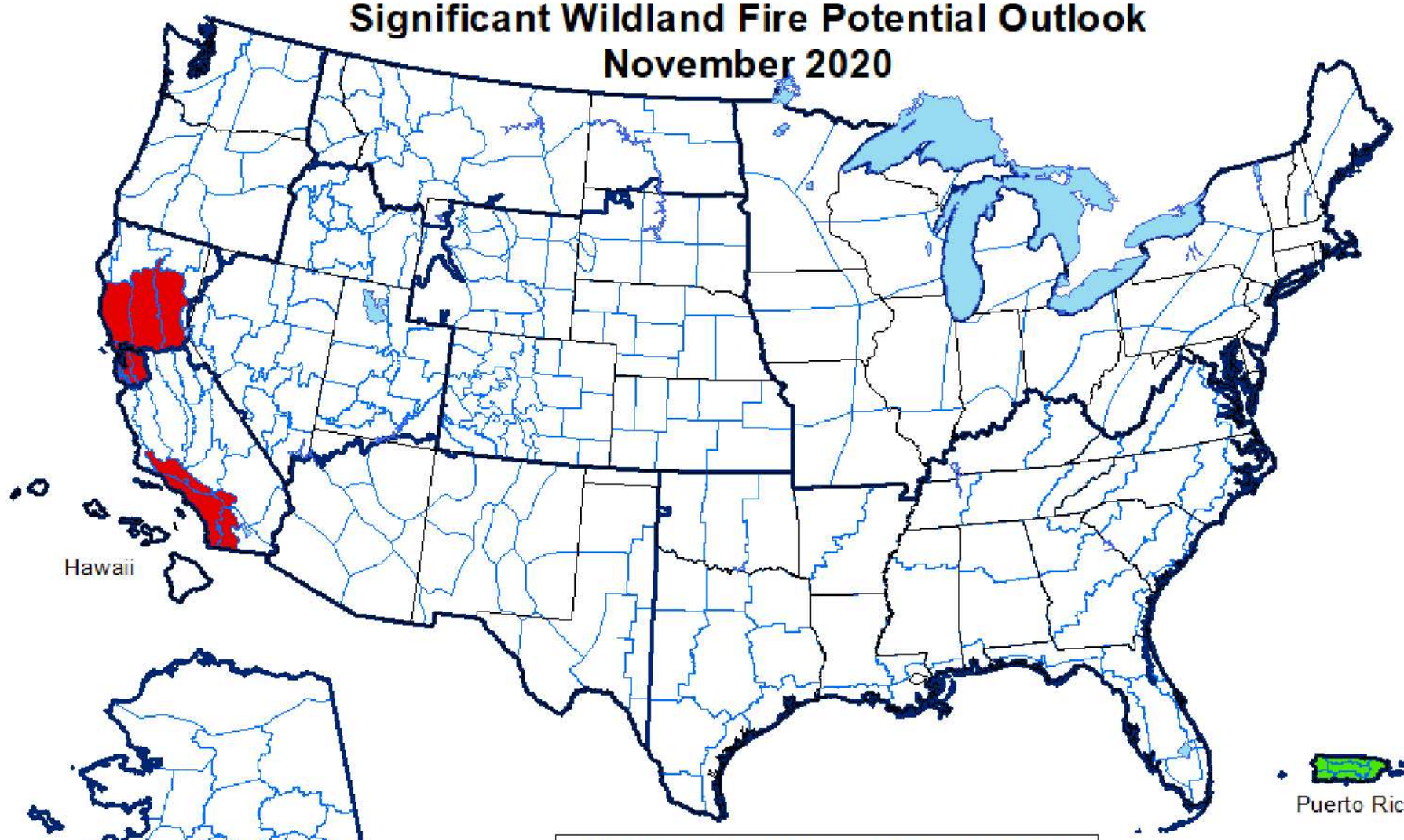
MS-DOH-21-1816-A-000924

Daily Update Brief

As of 11/10/2020 4:59 AM

Significant Wildland Fire Potential Outlook
November 2020



Significant Wildland Fire Potential

- Above Normal
- Below Normal
- Normal
- Geographic Area Boundary
- Predictive Services Area Boundary
- State Border

Above normal significant wildland fire potential indicates a greater than usual likelihood that significant wildland fires will occur.
Significant wildland fires should be expected at typical times and intervals during normal significant wildland fire potential conditions.
Significant wildland fires are still possible but less likely than usual during forecasted below normal periods.

Map produced by
Predictive Services,
National Interagency Fire Center
Boise, Idaho
Issued November 1, 2020
Next issuance December 1, 2020

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Daily Update Brief

As of 11/10/2020 4:59 AM

Mississippi News of Interest

Coast cities still cleaning up nearly two weeks after Zeta

The power may be back on and life is returning to normal, but examples of Hurricane Zeta's destruction are a constant presence across South Mississippi.

Reeves slams Cuomo's "despicable" vaccine comments

America woke up to good news this morning as Pfizer, one of the nation's leading pharmaceutical companies, announced that its COVID-19 vaccine has proven to be 90% effective during phase three of its clinical trial.

Toys for Tots registration dates still open ahead of holiday season

Time is running out for families in need to apply for help from the 2020 Toys For Tots campaign. To apply, documents must be presented at the time of registration. Only children from ages 0-12 years are eligible.

Ridgeland police chief: Practice of dropping off homeless in Jackson is a violation of department policy

Ridgeland police are implementing crisis intervention training for officers along with a diversion program, to better help the homeless, instead of just moving the problem from one city to another.

Affordable Care Act protections at-risk for Mississippi patients, clinics

The Supreme Court this week will hear arguments for and against the Affordable Care Act as advocates say COVID-19 has ravaged an already thin health safety net for Mississippi.

Yazoo Area Pump Project virtual meeting set for Tuesday

The U.S. Army Corps of Engineers (USACE) Vicksburg District will hold a virtual public meeting for the Yazoo Area Pump Project, Tuesday, November 10th, at 6 p.m.

Several schools going virtual after 'outbreak' of COVID-19 cases in Attala Co. School District

In response, the school district will be switching to virtual learning for several of the schools in the district for the next two weeks, according to Breezy News.

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Daily Update Brief

As of 11/10/2020 4:59 AM

Emergency Management News

At this time, Mississippi is in the clear from #TropicalStormEta as the system meanders through the eastern Gulf

However, a tropical wave is expected to move over the central Caribbean later this week and has a medium chance of tropical development. We'll monitor this closely!

Pearl River flood victims, who feel forgotten, to receive donations from social services employees

The Mississippi Association of Community Action Agencies saw the impact of the flood on residents and chose to give back to them during their annual conference.

Despite mask mandates in 16 counties, average daily COVID-19 cases in Miss. hit nearly three-month high

Daily average coronavirus cases in Mississippi have jumped in the last week, showing little if any significant statewide impact from the mask mandates that have been in place since late October.

Free Crisis Counseling Available for Delta and Laura Survivors

Free counseling services offered by the Substance Abuse and Mental Health Services Administration (SAMHSA) are available 24 hours a day, seven days a week to help

U.S. Department of Labor Acts to Help American Workers and Employers During the Coronavirus Pandemic

During the coronavirus pandemic, the Department of Labor is focused on protecting the safety and health of American workers, assisting our state partners as they deliver traditional unemployment and expanded unemployment benefits, ensuring…

Construction Workers Have Higher Risk of COVID-19 Hospitalization

Researchers analyzed hospitalization records at three major health system in the Austin metropolitan area between March and August 2020. Of those patients who listed their occupation, construction workers aged 18-64 were five times more likely than…

Preventing Workplace Violence

This presidential election year has seen its share of violence, including rioting, looting and violence over perceived racial injustice. Add in the passions stirred up by political divisions over the direction of the country, and the economic and psychological anxiety..

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Daily Update Brief

As of 11/10/2020 4:59 AM

Significant MEMA Future Events

Date(s)	Event	Location
10NOV20	Procurement Under Grants Training 1hr	FEMA Virtual
09-10NOV20	G358 – Evac/Re-Entry Virtual Training	MEMA Virtual
19-20NOV20	G400 – Virtual Training	MEMA Virtual
01-30DEC29	Request Only Training	MEMA

To sign up for or inquire about training opportunities, please contact MEMA's Training Bureau at 601-933-6370

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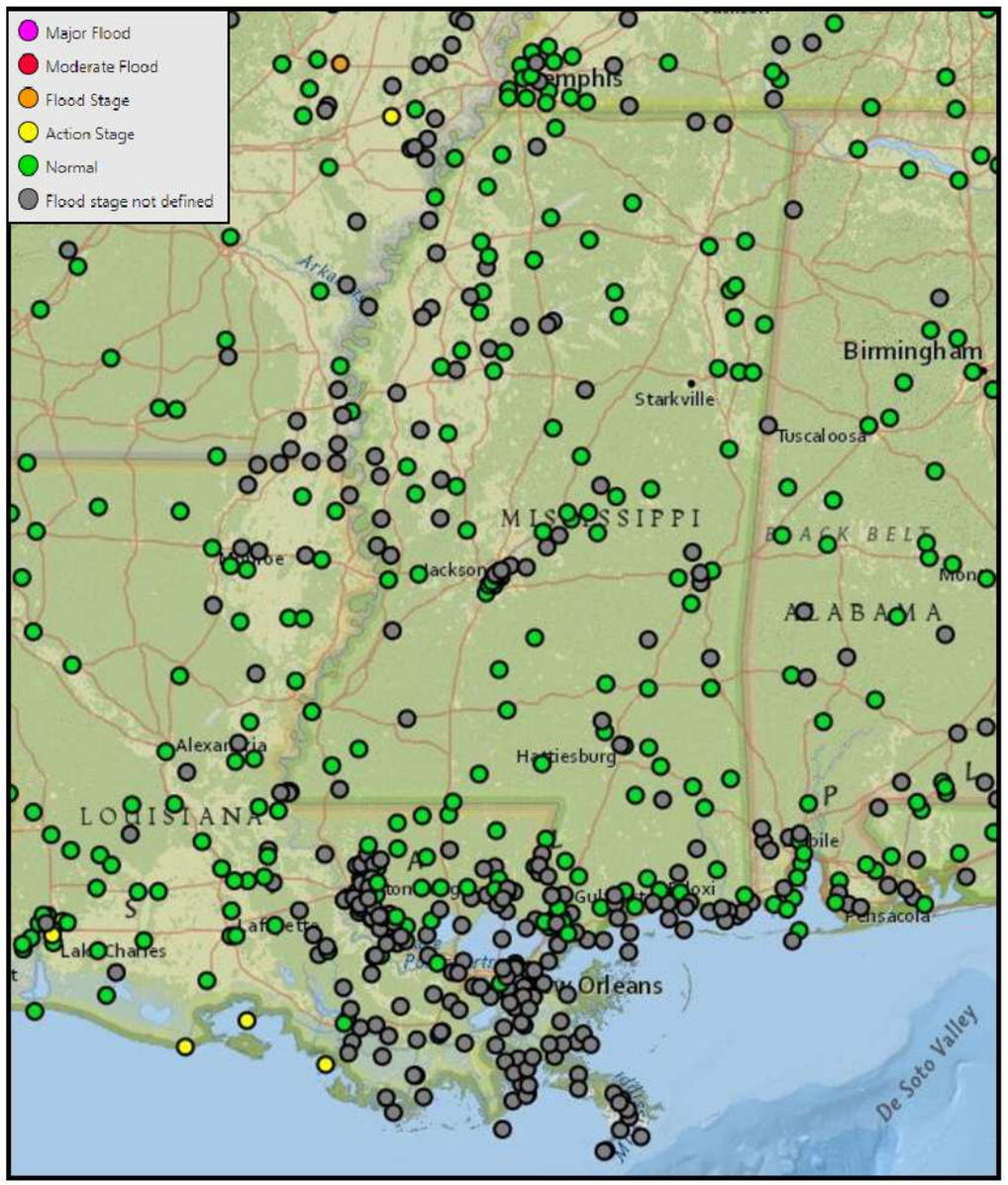
Daily Update Brief

As of 11/10/2020 4:59 AM

NWS Enhanced Data Display

Observed River Gauges and Forecasted to Flood

NWS – Observed River Gauges



NWS – Near or Above Flood Stage

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MS-DOH-21-1816-A-000929

Daily Update Brief

As of 11/10/2020 4:59 AM

New Madrid Seismic Data – 30 Day, Magnitude 2.5+ Update

M 2.5 - 5 km ENE of Maynard, Arkansas
2020-10-29 01:20:23 (UTC) 36.441°N 90.842°W
11.8 km

M 2.6 - 5 km NE of Maynard, Arkansas
2020-10-28 20:22:58 (UTC) 36.459°N 90.857°W
3.7 km

M 2.5 - 4 km NE of Maynard, Arkansas
2020-10-28 10:11:27 (UTC) 36.454°N 90.864°W
3.4 km

M 2.5 - 5 km ENE of Maynard, Arkansas
2020-10-27 00:02:18 (UTC) 36.439°N 90.842°W
7.9 km

M 2.6 - 6 km ENE of Maynard, Arkansas
2020-10-26 00:07:03 (UTC) 36.433°N 90.829°W
11.8 km

M 2.5 - 6 km E of Maynard, Arkansas
2020-10-13 21:48:14 (UTC) 36.430°N 90.828°W
10.1 km

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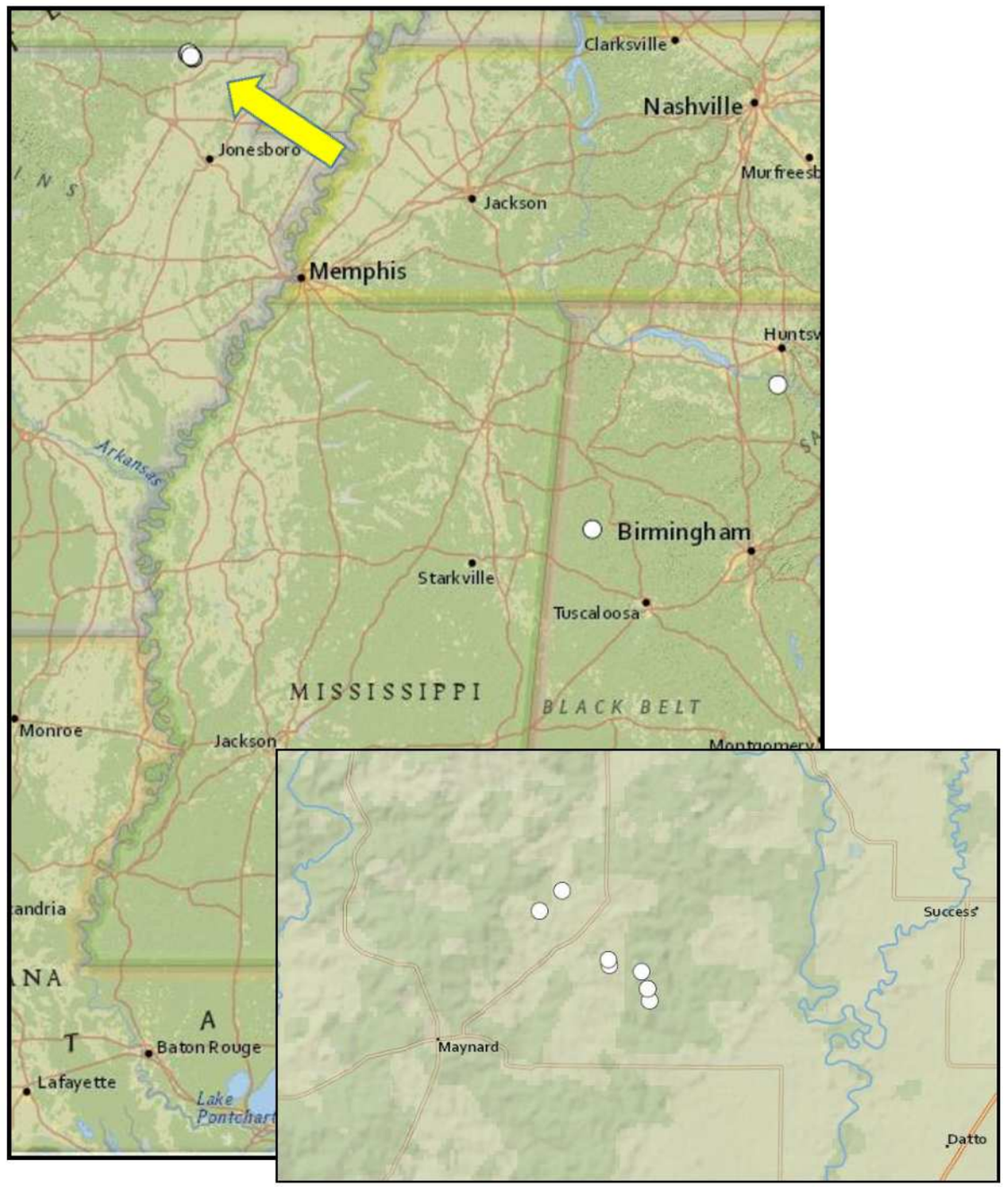
Daily Update Brief

As of 11/10/2020 4:59 AM

New Madrid Seismic Data – 30 Day, Magnitude 2.5+ Update

M 2.6 - 6 km ENE of Maynard, Arkansas
2020-10-12 01:35:46 (UTC) 36.438°N 90.831°W
9.9 km

M 2.6 - 6 km E of Maynard, Arkansas
2020-10-08 18:11:52 (UTC) 36.426°N 90.825°W
8.6 km



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MS-DOH-21-1016-A-000931

Daily Update Brief

As of 11/10/2020 4:59 AM

Websites of Interest

MEMA: http://www.msema.org

MEMA Facebook: https://www.facebook.com/msemaorg facebook

MEMA Twitter: https://twitter.com/msema

MEMA YouTube: https://www.youtube.com/user/MSEMAorg1 YouTube

MEMA Snapchat: @msemergencymgmt

MEMA Situation Room (Adobe Connect): Daily Sitroom – https://share.dhs.gov/msema
EMAC Sitroom – https://share.dhs.gov/ms-emac

Federal Emergency Management Agency (FEMA): http://www.fema.gov

Emergency Management Institute (EMI): https://training.fema.gov/emi.aspx

Dept. of Homeland Security (DHS) : https://www.dhs.gov
https://www.dhs.gov/dhs-component-websites

Homeland Security Information Network (HSIN): https://www.dhs.gov/homeland-security-information-network-hsin

US Army Corps of Engineers – Vicksburg District: http://www.mvk.usace.army.mil

Mississippi Forestry Commission: http://www.mfc.ms.gov

Mississippi Department of Transportation – Traffic: https://www.mdottraffic.com

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MS-DOH-21-1816-A-000932

From: [redacted]
To: Dobbs, Thomas E
Subject: Just got this from CDC
Date: Wednesday, December 8, 2021 12:25:54 PM
Attachments: PART+VI+FORMS+and+ATTACHMENTS.pdf
FY22+CDC+BAA+Solicitation+Posting+75D301-22-R-72097.pdf

Dr. Dobbs,
Thanks so much again for coming to our Rotary Club meeting. Hope you enjoyed it as much as the Rotarians did! I just attended a Zoom meeting with CDC in regards to Covid-19 Molecular Surveillance and these documents were distributed. Please feel free to share at will inside MSHD.
I am about to send the email out to Mrs. Fanning asking for the support to have my Orientation and the first 3 days through telework given the traveling circumstances.
Best and kind regards,
NA.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

BROAD AGENCY ANNOUNCEMENT (BAA)

75D301-22-R-72097

"Applied Research to Address Emerging Public Health Priorities"

ISSUANCE DATE:	**December 6, 2021**
CLOSING DATE:	**January 14, 2021**

MS-DOH-21-1816-A-000934

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PART I - INTRODUCTION

Authority

The Centers for Disease Control and Prevention (CDC), the Office of Science (OS) issues this Broad Agency Announcement (BAA) under the provisions of FAR 35.016 and FAR 6.102(d)(2) which provides for the competitive selection of research proposals. Contracts that are awarded based on responses to this BAA are as a result of full and open competition and therefore in full compliance with the provisions of PL 98-369, "The Competition in Contracting Act of 1984."

The CDC may award contracts with educational institutions, nonprofit organizations, not for profit organizations, state and local government, and private industry for research and development (R&D) in those areas covered in Part II of this BAA.

Within the meaning of FAR 6.102 and 35.016, this announcement constitutes the government's solicitation for this effort. There will be no other solicitation issued in regard to this requirement. Offerors should be alert for any BAA amendments that may be posted on beta.SAM.gov.

Process

Funding of research within CDC will be determined by funding constraints and research priorities set during each fiscal year. Therefore, those contemplating submission of a white paper are encouraged to contact the CDC BAA technical point of contact as noted below to determine whether the research warrants further inquiry. If the research warrants further inquiry and if funding is available, then submission of a white paper/proposal will be entertained. **For all email inquiries to the Subject Matter Expert Technical POC, please copy the CDC BAA Technical Coordinator as well.**

The following four-step sequence is established for offerors contemplating submission of a white paper or a proposal under this BAA. This sequence allows for an early determination of the potential for interest based on technical merit, applicability to CDC and projected funding. This process is designed to limit offeror and Government expenditure of effort to prepare and review formal proposals for research that may have little chance of being funded.

Step 1 – Email Contact (Technical Dialogue)

Once the BAA is issued, technical dialogue can began. Technical dialogue between the Government and the potential offeror is the first step. The initial point of contact may direct offerors to a specific scientific/technical point of contact based on the topic area and specifics of the proposed research project. The initial contact points for each area of research interest identified in Part II is listed below.

Research Interests	Point of Contact (POC)	POC e-mail address
Topic 1. Exploring best strategies to interrupt poliovirus transmission in outbreak-affected countries (CGH)		
1.1. Modeling to inform effective polio outbreak response strategies	Gabe AnayaCGH Extramural Research Program Office	gda1@cdc.gov cgherpo@cdc.gov
Topic 2. Public Health Communication Approaches to Increase Trust in Public Health Emergency Preparedness (CPR)		
2.1 Public Health Communication Approaches to Increase Trust in Public Health Emergency Preparedness	Kimberly Leeks	kleeks@cdc.gov
Topic 3. Address critical gaps in knowledge regarding personal protective equipment (PPE) standards in a laboratory setting (CPR)		
3.1. Comparison of PPE used in the United States and globally in terms of physical and barrier resistance using standardized performance tests (e.g., water resistance, viral penetration tests)	Christy Ottendorfer Selcen Kilinc-Balci	uyk0@cdc.gov jcq8@cdc.gov

3.2. Effects of chemical decontamination on the durability and reliability of PPE in standardized performance tests (e.g., water resistance, viral penetration tests)	Christy Ottendorfer Selcen Kilinc-Balci	uyk0@cdc.gov jcq8@cdc.gov
3.3. Effects of reuse of PPE in standardized performance tests (e.g., viral penetration tests)	Christy Ottendorfer Selcen Kilinc-Balci	uyk0@cdc.gov jcq8@cdc.gov
Topic 4. Address Critical Knowledge Gaps related to Emerging and Re-emerging Infectious Diseases During Pregnancy and the Risks, Benefits and Acceptance of Prevention and Treatment Strategies (NCBDDD)		
4.1. Mother-baby linked longitudinal cohort studies to examine the impact of emerging and re-emerging infectious diseases and prevention and treatment strategies on pregnancy, birth, and early childhood outcomes	Suzanne Gilboa Dana Meaney-Delman Van Tong Kara Polen	suz0@cdc.gov vmo0@cdc.gov vct2@cdc.gov fvc1@cdc.gov
Topic 5: Expand the portfolio of effective interventions to prevent or delay type 2 diabetes and manage diabetes among populations who are underserved (NCCDPHP)		
5.1. Identify, test, implement, and evaluate innovative evidence-based interventions, strategies, programs, or policies that reduce health inequities in type 2 diabetes prevention.	Bryce Smith	Bsmith6@cdc.gov
5.2. Identify, test, implement, and evaluate innovative evidence-based interventions, strategies, programs, or policies that reduce health inequities in diabetes management.	Bryce Smith	Bsmith6@cdc.gov
5.3. Study the effectiveness of various approaches/supports currently used by recognized organizations in the National Diabetes Prevention Program (National DPP) to eliminate or reduce barriers to enrollment and retention in the National DPP lifestyle change program related to the social determinants of health (e.g., food insecurity/limited access to healthy foods, lack of reliable transportation or internet access, lack of safe places to get physical activity, others). Determine which approaches are effective in addressing these barriers for populations currently underrepresented in the program.	Bryce Smith	Bsmith6@cdc.gov
Topic 6. Wastewater Surveillance (NCEZID)		
6.1. Detection and typing of disease targets from wastewater	Rory Welsh	Mpo6@cdc.gov
6.2. Fecal shedding of SARS-CoV-2 RNA	Amy Kirby	Agk1@cdc.gov
Topic 7. Genomic sequencing of SARS-CoV-2 to investigate viral evolution, and emergence and spread of variants in communities and populations. (NCEZID)		
7.1. Incorporate viral genomic data, clinical and demographic data to better predict poor outcomes of SARS-CoV-2 infection, increased likelihood of reinfection and risk factors for vaccine breakthrough.	Ellie Click Duncan MacCannell	Eoc9@cdc.gov fms2@cdc.gov
7.2. Conduct studies that compare SARS-CoV-2 sequence diversity and viral phylodynamics within and between regions with different public health response timelines and strategies, especially studies that evaluate changes in viral diversity in the context of vaccination campaigns.	Ellie Click Duncan MacCannell	Eoc9@cdc.gov fms2@cdc.gov
7.3. Adapt and optimize sequencing instrumentation, reagents and workflows for the specific needs of public health infectious disease laboratories and field activities.	Ellie Click Duncan MacCannell	Eoc9@cdc.gov Fms2@cdc.gov
7.4. Develop or enhance open source bioinformatic tools, databases and visualization software that improve the availability, utility, integration and interpretation of genomic data from SARS-CoV-2 and other pathogens of public health concern.	Ellie Click Duncan MacCannell	Eoc9@cdc.gov Fms2@cdc.gov
Topic 8. Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection, and preparedness (NCEZID)		
8.1. Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection, and preparedness by distributing assays through the Laboratory Response Network (LRN)	Julie Villanueva	Jfv3@cdc.gov
Topic 9. Address gaps in direct detection diagnostic assays for Lyme borreliosis (NCEZID)		
9.1 Investigations to discover chemoattractants for B. burgdorferi in tick saliva for development of a xenodiagnostic-like assay for direct detection of the Lyme spirochete in infected individuals	Bob Gilmore	rbg9@cdc.gov
Topic 10. Address critical gaps in human tick bite prevention (NCEZID)		

10.1. Development and evaluation of human tick bite prevention methods	Lars Eisen	evp4@cdc.gov
10.2. Killing of ticks that go undetected while biting humans	Lars Eisen	evp4@cdc.gov
Topic 11. Novel prevention methods to reduce transmission of Rickettsia rickettsii by brown dog ticks(NCEZID)		
11.1 Development of a canine vaccine against *Rickettsia rickettsii*	William Nicholson	wan6@cdc.gov
Topic 12. Evaluation of novel Aedes aegypti control tools (NCEZID)		
12.1 Evaluate effectiveness of dried attractive bait stations to control Aedes aegypti, the main vector of dengue viruses	Ryan Hemme	rhemme@cdc.gov
Topic 13. Novel Assays for Dengue Vaccine Evaluation (NCEZID)		
13.1. Correlates of protective immunity against dengue	Jorge L. Munoz-Jordan	ckq2@cdc.gov
13.2. Measurement of dengue type-specific antibody binding	Jorge L. Munoz-Jordan	ckq2@cdc.gov
13.3. Assessments of dengue vaccine immunogenicity	Jorge L. Munoz-Jordan	ckq2@cdc.gov
13.4. Dengue immunoassay development or optimization	Jorge L. Munoz-Jordan	ckq2@cdc.gov
13.5. Sample collections for test development or validation	Jorge L. Munoz-Jordan	ckq2@cdc.gov
Topic 14. Implementation of Wolbachia-based strategies for dengue control in Central America (NCEZID)		
14.1. Establish surveillance systems to track climate-sensitive mosquito-borne diseases and monitor if they are increasing or shifting over time**.**	Gabriela Paz-Bailey	gmb5@cdc.gov
14.2. Evaluate the implementation and sustainability of *Wolbachia* replacement intervention in Central America	Gabriela Paz-Bailey	gmb5@cdc.gov
14.3. Develop the evidence base for *Wolbachia* replacement implementation in international settings to support implementation of effective strategies in the United States and help reduce risk of importation of vector borne diseases to the U.S.	Gabriela Paz-Bailey	gmb5@cdc.gov
Topic 15. Towards dengue elimination: enhanced vector control and surveillance in Puerto Rico (NCEZID)		
15.1. Develop and implement methods for enhanced surveillance and response to dengue hotspots in Puerto Rico	Gabriela Paz-Bailey	gmb5@cdc.gov
15.2. Evaluate the effectiveness of hotspot responses in preventing additional disease spread	Gabriela Paz-Bailey	gmb5@cdc.gov
Topic 16. Research to inform optimal approaches to environmental sampling and understanding of the prevalence and distribution of pathogenic fungi in healthcare settings (NCEZID)		
16.1. Develop innovative methods for detection and surveillance of pathogenic fungi in healthcare environments	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
16.2. Quantify baseline levels of pathogenic fungi within healthcare environments	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
16.3. Correlate fungal quantitative data with episodes of fungal infections or transmission in patients.	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
16.4. Pilot early detection and surveillance methods for invasive mold and other fungi in patients and in the environment to guide public health efforts.	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
16.5. Evaluate the feasibility and utility of different environmental sampling approaches for pathogenic fungi in healthcare environments.	Ana Litvintseva, Jeremy Gold Joe Sexton	frq8@cdc.gov leo3@cdc.gov ogi3@cdc.gov
Topic 17. Understanding the impact of climate change and other predictors on the distribution and severity of fungal diseases (NCEZID)		
17.1. Evaluate the influence of climate on diversity and abundance of human-pathogenic fungi in the environment -	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
17.2. Model geographic spread of fungal diseases based on predicted and observed climate changes	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
17.3. Understand the effect of severe weather events on the incidence of fungal infections	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
17.4. Assess role of social factors (e.g., health disparities) in determining severity of fungal diseases.	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
17.5. Assess role of host factors on determining severity of fungal diseases.	Brendan Jackson Mitsuru Toda	iyn0@cdc.gov, nrk7@cdc.gov
Topic 18. Development of rapid point-of-care (POC) syphilis diagnostic tests (NCHHSTP)		

18.1 Development of a rapid point-of-care combo treponemal/ nontreponemal antibody test for active syphilis diagnosis	Mayur Shukla Kim Kitzler	Iun9@cdc.gov nin1@cdc.gov
18.2 Development of a direct detection test for *T. pallidum,* ideally for all stages of syphilis	Allan Pillay Kim Kitzler	ajp7@cdc.gov nin1@cdc.gov
Topic 19. Decreasing disparities in the incidence, morbidity, and mortality associated with HIV, viral hepatitis, other sexually transmitted infections (STIs), tuberculosis and adolescent health (NCHHSTP).		
19.1 Develop, implement, and/or evaluate innovative evidence-based interventions to reduce population-level disparities in the incidence, morbidity and mortality associated with HIV, viral hepatitis, STIs, or tuberculosis.	Kirk Henny Harrell Chesson	KHenny@cdc.gov HChesson@cdc.gov
Topic 20. Influenza and Other Acute Respiratory Infections (NCIRD)		
20.1. CRISPR-Based Diagnostic Assays for Multi-Pathogen and Multi-Analyte Detection	Marie K. Kirby	pbi0@cdc.gov
20.2. Assessing the role of non-pharmaceutical interventions (NPI) in preventing influenza	Sonja Olsen	sco2@cdc.gov
Topic 21. SARS-CoV-2 (COVID-19) and Children (NCIRD)		
21.1. Describing respiratory virus transmission in educational settings.	Hannah Kirking	hrj7@cdc.gov
21.2 Evaluating COVID-19 vaccine effectiveness in schools.	Hannah Kirking	hrj7@cdc.gov
21.3. Children 5-17 years: Evaluating the duration of immune protection following COVID-19 vaccination	Hannah Kirking	hrj7@cdc.gov
21.4. Children 0-17 years: Estimating COVID-19 vaccine effectiveness in ambulatory healthcare settings	Leora Feldstein	nqw5@cdc.gov
21.5. COVID-19 and Multisystem Inflammatory Syndrome in Children (MIS-C)	Angela Campbell	app4@cdc.gov
21.6. COVID-19 and Acute Otitis Media (AOM)	Katherine Fleming-Dutra	ftu2@cdc.gov
Topic 22. Bacterial Respiratory and Vaccine-Preventable Diseases (NCIRD)		
22.1. Assessing the molecular epidemiology of group A Streptococcus (GAS) isolates among children.	Katherine Fleming-Dutra	ftu2@cdc.gov
22.2. Understanding the spectrum of clinical pertussis.	Susan Hariri	bse4@cdc.gov
22.3. Understanding immune response to pertussis infection.	Susan Hariri	bse4@cdc.gov

Step 2 – Submission of Informal White Paper (Technical Dialogue)

This step is a continuation of the technical dialogue for projects of interest. Submission of a white paper **does not require an explicit request or invitation from CDC**. Offerors may submit a white paper even if there was no technical dialogue with the SME. Additionally, from time to time, the scientific point of contact may request that an offeror submit an informal white paper. The white paper can be **no more than 4 pages in length, all inclusive.** The purpose of the white paper is to facilitate the SME's understanding of the scientific and technical aspects of the proposed research project. Use of the white paper is intended to determine which efforts are of sufficient scientific and technical merit prior to submission of a formal research proposal as described in Part IV; therefore, informal white papers should not be so lengthy or detailed as to constitute a formal proposal (see Part IV). Informal white papers should contain a Rough Order of Magnitude (ROM) (e.g. "Estimated Cost"). A ROM **is NOT** a full blown business proposal. Instead, it is merely a "statement or a range" that provides a high level estimate of what the offeror believes the project will cost.

NOTE: CDC cannot discuss budget estimates or number of awards expected and cannot review draft white papers prior to submission.

Please note that the Government may use non-Government participants during the white paper review process (See Part III – Use of Non-Government Personnel).

All submitted white papers will undergo an initial review for technical merit and program applicability. **See Part III for specific evaluation criteria.**

NOTE: Once white papers are submitted technical dialogue STOPS!

Step 3 - Submission of Formal Research Proposal

If there is sufficient interest in a proposed research project, the Contracting Officer will invite the offeror to submit a formal research proposal (see Part IV). **During the preparation of the offeror's proposal, technical dialogue may resume.** The purpose of the technical dialogue is to facilitate the Government's understanding of the scientific and technical aspects of the proposed research project. **However, once proposals are submitted, communication between scientific personnel and the technical review team STOPS!**

Please note that the Government may use non-Government participants during the evaluation of the proposals technical section (See Part III – Use of Non-Government Personnel).

Step 4 - Contract Award for Selected Projects

All proposals will receive an initial review (see Part V) and the Contracting Officer will notify the offeror, in writing, whether the proposal will be processed for award. The primary basis for selecting proposals for award shall be scientific/technical merit, importance to agency programs, corporate capabilities, and personnel. Cost realism, reasonableness and fund availability will also be considered to the extent appropriate. Past performance will also be considered. **Any contract resulting from this process will include all standard FAR clauses or the appropriate alternates applicable to the contract type for the proposed project and offeror institution. See Part V for specific evaluation criteria.** The Government has the right to make multiple awards.

NOTE: Projects will be funded as contracts, NOT GRANTS.

Government obligation

Persons submitting white papers and proposals are cautioned that only a Contracting Officer may obligate the Government to any contract involving expenditure of Government funds. **The Government is under no obligation to pay for the cost of for the development of white papers or proposals. Furthermore, there is no commitment on behalf of the Government to fund any proposal.** Contractors are caution that the submission of a white paper and a proposal is submitted strictly on a voluntary bases.

BAA POINTS OF CONTACT

CDC's BAA Technical Coordinator and point of contact is Diana Bartlett, MPH, MPP who may be reached by email at dbartlett@cdc.gov.

Based on the research topic area, CDC has multiple contractual points of contact. The POCs and the research areas they are responsible for is listed below.

Name	Research Topic Area	Email
Mr. Timothy Barnes	1	krz3@cdc.gov
Mr. Tray Burch	5, 6	vwa8@cdc.gov
Elizabeth Cole Greenblatt William O'Bryan	3	qst7@cdc.gov rvq0@cdc.gov
Ms. Latoya Hill	7, 8, 9	mdx7@cdc.gov
Mr. Kristopher Lemaster	10	ene3@cdc.gov
Ms. Marva D. Lewis	2	knn5@cdc.gov
Mr. Marty Nemec	18, 19	oga2@cdc.gov
Ms. Jasmine Powell	11, 12, 13	qes1@cdc.gov
Ms. Denedra Threatt	4	qfa5@cdc.gov
Mr. Ronnie Williams	14, 15, 16, 17	oga3@cdc.gov
Mr. Tim Williams	20, 21, 22	tpw8@cdc.gov

PART II - CDC RESEARCH INTERESTS

Overview

The Centers for Disease Control and Prevention (CDC) works to protect the U.S. from health, safety and security threats, both foreign and domestic. Specifically, CDC works with its partners to monitor health, detect and investigate health problems, conduct research to enhance and implement prevention strategies, develop and promote sound public health policies, promote healthy behaviors, foster safe and healthful environments, respond to current and emerging threats, and CDC's role as the nation's health protection agency is to operate 24/7 in order to keep people healthy and safe. The agency accomplishes this goal by working to: detect and respond to new and emerging health threats; address the biggest health problems causing death and disability; move science and advanced technology into actions to prevent disease; promote health and safe behaviors, communities and environments; develop leaders by training the public health workforce; and understand the health pulse of the nation.

For this announcement, CDC is requesting white papers for the following areas, which are further described below:

Topic 1. Exploring best strategies to interrupt poliovirus transmission in outbreak-affected countries (CGH)

1.1. Modeling to inform effective polio outbreak response strategies

Wild poliovirus type 2 was declared eradicated in 2015 and thereafter in April of 2016, routine immunization (RI) programs across the globe switched ("global switch") from the trivalent oral poliovirus vaccine (tOPV; contains types 1, 2, and 3) to the bivalent vaccine OPV (bOPV; contains types 1 and 3). In addition, a single dose of the trivalent inactivated poliovirus vaccine (IPV) was introduced into routine immunization programs to provide protection against type 2 paralysis which does not lead to intestinal immunity necessary to stop virus transmission like OPV. A second dose is being introduced into routine immunization programs in OPV-using low and lower-middle income countries to increase the proportion protected. Outbreaks of circulating vaccine-derived poliovirus (cVDPV) result from use of OPV in under-immunized and unimmunized populations, permitting the vaccine virus to spread among susceptible individuals for prolonged periods, increasing the chance for the virus to revert and re-acquire the ability to cause paralysis. Despite intentions to boost type 2 intestinal immunity ahead of the global switch in 2016, pockets of susceptible children remained in countries with chronically low polio vaccination coverage. The increasing number of susceptible cohorts of infants without type 2 intestinal immunity increases the risk and spread of virus. As of 14 October 2021, cVDPV2 outbreaks have been detected in 19 countries, affecting 333 individuals. Responding to cVDPV2 outbreaks requires the use of monovalent Sabin strain oral poliovirus vaccine type 2 (mOPV2) in Supplementary Immunization Activities (SIAs) to quickly increase type 2 population intestinal immunity and halt the spread of the virus. When high quality SIAs are not achieved, the mOPV2 virus continues to spread unabated, increasing the potential for emergence of a new VDPV, and transmission of the originally detected cVDPV2 continues.

To respond to cVDPV2 outbreaks effectively, policy makers must weigh response scenarios to inform optimal response strategies to quickly interrupt virus transmission. For example, the promptness in which SIAs are conducted (i.e., time between initial virus detection and first SIA), quality of the SIAs (i.e., true coverage effectiveness vis-á-vis performance indicators assessing vaccine coverage), number of SIA rounds, vaccine choice, geographic scope of SIAs, and age group targeted for SIAs. Modeling is one approach that can be used to inform outbreak responses.

CDC seeks to identify effective strategies to hasten the end of poliovirus transmission in cVDPV2 outbreak-affected countries. Key to this will be the development of an infectious disease model that can

serve as the testing environment for different response strategies. Evaluation will include the identification of strategies that result in 1) no breakthrough cases (i.e., no cases occur after the standard operating procedure recommended initial number of outbreak response SIAs); 2) interrupt virus transmission with the fewest number of vaccination campaigns; 3) interrupt virus transmission in the least amount of time; and 4) lead to the fewest overall number of cases of paralysis.

Topic 2. Public Health Communication Approaches to Increase Trust in Public Health Emergency Preparedness (CPR)

2.1 Public Health Communication Approaches to Increase Trust in Public Health Emergency Preparedness

Public trust in science is of heightened importance during a public health emergency, which is further compounded by the need for clear, correct, and targeted messages to effectively garner public health trust. Johns Hopkins University surveyed 1,468 adults in the US and found that about half (54%) trusted science "a lot" with 46% split across other response categories ("some", "not much", and "not at all"). Public trust in science is essential when the risks and benefits of new policies and practices are not well understood because the public must rely on the decision-makers to make informed judgments, as demonstrated during the COVID-19 pandemic. For example, the public may not adhere to mitigation strategies if they do not know, understand, or trust the evidence supporting the strategy. There are a number of plausible explanations for the decline in the trust of science including the politicization of scientific issues. CDC and other key stakeholders, including the public, would benefit from the development of evidence-based knowledge about the state of the public's current knowledge of and attitudes towards public health emergency preparedness and response (PHEPR) science. This evidence-based knowledge will allow us to develop effective strategies to establish and maintain public confidence and trust in PHEPR science.

Communication approaches have been effectively used to change public perceptions standard marketing for products such as food or automobiles as well as health messages related to smoking, exercise, preventive care, and medication adherence. Effective communication approaches that promote public health preparedness and response awareness, dialogue, trust-building, and knowledge, while also combating misperceptions and complacency, particularly about the scientific underpinnings of public health recommendations and how science evolves are urgently needed.

With a focus on risk communication, white papers should describe communication approaches or interventions that use an existing (e.g., mass media, small media, social media, application) or innovative channel and are supported by formative research (either completed prior to or as part of the contract), process evaluation, and outcome evaluation. Formative research can identify and prioritize needs, desires, and values of the target audience and test message frames. Determining the theoretical conceptual foundation and examining the prospective target audience's their behavior(s) and the factors which influence their behavior(s) are also key to successful messaging. Overall, white papers should include a description of the problem, market research, a defined market strategy, newly developed communication approaches, and evaluation of the communication approaches.

The objectives are to:

- Develop, implement, and evaluate communication approaches to increase trust in PHEPR science in subpopulations, jurisdictions, or the entire United States and its territories
- Build public health trust around PHEPR and various types of emergencies, hazards, and public health crises
- Increase the evidence-base, skills, and capacities of the state, tribal, local, and territory (STLT) health departments and communities

Priority will be given to offerors who:

- Have a successful track record of development, implementation, and evaluation of similar intervention activities

- Have the capacity to enroll and maintain large cohorts that include diversity in sociodemographic characteristics while minimizing selection and participation biases
- Experience in PHEPR research and evaluation
- Experience in conducting inclusive and population appropriate research
- Capacity to collect and manage the data required by this effort
- Can initiate and implement the study in a timely manner
- Are or work in partnership with an academic institution
- Are or work in partnership with STLT health departments
- Provide a plan to scale the approach as well as a sustainability plan (if the studied communication approach is effective)
- Be designed to increase trust in people who are traditionally underserved and underrepresented in the US
- Not focus on single issues, but more broadly on science or the scientific process (e.g., COVID-19, vaccines)
- Include measurement outcomes that address general awareness and knowledge about PHEPR; increased understanding of how to prepare for various types of emergencies; an overall increase in public trust, particularly during a public health crisis; and an increase in intentions to follow future public health guidance during public health emergencies
- Include knowledge, translation, and dissemination into practice products (for example, how to implement an approach determined to be effective) or messages (for example, translating the results into a webinar for practitioners) to share information to large audiences.

Topic 3. Address critical gaps in knowledge regarding personal protective equipment (PPE) standards in a laboratory setting (CPR)

CDC seeks to investigate the performance of personal protective equipment (PPE) manufactured domestically and globally (and met certain local and global standards) for impact penetration, tensile strength, tear resistance, and viral penetration with a simulated laboratory environment and the effects of chemical decontamination and reuse on PPE efficacy. PPE serves a critical function in protecting laboratory workers from biohazards with enhanced PPE providing an increasingly important line of defense for poliovirus post-eradication. Although new research has become available since the COVID-19 pandemic, most information is focused on healthcare settings and may not have comparable characteristics to poliovirus, a 20-30 nm non-enveloped virus resistant to many disinfectants, and common laboratory matrices that may impact surface tension properties important in PPE testing standards. This effort will: 1) evaluate national and international standards that assess performance requirements for PPE manufactured domestically and globally such as: impact penetration, tensile strength, tear resistance, viral penetration analyzed with and without the introduction of a chemical disinfectant (i.e. sodium hypochlorite or alcohol) and/or reuse in a simulated laboratory environment, 2) conduct standard test methods for PPE based on PPE commonly used in a laboratory setting using a poliovirus or surrogate virus, common laboratory matrices, with and without chemical decontamination and/or reuse for articles of PPE (e.g., gloves, gowns, coveralls), 3) develop evidence-based guidance on selection of PPE for biohazardous agents in a laboratory setting that consider chemical decontamination and reuse of articles of PPE, and 4) investigation of leakage through glove and protective clothing interface and the impact of mitigation methods (e.g. taping).

3.1. Comparison of PPE used in the United States and globally in terms of physical and barrier resistance using standardized performance tests (e.g., water resistance, viral penetration tests)
3.2. Effects of chemical decontamination on the durability and reliability of PPE in standardized performance tests (e.g., water resistance, viral penetration tests)
3.3. Effects of reuse of PPE in standardized performance tests (e.g., viral penetration tests)

Priority will be given to offerors who:

- Have a successful track record in conducting standardized testing methods for PPE
- Have demonstrated experience and capacity to perform virological studies

- Are interested and motivated to collaborate with CDC on testing projects and timely dissemination of the scientific data; and
- Are interested and motivated to use these data to inform public health and laboratory biosafety practice

Topic 4. Address Critical Knowledge Gaps related to Emerging and Re-emerging Infectious Diseases During Pregnancy and the Risks, Benefits and Acceptance of Prevention and Treatment Strategies (NCBDDD)

Current research about infectious diseases during pregnancy and their impact on pregnant individuals and infants is limited for several reasons. First, pregnancy status is not routinely captured in electronic health records and there are no standard data linkages in clinical or administrative datasets to capture the mother-infant dyad. Second, pregnant people are often excluded from randomized clinical trials of preventive therapies or treatment for infectious diseases leaving pregnant people and their health care providers to rely on small non-comparative cohort studies to make clinical decisions about these therapies. Finally, many studies do not capture a diverse group of pregnant people and infants. As part of this BAA focused on data modernization and health equity, CDC is seeking white papers to address research questions related to the primary objectives below, around the pregnancy, birth, and early childhood outcomes associated with emerging and reemerging infectious diseases in pregnancy and the risks and benefits of preventive and treatment strategies for these infectious diseases and their sequelae.

Given the period of performance for the contracts developed under this BAA mechanism, the most competitive applicants are those with existing cohorts in which data about the pregnant person and the infant are already linked (i.e., mother-baby linked longitudinal cohort). These data can include linked clinical data, administrative data, or other sources. Cohorts with existing protocols, procedures and institutional review board (IRB) approvals with existing infrastructure to address research questions may be most competitive, and able to accomplish the objectives within the period of performance of the contract. Using the pregnancy and infant cohort along with the appropriate comparison group(s), the research should assess the impact of infectious disease on mothers, infants and young children, as well as the acceptance of and use of applicable preventive strategies (e.g., masking, social distancing, routine testing, vaccination, mosquito repellent use, hand washing and other infection control practices, prophylactic medications) and treatments (e.g. antivirals, antimicrobials, novel therapeutics, intensive care). Existing protocols, including linked electronic datasets are encouraged to include the appropriate comparison cohort(s) (e.g., pregnant and/or non-pregnant; unexposed pregnancies and infants). Proposed target subpopulations of interest are also encouraged to include pregnant people from diverse racial/ethnic minority groups and sociodemographic backgrounds.

4.1. Mother-baby linked longitudinal cohort studies to examine the impact of emerging and re-emerging infectious diseases and prevention and treatment strategies on pregnancy, birth, and early childhood outcomes

Objectives of analyses of the electronic mother-baby linked longitudinal cohort may include the following:

- Examine susceptibility to the infectious disease by comparing the incidence of selected emerging and reemerging infectious diseases among pregnant and non-pregnant people.
- Compare the clinical severity of infection during pregnancy to the clinical severity of infection among non-pregnant people and describe risk factors and characteristics that increase the risk of severe disease.
- Estimate the risk of adverse outcomes associated with emerging and reemerging infectious disease during pregnancy, including, but not limited to early pregnancy loss, stillbirth, preterm delivery, preeclampsia, fetal distress perinatal transmission of infection, congenital infection, birth defects, and neonatal and post-neonatal morbidity and mortality. To understand the risks of these outcomes with untreated infection requires an appropriate comparison group of uninfected pregnant people matched for potential confounding characteristics.
- Estimate the risks and benefits of prevention and treatment strategies by comparing maternal, fetal, neonatal, and infant outcomes and other clinical parameters between pregnant people receiving and not receiving timely and appropriate prevention and/or treatment for the disease.

To address secondary objectives, ancillary quantitative or qualitative data collection (e.g., focus groups and surveys) of subpopulations within the cohort are encouraged to assess the uptake and acceptance of prevention (e.g., vaccine) and treatment (e.g., antivirals) strategies during pregnancy, and any barriers and challenges to acceptance among healthcare providers and patients. For the ancillary quantitative and qualitative data collection, proposed target subpopulations of interest would include pregnant people from diverse racial/ethnic minority groups and sociodemographic backgrounds as well as diversity in the healthcare provider population caring for pregnant people and infants in the main cohort and in the comparison groups. Assessment of uptake and acceptance of prevention and treatment strategies are encouraged to include but healthcare providers of various racial and ethnic backgrounds, those in private and academic clinical practice, and those with different medical specialties (e.g., obstetrics and gynecology, midwifery, family medicine, infectious disease, pediatrics, neonatology).

Objectives of ancillary data collections (e.g., focus groups and surveys) include:

- Compare acceptance of preventive and treatment strategies by pregnancy status using a cohort of pregnant and similar-aged non-pregnant people.
- Compare acceptance of preventive and treatment strategies for pregnant people based on racial/ethnic diversity and other sociodemographic characteristics and clinical factors such as prior pregnancy status and prior acceptance of preventive strategies (e.g., vaccines and prophylactic medications) and treatments (e.g., antivirals and antimicrobials).
- Assess acceptance of preventive and treatment strategies by provider type, provider characteristics, practice type, provider age and other factors and monitor over time.
- Elicit barriers and challenges to acceptance of preventive and treatment during pregnancy (e.g., availability of medications/vaccines, accessibility, and the role of myths and misinformation).

This announcement is not restricted to any specific infectious diseases; however, the emerging and re-emerging infectious diseases in pregnancy monitored and tracked by the Centers for Disease Control and Prevention, and specifically those included in the Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET) are of particular interest https://www.cdc.gov/ncbddd/aboutus/pregnancy/emerging-threats.html.

Priority will be given to applicants who

- Have an established history of successful implementation of similar activities with cohorts of pregnant people, infants, and appropriate comparators;
- Demonstrate experience designing and implementing electronic cohorts with defined, appropriate analytic questions;
- Demonstrate capacity to collect, manage, analyze, and publish the data required by this effort with a focus on data modernization and health equity;
- Are most likely to initiate and implement the study in a timely manner using innovative methodology;
- Are interested and motivated to collaborate with CDC on analytic projects and timely dissemination of the scientific data; and
- Are interested and motivated to use these data to inform public health and clinical practice.

Topic 5: Expand the portfolio of effective interventions to prevent or delay type 2 diabetes and manage diabetes among populations who are underserved (NCCDPHP)

CDC currently has one evidence-based intervention [the National Diabetes Prevention Program (DPP)'s lifestyle change program (LCP)] that has been shown to reduce or delay the onset of type 2 diabetes and a limited number of evidence-based interventions (i.e., diabetes self-management education and support services, clinical efforts to improve detection of chronic kidney disease (CKD), screening for diabetic retinopathy) that have been shown to improve outcomes for those living with diabetes. CDC seeks to expand this portfolio to support other evidence-based interventions, strategies, programs, or policies to achieve these goals. CDC is particularly interested in white papers that reduce health inequities through interventions, strategies, programs, or policies that are targeted to populations who are historically underserved by these interventions (Black or African

American persons, Hispanic or Latino persons, Asian and Pacific Islander persons, persons with disabilities, men, young adults, and others).

5.1. Identify, test, implement, and evaluate innovative evidence-based interventions, strategies, programs, or policies that reduce health inequities in type 2 diabetes prevention.
Issues to consider:

- Scalability: CDC seeks to support interventions, strategies, programs, or policies that can demonstrate a feasible path to scaling beyond the context in which they are tested, but interventions should still be tailored to reach populations who are underserved.
- Sustainability: To expand access interventions, strategies, programs, or policies need to be easy to access for the population being served. Interventions, strategies, programs, or policies should not place a consider burden on the recipient/participant.
- All interventions, strategies, programs, or policies for type 2 diabetes prevention should be targeted to persons living with prediabetes [as determined by the CDC risk test (https://www.cdc.gov/prediabetes/takethetest/) or a HbA1c of 5.7-6.4].
- Outcomes for type 2 diabetes prevention interventions could include one of the following: reduction of weight by 5%-7%, or reduction of HbA1c by 0.2% coupled with weight loss of 4%.
- CDC is also interested in intermediate implementation improvement strategies (e.g., acceptability, adoption, length, cost, etc.).

Use of the National DPP LCP curriculum is not required, but not disallowed. Alternative versions of the LCP (e.g., difference in length, unique tailoring to specific audiences, other delivery mode or implementation modifications) are eligible for consideration but not required. Two alternate versions that are already developed but not required include the Road to Health (https://www.cdc.gov/diabetes/professional-info/toolkits/road-to-health.html) and On Your Way (https://www.cdc.gov/diabetes/prevent-type-2/guide-prevent-type2-diabetes.html).

Place-based or venue-based (e.g., Federally Qualified Health Center, faith-based institutions, employers, community-based organizations) interventions, strategies, programs, or policies are encouraged.

5.2. Identify, test, implement, and evaluate innovative evidence-based interventions, strategies, programs, or policies that reduce health inequities in diabetes management.

Issues to consider:

- Scalability: CDC seeks to support interventions, strategies, programs, or policies that can demonstrate a feasible path to scaling beyond the context in which they are tested, but interventions should be tailored to reach populations who are underserved.
- Sustainability: To expand access interventions, strategies, programs, or policies need to be easy to access for the population being served. Interventions, strategies, programs, or policies should not place a consider burden on the recipient/participant.
- All interventions, strategies, programs, or policies for diabetes management should be targeted to persons living with diabetes
- Outcomes for diabetes management interventions can include clinical changes (e.g., HbA1c, blood pressure, cholesterol, weight), behavioral changes (e.g., self-care behaviors, physical activity), awareness of **diabetes** self-management education and support (**DSMES**) and when to go, or others.

5.3. Study the effectiveness of various approaches/supports currently used by recognized organizations in the National Diabetes Prevention Program (National DPP) to eliminate or reduce barriers to enrollment and retention in the National DPP lifestyle change program related to the social determinants of health (e.g., food insecurity/limited access to healthy foods, lack of reliable transportation or internet access, lack of safe places to get physical activity, others). Determine which approaches are effective in addressing these barriers for populations currently underrepresented in the program.

The CDC-led National Diabetes Prevention Program (National DPP: http://www.cdc.gov/diabetes/prevention/index.html) is a public/private partnership working to scale and sustain an evidence-based lifestyle change program (LCP) for people with prediabetes to prevent or delay onset of type 2 diabetes. The LCP is founded on the Diabetes Prevention Program research study and subsequent translation studies which showed that making achievable behavior changes helped participants lose 5% to 7% of their body weight and reduced the risk of developing type 2 diabetes by 58% (by 71% for people 60 years and older). The National DPP LCP consists of a minimum of 16 weekly, then a minimum of six monthly group sessions conducted over a year. A trained lifestyle coach facilitates the sessions to guide people in changing their lifestyle by eating healthier, increasing physical activity, managing stress, and maintaining these healthier behaviors over time to lose weight and ultimately reduce risk for type 2 diabetes.

Priority will be given to offerors who establish:
• A track record of successful implementation of similar research or evaluation activities with populations who are underserved, including established partnerships with organizations/institutions serving populations who are undeserved.
• Capacity to conduct rigorous scientific studies to determine effectiveness based on selected outcomes;
• Capacity to collect, manage, and analyze the data required by this effort;
• The overall likelihood that they can initiate and implement the study in a timely manner.

Topic 6. Wastewater Surveillance (NCEZID)
6.1. Detection and typing of disease targets from wastewater

Wastewater testing can provide a complimentary and independent surveillance system to traditional disease-based pathogen surveillance. Most disease surveillance programs are linked to clinical care, but clinical surveillance is impacted by healthcare-seeking behaviors and can be biased towards symptomatic and severe infections. Wastewater surveillance can provide systematic data to mitigate such biases, reflecting the total infection burden at the community level. It can also be used to help address health equity issues by providing infection data where clinical testing is limited or absent. However, the sample matrix, the laboratory methods, and bioinformatics approaches can impact detection and molecular typing of pathogen and antibiotic resistance (AR) targets from wastewater.

CDC seeks projects that evaluate multiple methods with respect to the ability to recover spiked controls and mock communities under various concentration and background nucleic acid scenarios for liquid wastewater and sludge. The well-characterized spiked control material should include clinically relevant viral, bacterial, fungal, and antibiotic resistance targets (e.g. norovirus, foodborne bacteria, *Candida auris*, *Cryptosporidium*, and carbapenem and colistin-resistance genes and other high consequence AR threats described in the CDC 2019 AR Threats Report). CDC is specifically interested in quantitative detection and subtyping of pathogens from wastewater and characterization of sequencing performance for quantitative detection of multiple health targets from liquid wastewater and primary sludge. Innovative methods will also be considered. Methods that can provide information on multiple targets in a single run are preferred.

6.2. Fecal shedding of SARS-CoV-2 RNA

Understanding fecal shedding of SARS-CoV-2 RNA is important for interpreting COVID-19 wastewater surveillance data. Quantitative measurements in stool over the full time-course of infection, from individuals representing a range of demographic profiles, and illness severities, could help map wastewater measurements to community infection burden and help understand the potential for wastewater measurements to lead other COVID-19 surveillance indicators, like reported cases and syndromic surveillance. However, few quantitative fecal shedding data are published, and capturing fecal shedding dynamics over the full course of infection is challenging. CDC seeks a study that provides quantitative data on SARS-CoV-2 RNA levels in human stool over the full time-course of infection, including stool from individuals representing a range of demographic profiles, vaccination status, and illness severities. A study that measures RNA quantities per unit stool using molecular tools is preferred. Quantitative sample and laboratory controls, including matrix recovery controls and

endogenous fecal microbial controls, are encouraged. In particular, data between the period of infection and illness onset, and data from asymptomatic individuals, are desired, as well as viral variant data. Projects that characterize the stool composition, including solids content, and that use archived samples will be prioritized.

Topic 7. Genomic sequencing of SARS-CoV-2 to investigate viral evolution, and emergence and spread of variants in communities and populations. (NCEZID)

7.1. Incorporate viral genomic data, clinical and demographic data to better predict poor outcomes of SARS-

CoV-2 infection, increased likelihood of reinfection and risk factors for vaccine breakthrough.
The clinical picture of SARS-CoV-2 infection is often complicated by a range of viral, host and environmental factors. White papers for this subtopic, might include studies of SARS-CoV-2 infection that include both viral genomic and detailed host profiling (e.g., host genetic, immunologic, clinical data) to identify biomarkers that predict poor outcomes of SARS-CoV-2 infection, vaccine or therapeutic failure (e.g., clinically severe disease, multi-system inflammatory disease, breakthrough infection).

7.2. Conduct studies that compare SARS-CoV-2 sequence diversity and viral phylodynamics within and between regions with different public health response timelines and strategies, especially studies that evaluate changes in viral diversity in the context of vaccination campaigns.

As states implement safe re-open strategies and proceed with large-scale vaccination campaigns, monitoring circulating viruses and patterns of transmission will help adjust the timing and nature of public health prevention and mitigation efforts. Studies that establish sustainable, population-based surveillance of circulating SARS-CoV-2 sequence variants within a state or region, and assess patterns of regional introductions and transmission over time, are of particular interest. Studies that assess changes in circulating viral diversity and characteristics, particularly in the context of vaccine roll-out are also strongly encouraged. Additional consideration will be given to white papers that plan to engage state or local public health departments, to better apply new data and insights to public health decision-making.

7.3. Adapt and optimize sequencing instrumentation, reagents and workflows for the specific needs of public health infectious disease laboratories and field activities.

Over the course of the past several years, many laboratories have developed specific workflows to support SARS-CoV-2 sequencing efforts in different scales and contexts. This topic area is intended to help translate these new and optimized sequencing strategies and package them for routine public health use. Interested respondents may propose projects related to: 1) the miniturization of sequencing reactions and workflows; 2) efforts to streamline automation, decrease workflow complexity and limit overall consumable requirements of sequencing; 3) strategies to improve overall sequencing throughput, while reducing per-sample cost; 4) tools to simplify CLIA-compliant microbial sequencing in regulated laboratory settings; 5) the development and optimization of laboratory and bioinformatic methods for the analysis and deconvolution of complex surveillance samples, such as pooled testing, wastewater and environmental; and 6) the development and standardization of robust, field-deployable systems for surveillance support and outbreak response. While this white paper topic is meant to encourage innovation in laboratory protocols and technology, proposed solutions could include open-source software (e.g., for use with mobile devices) or mobile sequencing tools that provide rapid turn-around with high quality data.

7.4. Develop or enhance open source bioinformatic tools, databases and visualization software that improve the availability, utility, integration and interpretation of genomic data from SARS-CoV-2 and other pathogens of public health concern.

With the advent of rapid, open sequence data sharing for SARS-CoV-2 and other pathogens, there is a growing wealth of data available to help guide state and local infectious disease surveillance and public health response. CDC is soliciting white papers for the development or enhancement of open source tools, databases, standards and curation efforts that improve the overall accessibility, quality and usefulness of publicly-shared sequence data in public repositories. Data visualization and dashboarding tools that improve the interpretation and

reporting of public domain/public access sequence data are encouraged, as are those that facilitate the linking and deduplication of sequence records across public repositories, enable linkage to other surveillance data sources (e.g., case reports, wastewater surveillance data, etc.) or simplify standardized analysis and electronic laboratory reporting or improve linkage to medical records systems.

Priority will be given to projects that facilitate and enable the use of molecular epidemiologic data for state and local investigations and response activities. As such, projects for this subtopic could also include tools that may be used by public health departments for field applications (e.g., contact investigation), with an emphasis on field-deployable open solutions for use by front-line public health workers.

Topic 8. Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection, and preparedness (NCEZID)

8.1. Strengthening emerging, re-emerging, and biothreat infectious disease surveillance, detection, and preparedness by distributing assays through the Laboratory Response Network (LRN)

With more than 120 national, state, and local laboratories, the Laboratory Response Network (LRN) is an integral part of the National Response Framework. The LRN ensures consistent, high confidence results by developing and distributing laboratory assays, offering specialized training, and supporting secure data reporting. In the 20 years since its creation, the LRN has played an instrumental role in boosting laboratory capacity and building a domestic public health infrastructure for response.

In order to maintain response readiness, and to support day-to-day critical, time-sensitive emerging infectious disease (EID) testing needs, the LRN is pursuing cutting edge technologies that can strengthen, expand or enhance the LRN's existing capabilities and inform public health policies and decisions. Whether a single suspect case of a novel EID or a public health emergency, authorities need to know what pathogen is causing illness for a fast response. Rapid, accurate laboratory identification and characterization of pathogens from clinical specimens or environmental samples provides public health authorities the data necessary to deploy subject matter experts, provide appropriate medical countermeasures, facilitate rapid evaluation and tracing of potentially exposed contacts, and communicate potentially lifesaving information to the public as well as decision makers.

CDC is interested in the development and evaluation of innovative methods, tools, and strategies for deployment to the LRN for detection and characterization of existing and novel pathogens that are associated with a biothreat event or could cause a novel EID outbreak and/or public health emergency.
Solutions should include a framework for data reporting and analytics necessary for determination of public health action. In addition, the white paper should provide plans associated with analytical verification and deployment.

Topic 9. Address gaps in direct detection diagnostic assays for Lyme borreliosis (NCEZID)
Human infection by the tick-borne spirochete, *Borrelia burgdorferi* results in Lyme borreliosis, a disease that often initially presents with a skin lesion termed erythema migrans accompanied by viral-like symptoms e.g., malaise, fatigue, headache, arthralgias, myalgias, fever and regional lymphadenopathy. The infection can progress to more severe manifestations (arthritis, carditis, neurologic) if not accurately diagnosed and treated properly with antibiotics.

B. burgdorferi exists in an enzootic life cycle of obligate symbiosis consisting of reservoir hosts, primarily rodents and birds, and *Ixodes* spp. ticks that serve as vectors to transmit the pathogen to other hosts including humans. In vertebrate hosts, *B. burgdorferi* disseminates to tissues and organs but does not produce sustained, high density spirochetemia thereby rendering direct detection (e.g. culture isolation) of the organism difficult if not impossible. Therefore, laboratory diagnosis currently is dependent mainly upon serological testing which has limitations, particularly for detection of early infection. In addition, there are not laboratory tests to indicate cleared infections or for the possibility of latent infection in patients with Post-treatment Lyme disease syndrome (PTLDS) or antibiotic-refractory arthritis. These examples represent gaps in diagnostic testing for

Lyme borreliosis that could be alleviated by development of new direct detection assays for *B. burgdorferi* in infected patients.

B. burgdorferi is highly motile by virtue of a structure of bundled periplasmic flagella and chemotaxis proteins that are recognized as virulence factors essential for infection. Motility and chemotaxis are important factors enabling *B. burgdorferi* to i) move from tick midgut to salivary glands in preparation for deposition into the host, ii) disseminate within the host to distal organs and tissues, and iii) migrate from within the host to a newly feeding tick.

The acquisition of *B. burgdorferi* by ticks feeding on infected individuals is the principle behind xenodiagnosis, a sensitive approach to determine the infection status of a host suspected of harboring an organism. Xenodiagnosis has been used as a method to detect *B. burgdorferi* in animals and has been modeled as a potential direct detection tool to determine latent or active *B. burgdorferi* infections in humans. The mechanisms responsible for signaling borreliae from disseminated tissues to an attached tick are largely unknown although undoubtedly involves the chemotactic and motility machinery of the spirochete responding to substances from tick saliva.

9.1. Development of a xenodiagnostic-like assay for direct detection of the Lyme spirochete in infected individuals.
CDC seeks creative investigations for direct detection assays based on chemoattractant capabilities of tick saliva components that act as signals for *B. burgdorferi* to migrate to the tick attachment site. The objectives are to:

i. Create a mouse model of infection to assess *B. burgdorferi* migration from tissues to chemoattractant inoculation site
ii. Identify components of tick saliva with chemoattractant properties (jointly with SME laboratory)
iii. Develop technical process for chemoattractant inoculation
iv. Generate successful endpoint to determine *B. burgdorferi* migration to chemoattractant inoculation site

Topic 10. Address critical gaps in human tick bite prevention (NCEZID)

10.1. Development and evaluation of human tick bite prevention methods
10.2. Killing of ticks that go undetected while biting humans

Personal protection measures aiming to prevent human tick encounters from resulting in bites are widely recommended as the first line of defense against health impacts associated with ticks (tick-borne diseases, tick paralysis, and Alpha-gal syndrome/red meat allergy). Despite well-documented use by the public of personal protection measures to prevent tick bites, there are major knowledge gaps for the effectiveness of these measures to prevent tick bites and tick-borne infections when they are used by the public in their daily lives. Additionally, as evidenced by Lyme disease patients often not being aware of a tick bite prior to symptom onset, some proportion of tick bites go undetected. Novel methods to kill ticks that go undetected while biting humans therefore would be of value to public health.

The objectives consequently are to:
1) Develop novel methods to prevent human tick bites and evaluate the effectiveness of existing tick bite prevention methods to reduce human tick bites and tick-borne infections
2) Develop novel methods capable of killing biting ticks that go undetected while feeding on humans

Topic 11. Novel prevention methods to reduce transmission of *Rickettsia rickettsii* by brown dog ticks(NCEZID)

11.1 Development of a canine vaccine against *Rickettsia rickettsii*

Rocky Mountain spotted fever (RMSF) is a severe disease caused by the tick-borne pathogen, *Rickettsia rickettsii*. Over the last 20 years, epidemic levels of RMSF have been observed in Northern Mexico and among tribal communities in the Southwestern U.S., with the incidence of spotted fever in some tribal communities being 150 times the national average. In these settings, *R. rickettsii* is transmitted by the brown dog tick, which is maintained by the local dog populations. Prevention of RMSF in these areas has been shown to be possible by application of tick preventives to dogs, acaricide application to homes, spay/neuter campaigns, and community education. A potential new prevention tool would be a vaccine given to dogs that prevents the acquisition of *Rickettsia rickettsii* by ticks. This broad agency announcement solicits white papers for the production and initial evaluation of a prototype vaccine aimed at the immunization of dogs to reduce the human risk for Rocky Mountain spotted fever. The prototype vaccine should elicit broad immunity to *Rickettsia rickettsii* in canines and be able to prevent acquisition of rickettsia from immunized dogs by feeding ticks.

The specific objectives are:
1) Create a prototype vaccine that could be a whole cell vaccine, a subunit recombinant DNA vaccine, an mRNA vaccine, or other novel vaccine.
2) Test the vaccine in canines to demonstrate safety and the production of an immune response against *Rickettsia rickettsii.* Data on both humoral and cellular immunity are desired.
3) Demonstrate the effect of canine vaccination on acquisition of *Rickettsia rickettsii* by brown dog ticks.
4) Demonstrate the effect of canine vaccination on disease in dogs infected with *Rickettsia rickettsii* post-vaccination.

Topic 12. Evaluation of novel Aedes aegypti control tools (NCEZID)
12.1 Evaluate effectiveness of dried attractive bait stations to control *Aedes aegypti*, the main vector of dengue viruses
Aedes aegypti is the primary vector of dengue virus and other *Aede*s mosquito transmitted arboviruses including chikungunya and Zika. Approximately 95% of locally acquired dengue cases in the U.S. occur in Puerto Rico, causing a high burden of disease in the population. The threat of arbovirus transmission in Puerto Rico is exacerbated by the rapid evolution of insecticide resistance in *Ae. aegypti* and the loss of an effective control measures. New, effective, and sustainable mosquito control strategies are needed to reduce the morbidity and mortality caused by these diseases. Attractive Toxic Sugar Baits (ATSBs) control mosquito populations by exploiting nectar-seeking behaviors. ATSBs attract female and male mosquitoes to aromatic natural sugar sources, which are comprised of an attractant, and a toxicant like boric acid. ATSBs are delivered to mosquitoes by foliar spraying methods or bait-stations. Dried attractive toxic sugar bait stations (DABs) are an innovative modification of ATSBs and differ in that they use both visual and olfactory cues to attract mosquitoes and can be used inside of homes where *Ae. aegypti* are most often found. Because of these characteristics, DABs minimize exposure to non-target insects (e.g., pollinators) and maximizes potential exposure to *Ae. aegypti*. DABs are a low-cost and noninvasive intervention that can be scaled in low resource settings and do not require a strong and expensive infrastructure or trained personnel, supplies, and logistics. Current research has shown the DABs are effective in semi-field environments and the next step would be to optimize the intervention in full field studies with entomological endpoints. If successful, a much needed new intervention to control Ae. aegypti will be added to our toolbox of vector control strategies.

CDC seeks to support research projects that implement and evaluate the effectiveness of DABs at the community level to control *Ae. aegypti* in Puerto Rico by (1) monitoring entomological endpoints in intervention and non-intervention communities, (2) determining the optimal number and locations of DABS needed at each house to successfully reduce mosquito abundance in intervention communities and (3) understand the acceptability of DABs from residents that have them deployed in their homes.

Topic 13. Novel Assays for Dengue Vaccine Evaluation (NCEZID)
Dengue is a growing public health threat, with increasing numbers globally and regular outbreaks in dengue-endemic areas in the United States. One of the most important risk factors for severe dengue is second infection with a different dengue virus serotype, as antibody-dependent enhancement can lead to increased viral uptake, higher levels of viremia, and poor outcomes after a secondary dengue infection. Achieving balanced, protective immunity for the four dengue virus serotypes has been challenging for the development of effective tetravalent

dengue vaccines, as there are no reliable correlates of protection against dengue. The only FDA approved dengue vaccine and other vaccines in the pipeline show uneven serotype-specific protection. In addition, these vaccines show enhanced protection in pre-exposed individuals. Therefore, it is critical to assess the level of protective immunity to the four dengue virus serotypes through laboratory testing of individuals and communities in endemic areas to determine previous infection, balanced protection against future dengue infection after vaccination, and potential risks for post-vaccination infections.

Quantification of total neutralizing antibody titers through tissue culture-based methodologies, such as plaque reduction neutralization tests currently used to measure vaccine immunogenicity, are not accurate correlates of protection and are impractical and difficult to standardize. Additionally, they do not contribute to our understanding of the specificity, strength, and duration of subsets of serotype-specific protective antibodies. Infection with other flaviviruses like Zika virus create an additional challenge in detecting serotype-specific antibodies, which may cause false positive results in current dengue serological tests.

This announcement addresses the compelling need to identify reliable immune correlates of protection after dengue infection or vaccination by encouraging research to detect serotype-specific antibody responses. The proposed research should have the following objectives: (1) Demonstrate serotype specificity of antibody binding for relevant, serotype-specific antigenic virus epitopes, assessments of natural or vaccine-induced monotypic antibody responses, or depletion of cross-reactive antibodies to improve specificity of immunoassays; (2) Establish sample-sparing, high-throughput tissue culture-free methods for the detection of dengue serotype-specific antibody binding to selected virus epitopes; (3) Thought should be given to implementation of testing for serotype-specific immunity in existing cohorts or populations following implementation of dengue vaccines with the aim of documenting acquired immunity over time. (4) Assembling panels of sera from participants with confirmed monotypic and multitypic immunity should assist stakeholders in evaluating and implementing these or similar assays. Tests developed for detection of dengue serotype-specific antibodies that correlate with protective immunity should show minimal or no cross-reactivity with ZIKV antibodies. The availability of these methods could help determine pre- and post-vaccination serostatus and balanced immunity against all dengue serotypes after vaccination. This work can guide vaccine developers to achieve balanced protection with next generation vaccines or facilitate implementing vaccines that may not require natural pre-exposure and therefore benefit children in endemic countries who are mostly DENV naïve. Thus, the work will support novel discoveries to drive innovation and positively influence the development and efficacy of dengue vaccine strategies.

13.1. Correlates of protective immunity against dengue
13.2. Measurement of dengue type-specific antibody binding
13.3. Assessments of dengue vaccine immunogenicity
13.4. Dengue immunoassay development or optimization
13.5. Sample collections for test development or validation

Topic 14. Implementation of Wolbachia-based strategies for dengue control in Central America (NCEZID)

As climate change increases the geographic spread of competent arboviral disease vectors, globally and in the continental United States, there is a need to develop an evidence base around novel vector control strategies. Developing the evidence base in international settings will help reduce risk of importation to the US, and rapidly eliminate disease spread when importation does occur to minimize the impact of tropical arboviral diseases in the US. Central America is a region endemic for dengue, with abundant populations of *Aedes aegypti*, and similar ecology to the U.S. territories and U.S. Southern States. Working in Central America where there is a high dengue incidence and transmission is endemic will provide opportunities to evaluate the implementation of vaccination and vector control and establish model surveillance approaches. It will also create an opportunity for meaningful collaboration with international partners and reducing current disease burden in parts of the world and populations disproportionately affected by both arboviral diseases and the impact of climate change. One of the most promising new methods for arboviral disease reduction is introduction of *Wolbachia*-infected mosquitoes. *Wolbachia* is a naturally occurring bacteria present in 60% of insect species, and have been shown to pose no risk to humans or the environment. When *Aedes* mosquitoes are infected with *Wolbachia*, it reduces

their ability to transmit arboviruses, including dengue, chikungunya, and Zika viruses. *Wolbachia* replacement is a strategy where *Wolbachia*-infected mosquitoes are introduced into wild mosquito populations. Because the bacteria are passed on when mosquitoes mate, the wild mosquito population is slowly replaced by *Wolbachia*-infected mosquitoes with a limited ability to transmit viruses. *Wolbachia* replacement has been studied in at least 11 countries globally and was shown to significantly reduce dengue incidence by 77% in a large randomized controlled trial in Indonesia.

CDC seeks to support research projects that implement *Wolbachia*-replacement in one or two countries in Central America, including the following activities: 1) Evaluate the viability of Wolbachia-infected mosquitoes in the local mosquito population;2) Release *Wolbachia*-infected mosquitoes in controlled sites in Central America; 3) Monitor the presence and spread of *Wolbachia*-infected mosquitoes; 4) Work with public health officials to evaluate the impact of *Wolbachia* replacement on arboviral incidence in treated areas; 5) Document the evidence base and lessons learned to support regulatory approval and implementation of *Wolbachia* replacement in US territories where dengue is endemic.

14.1 Establish surveillance systems to track climate-sensitive mosquito-borne diseases and monitor if they are increasing or shifting over time**.**
14.2 Evaluate the implementation and sustainability of *Wolbachia* replacement intervention in Central America
14.3 Develop the evidence base for *Wolbachia* replacement implementation in international settings to support implementation of effective strategies in the United States and help reduce risk of importation of vector borne diseases to the U.S.

Topic 15. Towards dengue elimination: enhanced vector control and surveillance in Puerto Rico (NCEZID)

Puerto Rico faces endemic and epidemic cycles of dengue and other *Aedes* mosquito transmitted diseases, causing significant morbidity and mortality. The burden of dengue among Americans falls disproportionately on residents of Puerto Rico and other U.S. territories, further exacerbating disparities in health linked to socioeconomic status, environmental factors, healthcare spending and access to care, and natural disasters. With recent approval of a dengue vaccine for children, promising mosquito control technologies, and advancements in field-based data systems, there is an opportunity to eliminate dengue from Puerto Rico in the next decade. A key component of dengue elimination is the ability suppress dengue transmission in hotspots and enhance mosquito-based dengue surveillance to detect new introductions of dengue and complement human-based disease surveillance. However, there are no evidence-based methods for how to stop re-introduction or further spread of dengue in areas at risk for outbreaks by responding to focal hotspots.

CDC seeks to support research projects that develop, implement, and evaluate the effectiveness of vector control techniques and enhanced mosquito surveillance in known and emerging dengue hotspots in Puerto Rico. Hotspots are urban areas where: A) an introduced case could lead to an epidemic of an emerging or re-emerging arbovirus, B) historical records show high incidence and persistence of cases, or C) concentrations of people can act as arbovirus “super-spreaders”, such as schools. This effort will support research in 1) developing and implementing mosquito surveillance programs with geographic representativeness across areas of known dengue transmission, 2) modernizing data systems and mapping to measure mosquito surveillance activities in real-time, 3) implementing evidence-based, comprehensive vector control strategies in known and emerging dengue hotspots, 4) supplementing vector control strategies with community-based education to ensure community buy-in and encourage prevention activities, 5) measuring and evaluating activities 1-4 to determine their impact on mosquito populations, human dengue incidence, and timeliness in responding to dengue hotspots and suppressing mosquito populations, and lastly 6) developing cross-cutting communication channels among a range of stakeholders to facilitate situational awareness, project sustainability, and capacity development.

In addition to the objectives described above, projects are encouraged to place a special emphasis on maximizing the impact of the proposed research on reducing health disparities within Puerto Rico associated with socioeconomic status and environmental/housing factors that put certain communities at greater risk of dengue transmission and morbidity.

15.1. Develop and implement methods for enhanced surveillance and response to dengue hotspots in Puerto Rico

15.2. Evaluate the effectiveness of hotspot responses in preventing additional disease spread

Topic 16. Research to inform optimal approaches to environmental sampling and understanding of the prevalence and distribution of pathogenic fungi in healthcare settings (NCEZID)
Healthcare-associated invasive fungal infections (HA-IFIs), including invasive aspergillosis, mucormycosis, and candidiasis, cause devastating morbidity and mortality. The utility of environmental sampling to prevent and respond to fungal infections and outbreaks is limited by the lack of established threshold values or regulatory levels for these pathogens in the healthcare setting and the lack of widely accepted industry qualification or practice standards for assessment and remediation of healthcare sources of fungal diseases. This effort would close key knowledge gaps regarding expected mold and other fungi concentrations in healthcare settings. Further, this effort would help determine optimal approaches to performing environmental sampling for both mold and yeasts with the ultimate goal of preventing HA-IFIs.

16.1. Develop innovative methods for detection and surveillance of pathogenic fungi in healthcare environments

16.2. Quantify baseline levels of pathogenic fungi within healthcare environments

16.3. Correlate fungal quantitative data with episodes of fungal infections or transmission in patients.

16.4. Pilot early detection and surveillance methods for invasive mold and other fungi in patients and in the environment to guide public health efforts.

16.5. Evaluate the feasibility and utility of different environmental sampling approaches for pathogenic fungi in healthcare environments.

Topic 17. Understanding the impact of climate change and other predictors on the distribution and severity of fungal diseases (NCEZID)
Climate change is an urgent public health threat. The environmental disturbances created by climate change will change the impact of fungal pathogens on human health, especially for fungi with environmental habitats. Several tools, including environmental sampling techniques, complex modeling (e. g. machine learning) may help researchers understand how climate change will impact the abundance and pathogenicity of fungi found in the environment. This topic is aimed at soliciting white papers that will help us to prepare for and mitigate climate change-induced fungal disease threats, whether by examining changes in geographic distribution of previously geographic-restricted fungi, evaluating disease risk from fungal spores, like those abundant in wildfire smoke (which is becoming more common with climate change), or better understanding the influence of specific environmental factors on pathogens in the environment.
17.1. Evaluate the influence of climate on diversity and abundance of human-pathogenic fungi in the environment –

17.2. Model geographic spread of fungal diseases based on predicted and observed climate changes

17.3. Understand the effect of severe weather events on the incidence of fungal infections

17.4. Assess role of social factors (e.g., health disparities) in determining severity of fungal diseases.

17.5. Assess role of host factors on determining severity of fungal diseases.

Topic 18. Development of rapid point-of-care (POC) syphilis diagnostic tests (NCHHSTP)
The resurgence of syphilis, an infection caused by the bacterium **Treponema pallidum subspecies** pallidum (*T. pallidum*), in the last two decades is a major public health concern in the United States (US). In 2019, US health

departments reported 129,813 cases of syphilis, an increase of more than 70% since 2015. Congenital syphilis has increased a staggering 279 percent since 2015. In 2019 alone, there were nearly 2,000 cases of congenital syphilis reported, including 128 deaths.

Serological tests that detect treponemal and nontreponemal antibodies remain the mainstay for routine laboratory diagnosis of active syphilis infection. A treponemal test is specific for detection of *T. pallidum* antibodies. They usually remain detectable for life, even after successful treatment. Therefore, such tests cannot distinguish between active or past infection. The nontreponemal antibody test detects antibodies against lipoidal antigens released as a consequence of cell damage from the infection. The nontreponemal titer, in conjunction with clinical signs and symptoms, can help identify acute infection and a reduction in the titer relative to baseline post-treatment usually signals response to therapy. Two current FDA-cleared rapid POC serological tests for syphilis, based on the detection of only total treponemal antibodies, cannot distinguish between active and past/treated syphilis. The WHO convened a panel of diagnostics experts to develop and publish target product profiles of point-of-care serological syphilis tests with potential to advance the field. Minimal and optimal criteria were developed. Results of the consult are publicly available TPPs_STIPOCT_MAY2021_draft (who.int).

However, Serology tests are not ideal because up to 46% of patients with primary syphilis do not have detectable antibodies and because in later stages of syphilis, titers may be low. In addition, persons with treated syphilis also have antibodies, making detection of active infection difficult. For a more targeted approach, polymerase chain reaction (PCR) and other nucleic acid amplification tests (NAATs) have been developed to directly detect *T. pallidum*. However, the sensitivity of NAATs decreases among individuals in later syphilis stages and in specimen sources other than lesion exudate because the lesions resolve. FDA-cleared molecular tests are still not available. Commercial molecular laboratory developed tests (LDTs) for *T. pallidum* are used in the US but not widely available. These assays require specialized laboratory equipment, highly trained staff and have a long turnaround time.

Innovative assays, be it serological or based on direct detection of genetic materials or antigens, that can rapidly and accurately detect active syphilis infection at the point-of-care are urgently needed.

18.1 Development of a rapid point-of-care combo treponemal/ nontreponemal antibody test for active syphilis diagnosis

Objective: CDC seeks white papers to develop a rapid combo treponemal/nontreponemal antibodies test for active syphilis diagnosis. The objectives are to:

1. Develop a rapid combo treponemal/nontreponemal antibodies diagnostic test: The developed POC test will simultaneously screen for the presence and quantitation (optional) of nontreponemal antibodies and confirm syphilis by the detection of antibodies to *T. pallidum*. This configuration of the test must allow for differentiation between current and historic (or treated) infections.
2. Design and perform clinical studies to validate the sensitivity and specificity of the developed dual rapid test using clinical syphilis reactive and nonreactive specimens. The initiation of clinical studies and data collection should proceed in accordance with FDA requirements for Premarket Approval (PMA) application.

18.2 Development of a direct detection test for *T. pallidum,* ideally for all stages of syphilis

Objective: CDC seeks to support the development and evaluation of a diagnostic assay for direct detection of *T. pallidum,* ideally for all stages of syphilis. Such an assay could be very useful for early diagnosis of syphilis to allow timely treatment and prevent horizontal and vertical (mother to infant) syphilis transmission. The expectation is that applicants will develop a POC NAAT or antigen assay for the direct detection of *T. pallidum* in mucocutaneous lesions and non-lesion samples from anatomical sites where lesions may not be apparent (anorectal, mouth) in primary and secondary syphilis, or whole blood specimens from different stages of

syphilis, or other accessible specimens, validate the sensitivity and specificity of the assay for diagnosing syphilis infection, and optimize assay performance for different specimen types and clinical stages.

Topic 19. Decreasing disparities in the incidence, morbidity, and mortality associated with HIV, viral hepatitis, other sexually transmitted infections (STIs), tuberculosis and adolescent health (NCHHSTP)

19.1 Develop, implement, and/or evaluate innovative evidence-based interventions to reduce population-level disparities in the incidence, morbidity and mortality associated with HIV, viral hepatitis, STIs, or tuberculosis.

There are stark disparities in the incidence, morbidity and mortality associated with HIV, viral hepatitis, other STIs, tuberculosis and adolescent health in the United States. CDC seeks to eliminate disparities in health and in all of its determinants through public health programs and policies that address the social and structural factors contributing to population-level disparities in HIV, viral hepatitis, STIs, and tuberculosis among adults and adolescents. Social and structural factors encompass the conditions in which people are born, grow, live, work, and age, as well as the complex interrelated social structures and economic systems that shape these conditions, including aspects of the social environment (e.g., discrimination, income, education level, and marital status), the physical environment (e.g., place of residence, crowding conditions, buildings, spaces, transportation systems, and products that are created or modified by people), and health services (e.g., access to care, quality of care, and insurance status).

The evidence to promote health equity is robust. However, there is a dearth of evidence-based interventions and strategies that are specifically designed to reduce population-level disparities in the incidence, morbidity, and mortality associated with the infections and diseases addressed by our Center. The goal of this announcement is to address that gap. Specifically, CDC seeks to develop, implement, and/or evaluate evidence-based interventions that can reduce population-level disparities in the incidence, morbidity, and mortality associated with HIV, viral hepatitis, STIs, tuberculosis, and adolescent health in the United States. We define evaluation as the systematic method for collecting, analyzing, and using data to examine the effectiveness and efficiency of public health interventions, and to contribute to continuous intervention improvement to address public health actions.
Priority will be given to:

- Offerors who intend to use both absolute and relative health disparity measures to measure reductions in disparities.
- Offerors with experience in screening, prevention, treatment, and care of HIV, viral hepatitis, STIs, or tuberculosis in disproportionately affected populations.
- Interventions that include multi-sector involvement (i.e., health, housing, labor, correctional, and other non-health sectors).
- Interventions that can be scaled up and sustained to achieve significant public health impact.
- Interventions that are focused on reducing disparities in screening, prevention, treatment, and care of HIV, viral hepatitis, STDs, or tuberculosis in large areas of the country with a disproportionate burden of one or more of the indicated diseases and infections.
- Interventions that are focused on addressing the social and structural factors (i.e., changing the conditions in which people are born, grow, live, work and age as described above) that contribute to population-level disparities in the incidence, morbidity, and mortality associated with HIV, viral hepatitis, STIs, tuberculosis, and adolescent health.

Topic 20. Influenza and Other Acute Respiratory Infections (NCIRD)

Influenza (flu) is a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and lungs. Some people, such as older people, young children, and people with certain health conditions, are at higher risk of serious flu complications. There are two main types of influenza (flu) viruses: Types A and B. The influenza A and B viruses that routinely spread in people (human influenza viruses) are responsible for

seasonal flu epidemics each year. The best way to reduce the risk of flu and its potentially serious complications is by getting vaccinated each year.

This area of interest involves two (2) focus areas.
1. Diagnostics
2. Prevention

The current gold-standard tool for detection and surveillance of pathogens is real time reverse transcription polymerase chain reaction (rRT-PCR) due to its high level of accuracy and sensitivity. However, there are sometimes limitations in using rRT-PCR as the primary tool for detection and further characterization of pathogens. For example, while rRT-PCR assays can be multiplexed to allow for detection of multiple pathogens simultaneously, the scalability of this multiplexed approach is limited by the filter options on the real time instruments, and typically only four to five targets can be detected within one multiplex design. Furthermore, scenarios can arise in which there is a genomic aberration of interest in a pathogen genome but in a region of the pathogen genome in which an rRT-PCR design is not feasible due to the surrounding sequence. There can also be situations in which it is difficult to design a single rRT-PCR design that can capture and detect the diversity within a specific pathogen (e.g., H5 influenza). Finally, in situations in which a pathogen is evolving rapidly during an outbreak, it would be beneficial to have access to additional diagnostic platforms beyond rRT-PCR that have the ability for a modular approach for design and approval, which could lead to quick implementation of widespread testing if needed. Clustered regularly interspaced short palindromic repeats (CRISPR) and CRISPR-associated endonuclease (Cas) systems function in nature as an immune mechanism in prokaryotes to detect and degrade foreign genetic material. This biological system has been recently leveraged to create CRISPR-based diagnostics due to its ability for rapid, sensitive nucleic acid detection with single-base specificity.

20.1. CRISPR-Based Diagnostic Assays for Multi-Pathogen and Multi-Analyte Detection

NCIRD's Influenza Division (ID) seeks to enhance its diagnostic repertoire towards respiratory pathogens, beyond rRT-PCR, through development of CRISPR-based diagnostics to allow for multi-pathogen and multi-analyte detection:

1) Implement a panel of CRISPR-based diagnostic assays that target common respiratory pathogens, which can be used for identification and surveillance purposes during outbreaks of respiratory disease.:
    - Create CRISPR-based diagnostic assays that target a variety of respiratory pathogens.
    - Demonstrate specificity of CRISPR-based diagnostics through inclusivity and exclusivity experiments.
    - Demonstrate relative sensitivity of CRISPR-based diagnostics to rRT-PCR in single infection and co-infection scenarios.
2) Establish a CRISPR-based diagnostic assays that can be used in a reflexive manner once a pathogen has been detected to gain more granular details around subtype or substitutions of interest within the identified pathogen. Establish CRISPR-based diagnostic assays that can be used in a reflexive manner once a pathogen has been detected to gain more granular details around subtype or substitutions of interest within the identified pathogen, and create a subpanel of CRISPR-based diagnostic assays that can:
    - Distinguish influenza virus subtypes of interest.
    - Detect substitutions relating to treatment-resistance within influenza viruses.
    - Detect substitutions within the SARS-CoV-2 genome predicted to affect transmission, diagnostics, therapeutics, or immune escape.
3) Evolve the CRISPR-based diagnostics into a portable version that can be used directly in-field at points of outbreak. Objectives include developing a method for testing CRISPR-based diagnostics in field with minimal equipment/reagent requirements.

Priority will be given to offerors who establish:

1) Experience in CRISPR-based diagnostic design and data analysis.
2) Access to viral materials necessary to evaluate and verify designs.
3) Skill in evolving laboratory-based testing into portable versions that can be implemented in the field.

The COVID-19 pandemic and the response have changed the landscape of influenza. Global circulation of influenza viruses has been universally disrupted and virus transmission has been at historic lows. Although surveillance systems for respiratory illness were severely disrupted in many places, there are now enough data to indicate these decreases in influenza were real and not an artifact of surveillance disruptions. This situation is likely time limited, and influenza is expected to return as measures are lifted and the population returns to pre-COVID behavioral patterns. Indeed, in some tropical countries we have already observed influenza epidemics. This short window of substantial change offers a unique opportunity to better understand the role of non-pharmaceutical interventions (NPIs, including school closures, workplace closures, cancelling public events, restrictions on gatherings, closing public transportation, stay at home requirements, restrictions on internal movements, international travel controls, physical distancing when gathered, hand washing, case isolation, contact tracing, improvements to ventilation, public information campaigns, and mask mandates) on influenza circulation.

NPIs are most effective when they are used in a layered approach, so it can be difficult to tease out which NPIs have or will work best to interrupt influenza circulation. However, knowing this could help us understand what is the least disruptive collection of NPIs that could effectively decrease influenza transmission among a diverse set of sociodemographic groups. Various global data sources exist to explore these questions. For instance, the Oxford School of Government developed the Oxford Stringency Index, which collected systematic data on measures taken by countries to address the threat of COVID-19. In addition, there is a global source for influenza data from routine surveillance systems. Countries report weekly influenza data (specimens tested and specimens testing positive for influenza viruses) to WHO through FluNet. Other, more granular country-specific data (including for the United States) exist on these and other variables of interest that could help explore NPI impact and factors that confound or modify that impact. Creative approaches are needed to explore the separate contribution of various NPIs and their adherence) on influenza circulation, both retrospectively and prospectively as NPI policies are modified. Comparisons to other infections or conditions may be necessary to ensure associations identified with influenza are robust.

20.2. Assessing the role of non-pharmaceutical interventions (NPI) in preventing influenza

NCIRD's Influenza Division (ID) seeks to estimate the separate and joint impact of COVID-19 NPI's and their adherence on influenza circulation to identify which measures were most effective in decreasing influenza transmission through creative and innovative methods to:

1) Estimate the separate and joint effects of layered NPIs on the timing and impact (e.g., reductions in cases, hospitalizations, and deaths) of influenza circulation, both domestically and/or internationally
2) Assess the equitability of NPI impact across a diverse set of sociodemographic groups

The period of interest to CDC is June 2022 to August 2025. Each year, an assessment by CDC will be made as to the utility to move forward, taking several factors into account, including the current level of influenza virus circulation.

Priority will be given to offerors who establish:

1) Track record of similar evaluation activities for COVID-19 or seasonal and pandemic influenza;
2) Track record of using multiple diverse data sources, including those not routinely used in PHh;
3) Experience with or knowledge of surveillance systems to identify acute illness and influenza;
4) Capacity to collect, manage, and analyze the data required by this effort, including data that measure observed or reported behaviors related to NPI policies (e.g., measures of adherence);

5) Estimate NPI effects among diverse sociodemographic groups to assess drivers of inequity;
6) Ability to quantify the preventive value of alternative non-pharmaceutical interventions;
7) Assessments conducted in multiple countries, including the United States.

Topic 21. SARS-CoV-2 (COVID-19) and Children (NCIRD)
School-aged children are exposed to significant respiratory virus transmission in schools, after-school programs, and other community settings. SARS-CoV-2 causes a significant burden of mild disease in children, but the extent of asymptomatic infection and transmission in educational settings remains under studied.

As children and adolescents return to in-person learning mitigation measures to prevent the spread of SARS-CoV-2 are critical. Mitigation measures such as frequent testing, distancing, and mask use have been shown to decrease school-associated SARS-CoV-2 infection; however, COVID-19 vaccination for children is another crucial measure necessary to preventing SARS-CoV-2 transmission.

In December 2020, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the use of COVID-19 Pfizer BioNTech mRNA vaccines in adolescents 16 years and older and expanded this to children 12 years and older in May 2021. Approvals for this same vaccine in children aged 5-11 years occurred in October and other COVID-19 vaccines for children will likely follow. This area of interest involves three (3) focus areas.
1. Transmission
2. Vaccine Effectiveness (VE)
3. Impact

CDC is hoping to leverage existing SARS-CoV-2 school-based testing programs to learn more about SARS-CoV-2 and other respiratory virus transmission in school settings, and to evaluate the effectiveness of COVID-19 vaccines among children and adolescents at varying levels of transmission intensity within schools. Further study of the transmission dynamics of other respiratory pathogens including influenza, and RSV, could also be prioritized from this collaboration to further inform mitigation strategies and improve understanding of best practices for transmission reduction in educational settings.

21.1. Describing respiratory virus transmission in educational settings

NCIRD's Division of Viral Diseases (DVD) seeks to expand the current knowledge base of respiratory virus transmission in schools.

Objectives include:
1) Documenting the proportion of children infected with priority viral respiratory pathogens including SARS-CoV-2, influenza, RSV and others such as parainfluenza, seasonal coronaviruses, human metapneumovirus annually through regular multi-pathogen testing of both symptomatic and asymptomatic children;
2) Estimating the proportion of respiratory virus infections that are symptomatic;
3) Estimating the duration of test positivity for different respiratory viruses;
4) Evaluating the impact of mitigation strategies on the proportion of children infection with priority viral respiratory pathogens;
5) Based on testing results and additional epidemiologic information, determining and/or describing likelihood of in-school transmission.

Priority will be given to offerors who establish:

1) Track record of collaboration with large or multiple school districts (ideally >10,000 children);

2) Capacity to enroll and maintain participation of children aged 5-11 years and adolescents aged 12-17 years in regular (preferably weekly) PCR-based testing of both vaccinated and unvaccinated children while minimizing selection and participation biases;
3) Capacity to document prior history of SARS-CoV-2 infection in enrolled children;
4) Capacity to document the presence or absence of symptoms at the time of testing;
5) Capacity to document the date and product of all COVID-19 doses and influenza vaccines received on or since 12/2020;
6) Capacity to collect and manage data required for this effort.

21.2. Evaluating COVID-19 vaccine effectiveness in schools

NCIRD's Division of Viral Diseases (DVD) seeks to expand the current knowledge base of COVID-19 vaccine effectiveness in educational settings.

Objectives include:

1) Estimating COVID-19 vaccine effectiveness against symptomatic SARS-CoV-2 infection in children aged 5-11 years and adolescents aged 12-17 years;
2) Estimating COVID-19 vaccine effectiveness against asymptomatic SARS-CoV-2 infection in children aged 5-11 years and adolescents aged 12-17 years;
3) Evaluating product-specific COVID-19 vaccine effectiveness by age group, time since second dose, and intensity of transmission within the school setting.

The implementation of SARS-CoV-2 vaccines in the United States has greatly reduced SARS-CoV-2 transmission but with the emergence of highly transmissible variants of concern, such as delta, and the reopening of schools and early care and educations programs, estimating vaccine effectiveness (VE) of COVID-19 among children is vital. While there are several existing pediatric study platforms that estimate VE against hospitalization, VE against asymptomatic infection, and VE against symptomatic infection from urgent care and emergency department settings, these platforms cannot assess VE in the ambulatory care setting and concurrently assess correlates of protection along with long-term follow-up.

A large scale platform is needed to concurrently 1) estimate VE against symptomatic infection among children 0-17 years attending the full range of ambulatory healthcare settings, including pediatrician offices, and identify factors that may modify VE 2) have capacity to collect and test respiratory specimens to report VE by variant and blood specimens to assess correlates of protection, and 3) conduct long-term follow-up to assess persistent symptoms and disruption of education. In addition to estimating VE, collecting this type of data, including genetic sequencing of the viruses, will provide early indicators for the next SARS-CoV-2 surge, emergence of new variants of concern, or different respiratory viruses of pandemic potential. With anticipated expansion of pediatric COVID vaccines to younger age groups, CDC seeks to estimate SARS-CoV-2 VE among children in ambulatory healthcare settings at multiple sites representative of the pediatric population in the US.

21.3. Children 5-17 years: Evaluating the duration of immune protection following COVID-19 vaccination

NCIRD's Division of Viral Diseases (DVD) seeks to evaluate the duration of immune protection in children 5-17 years old following COVID-19 vaccination.

Objectives include:

1) Estimating immune protection following vaccination for 5-11 years and adolescents aged 12-17 years using serologic testing/presence of antibodies;
2) Estimating immune protection following vaccination for 5-11 years and adolescents aged 12-17 years using epidemiologic outcomes, i.e. describing duration of protection from time of vaccination without incident infection at the individual level;
3) Conducting ecological analysis at the age-group (5-11 years or 12-17 years), classroom, and/or school level that quantifies the relationship between vaccine coverage and numbers of incident infections.

21.4. Children 0-17 years: Estimating COVID-19 vaccine effectiveness in ambulatory healthcare settings

NCIRD's Division of Viral Diseases (DVD) seeks to estimate SARS-CoV-2 vaccine effectiveness among children 0-17 years in ambulatory healthcare settings at multiple sites that are representative of the pediatric population in the US, including geographic regions with diverse racial/ethnic and socioeconomic groups.

Objectives include:

1) Determining vaccine effectiveness against symptomatic laboratory-confirmed SARS-Cov-2 among children 0-17 years in ambulatory healthcare settings
2) Determining duration of overall vaccine effectiveness and by variant among children 5-17 years in ambulatory healthcare settings
3) Estimating vaccine effectiveness against persistent symptoms and disruption of education among children 0-17 years attending ambulatory healthcare settings
4) Determining vaccine effectiveness of booster doses or heterologous vaccine schedules among children 0-17 years attending ambulatory healthcare settings
5) Genetically characterize SARS-CoV-2 viruses causing infection in children 0-17 years in ambulatory healthcare settings
6) Assessing correlates of protection against symptomatic SARS-CoV-2 infection among children 0-17 years in ambulatory healthcare settings
7) Identifying demographic and clinical factors that modify the effectiveness of COVID-19 vaccines in preventing SARS-CoV-2 infection among children 0-17 years
8) Estimating incidence of symptomatic laboratory-confirmed SARS-Cov-2 and other respiratory viruses of pandemic potential among children 0-17 years in ambulatory healthcare settings
9) Estimating the incidence of co-infection with SARS-CoV-2 virus and other respiratory viruses of pandemic potential in children 0-17 years
10) Estimating incidence of SARS-CoV-2 reinfection based on self-report history of a positive test and/or access to testing results

Priority will be given to offerors who establish:

1) Track record of successful implementation of similar evaluation activities among pediatric populations;
2) Experience designing and implementing surveillance systems in ambulatory healthcare settings;
3) Capacity to collect respiratory specimens and sera from participants and conduct all steps of specimen processing, management, testing, and sequencing;
4) Capacity to collect, manage, and analyze the data required by this effort.

21.5. COVID-19 and Multisystem Inflammatory Syndrome in Children (MIS-C)
Multisystem inflammatory syndrome in children (MIS-C) is a rare but severe condition in children and adolescents infected with SARS-CoV-2. The mechanisms of MIS-C are not well understood but include a dysregulated immune response to SARS-CoV-2 infection. The risk of recurrence of the same hyperinflammatory response following reinfection of SARS-CoV-2 or in response to COVID-19 vaccination among people with a history of MIS-C is unknown. Interim clinical considerations on the CDC website have suggested that people with a history of MIS-C should consider delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-C, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection. Data are needed in inform vaccination recommendations for persons who have had MIS-C. Because of the concern of a robust hyperimmune response in children with a history of MIS-C when they receive COVID-19 vaccination, evaluation of the immune response and data regarding safety and timing of COVID-19 vaccination after MIS-C are critically important for recommendations and decision-making about the use of COVID-19 vaccines in this population.

NCIRD's Division of Viral Diseases (DVD) aims to evaluate clinical and immune responses among children receiving COVID-19 vaccination after multisystem inflammatory syndrome in children (MIS-C).

Objectives include:

1) Conducting a systematic and prospective evaluation of the immunologic response to COVID-19 vaccination in children <21 years with a history of hospitalization for MIS-C and children in comparator groups, including humoral, T-cell, and innate immunity before and after COVID-19 vaccination.
2) Documenting adverse events by product and dose among children with a history of MIS-C who then receive COVID-19 vaccines.
3) Comparing clinical and immune responses after COVID-19 vaccination among children with a history of MIS-C to those of children in comparator groups. Comparator groups may include children with a history of other inflammatory syndromes (e.g., acute COVID-19, Kawasaki Disease, and Toxic Shock Syndrome) and previously healthy control children without history of an inflammatory/infectious syndrome, as feasible.
4) Identifying potential genetic polymorphisms associated with unique or aberrant immune response to COVID-19 vaccination among children with MIS-C and among children in the comparator groups.
5) Determining if the immune response to COVID-19 vaccination among children who have had MIS-C differs according to MIS-C treatment received (e.g., IVIG + corticosteroids, IVIG alone, corticosteroids alone, tocilizumab, etc.).
6) Describing clinical signs and symptoms associated with SARS-CoV-2 re-infection in persons with a history of MIS-C and COVID-19 vaccination.

Priority will be given to offerors who establish:

1) Past experience designing and implementing longitudinal surveillance of children who have had COVID-19 infection or MIS-C, and capacity to enroll adequate sample size for analysis by age stratification (e.g., ages 16-20, ages 12-15, ages 5-11, and younger as vaccination is authorized).
2) Capacity to perform laboratory testing including inflammatory markers and to collect prospective sera and whole blood samples for peripheral blood mononuclear cells from participants and conduct all steps of specimen processing and management, to include a pre-vaccination draw ideally within 2 weeks prior to COVID-19 vaccination and post-vaccination draws at time points after vaccination (e.g., at 1-2 weeks, 1 month, and every 1-2 months thereafter for 6-12 months.
3) Capacity to collect standardized questionnaires at the time of blood draws to record clinical signs and symptoms and any specific adverse reactions to COVID-19 vaccination (to include recurrence of an MIS-C-like illness, myocarditis, and other events), as well as to assess frequency and clinical manifestations associated with SARS-CoV-2 reinfections.
4) Capacity to perform chart abstraction for initial MIS-C hospitalization and subsequent acute care visits (e.g., clinic, urgent care, emergency department) and hospitalizations, as well as all SARS-CoV-2 laboratory testing to document potential SARS-CoV-2 reinfection through 12 months post-vaccination, as feasible.
5) Capacity to collect specimens and perform similar laboratory testing and questionnaire administration from enrolled comparison groups, including children who have had COVID-19 (or Kawasaki Disease or Toxic Shock Syndrome) and receive COVID-19 vaccination, and children without a history of inflammatory or infectious illness who receive COVID-19 vaccination.
6) Capacity to perform whole genome sequencing for a subset of children in the MIS-C and control groups.
7) Capacity to collect and manage the data required by this effort.
8) The overall likelihood that they can initiate and implement the study in a timely manner.

9) Offerors should describe the outcomes they propose will best evaluate the immunologic response to COVID-19 vaccination in children with a history of MIS-C, including evaluation in comparator group(s).

21.6. COVID-19 and Acute Otitis Media (AOM)

Otitis media is a group of inflammatory diseases of the middle ear. Acute otitis media (AOM) is an infection of rapid onset that usually presents with ear pain. The cause of AOM is related to childhood anatomy and immune function. Either bacteria or viruses may be involved. Risk factors include exposure to smoke, use of pacifiers, and attending daycare. AOM is the most common reason children receive antibiotics in the United States. Streptococcus pneumoniae, Haemophilus influenzae, and Moxerella catarrhalis are the three most common bacteria that cause AOM. New higher valency pneumococcal conjugate vaccines are expected to be licensed in the next few years and have the potential to reduce incidence of pneumococcal AOM, including disease resistant to commonly prescribed antibiotics. Understanding of the vaccine preventable burden of AOM is important to inform vaccine policy decisions. Understanding the impact of the COVID-19 pandemic on nasopharyngeal carriage of common otopathogens and on the etiology of AOM is important to inform treatment guidelines and vaccine policy in the coming years.

NCIRD's Division of Bacterial Diseases (DBD) Respiratory Diseases Branch (RDB) seeks white papers to assess the prevalence of nasopharyngeal carriage of Streptococcus pneumoniae in children and etiology of AOM during the COVID-19 pandemic in populations that have been disproportionately affected by pneumococcal disease.

Topic 22. Bacterial Respiratory and Vaccine-Preventable Diseases (NCIRD)

CDC aims to improve detection, prevention, and control of respiratory and related invasive bacterial pathogens and accelerate development, introduction, and monitoring of bacterial vaccines domestically and globally.

This area of interest involves two (2) focus areas.
1. Group A Streptococcus (GAS)
2. Pertussis Disease

Group A Streptococcus (GAS) is a persistent public health problem worldwide. GAS causes infections such as strep throat and impetigo. These bacteria also cause approximately 11,000–24,000 cases of severe (invasive) GAS disease, such as necrotizing fasciitis, in the United States each year. Each year, about 1,200–1,900 people die due to invasive GAS disease. The disease burden in developing countries, especially due to rheumatic heart disease, is much greater.

22.1. Assessing the molecular epidemiology of group A Streptococcus (GAS) isolates among children.

NCIRD's Division of Bacterial Diseases (DBD) Respiratory Diseases Branch (RDB) is seeking Offeror's to assess the molecular epidemiology of group A Streptococcus (GAS) isolates among children with pharyngitis and asymptomatic GAS carriage in geographically diverse sites and assess the relationship of these non-invasive GAS isolates to invasive GAS isolates from the Active Bacterial Core surveillance program.

Pertussis, also known as whooping cough, is a highly contagious respiratory disease. It is caused by the bacterium Bordetella pertussis. Pertussis is known for uncontrollable, violent coughing which often makes it hard to breathe. After cough fits, someone with pertussis often needs to take deep breaths, which result in a "whooping" sound. Pertussis can affect people of all ages, but can be very serious, even deadly, for babies less than a year old. Pertussis is a persistent public health problem in the United States despite sustained high vaccination rates, partly because vaccine-induced immunity wanes as demonstrated in numerous studies. Failure of current acellular pertussis vaccines to reduce disease transmission as suggested by animal studies and

differences in the immune response to acellular vs. whole-cell pertussis vaccines may also be drivers of the inability to bring pertussis under better control. The reasons that long-term immunity is not acquired after natural infection or vaccination remains unclear however, due to longstanding gaps in knowledge of the pathogenesis, infectivity, and the immune response to pertussis.

Controlled Human Infection Model (CHIM) studies have emerged as an important tool in the development of a variety of new drugs and vaccines and are suitable for study of pertussis given the infection can be eradicated when antibiotics are administered early in the course of infection. The PERtussIS Correlates Of Protection Europe (PERISCOPE) Consortium has developed a human pertussis colonization model in the United Kingdom and demonstrated that experimental infection with B. pertussis is safe. Because the type of pertussis vaccine used for the primary series has been shown to influence on the subsequent immune profile, pertussis CHIM studies in populations that received acellular vaccines for the childhood series are needed to better understand the immune response to early clinical disease for developing next-generation vaccines in the United States. Additionally, identifying biomarkers that correlate with clinical endpoints is a priority to accelerate FDA licensure of next-generation pertussis vaccines. This topic focuses on the use of a Controlled Human Infection Model platform to accelerate development and licensure of next-generation pertussis vaccines in the United States.

22.2. Understanding the spectrum of clinical pertussis.

NCIRD's Division of Bacterial Diseases (DBD) Meningitis and Vaccine Preventable Diseases Branch (MVPDB) seeks to expand understanding of the spectrum of clinical pertussis disease (through the catarrhal stage), influence of pre-existing vaccine-induced cellular immunity on disease progression, and predictors of symptomatic disease using a controlled human challenge model.

22.3. Understanding immune response to pertussis infection.

NCIRD's Division of Bacterial Diseases (DBD) Meningitis and Vaccine Preventable Diseases Branch (MVPDB) seeks to gain mechanistic insight into the innate and adaptive human immune response to pertussis infection and to identify immune biomarkers of protection using a systems immunology approach with samples from participants in a pertussis colonization trial.

PART III - WHITE PAPER SUBMISSION

Steps 1 and 2 provide for technical interchange prior to the submission of a formal proposal. Any questions or clarification of project objectives or methods may be directly discussed between the Government technical representatives and the potential offerors during the Technical Dialogue. The purpose of the Technical Dialogue is to obviate excessive expenditure of resources for projects that do not warrant consideration based on insufficient technical merits or funding limitations.

Use of Non-Government Personnel

Offerors are hereby notified that non-Government participants may have access to the offerors' white papers and that providing a white paper shall constitute consent to the disclosure of proprietary information to all non-Government participants in the white paper review process. The non-Government participants are employees of commercial firms under contract to the Government and they will be authorized access to only those portions of the white paper and discussions that are necessary to enable them to provide specific technical advice on specialized matters or on particular problems, and for tracking and recording purposes. All non-Government participants have executed a Certificate of Non-Disclosure.

WHITE PAPER EVALUATION CRITERIA

White papers will be reviewed to determine if the proposed effort supports the research interest identified in Part II of this BAA. White papers will be evaluated by a technical review team using the following criteria:

- Technical Merit (Novelty, Impact, Scientific Rigor)
- Program Applicability (Priority, Gap)
- Timeframe Feasibility (Risk, Experience, Resource)

Offerors receiving a **favorable review** of their white paper will be requested to submit a formal proposal. Offerors receiving an **unfavorable review** of their white paper will not receive a request to submit a formal proposal. To be eligible for award a white paper must be submitted.

Upon completion of white paper evaluations, offerors will be notified whether or not their white paper was favorably received. Favorable review of a white paper does not constitute selection of the proposed effort for contract award and will not establish a binding commitment for the Government to fund the effort in whole or in part.

The Government will not offer debriefs to offerors whose white papers are deemed unfavorable.

WHITE PAPER FORMAT AND CONTENT

Each white paper must adhere to all of the following requirements and should be no more than 4 pages (all inclusive) in length per subtopic area. The email subject line for the white paper shall include research topic number and subtopic title.

1. **Format**
   - Font size: 12-point, unreduced
   - Single-spaced and Printed only on one side
   - Paper size: 8.5 by 11 inches
   - Page Margin Size: One inch
   - Descriptive Title of the Proposed Project
   - BAA Number

2. **Inclusions:**
   - FORM 1: White Paper Cover Page and Checklist
   - Administrative point of contact and Subject Matter point of contact
   - Project Description addressing in sufficient detail the characteristics identified in Part II
   - Estimated Timeline to complete the project
   - Rough Order of Magnitude (ROM) /high level estimate of what the project will cost

   As applicable:
   - Select Agent Approvals for projects involving hazardous materials or select agents.
   - Public Health Service (PHS) Assurance number and expiration date along with AAALAC accreditation number and renewal date, and United States Department of Agriculture registration number (if applicable) for projects involving live vertebrate animals.
   - Institutional Review Board (IRB) number for projects involving human subjects or data collection.
   - Description of any proposed IT or IT systems development, including whether or not:
     - Investment uses cloud-based solution or modern technology to meet the defined business need
     - Investment provides re-usable functionality and/or data
     - Investment leverages existing solutions, services, or data available at CDC
     - Investment results in data or system modernization (e.g., improves sustainability, mitigates the risk/cost of inaction, uses modern technology and processes)
     -

- White paper submissions shall be unclassified.

- Project description addressing in sufficient detail the characteristics identified in **Part II.** The offeror may submit an individual white paper for any or all of the topic areas under Part II.

WHITE PAPER SUBMISSION

This BAA is open and in effect for 39 days from the date of release **(December 6, 2021 through January 14, 2022). THIS IS AN IMMEDIATE CALL FOR WHITE PAPERS.** Prior to submission of a white paper offerors are strongly encouraged to contact the CDC BAA technical point of contact for the research topic/subtopic of interest. White papers must be received electronically by 3:00 PM EST for **January 14, 2022** in order to be considered for further evaluation. White papers should be submitted electronically to the mailbox at oadsbaaprojects@cdc.gov with a copy to the BAA Technical Coordinator, Diana Bartlett at dbartlett@cdc.gov.

****Please allow adequate time for your submission to get through the CDC firewall. We highly recommend allowing 5 or more minutes for this process. All white papers received after the 3:00 p.m. deadline will not be considered for review****

To ensure your submission is received and processed in a timely manner, the subject line of your email must include the **BAA number**, **topic number** and the name of your **Organization**.

Once white papers are submitted technical dialogue STOPS!

PART IV - PROPOSAL PREPARATION AND SUBMISSION

General Information

This section is intended to provide information needed in preparing research proposals for submission to CDC. Proposals submitted under this BAA must contain technical, administrative, cost, and other supporting information as described below.

Most of the information needed to prepare a proposal will be found within this section. Blank proposal forms are included in Part VI and are designed to provide the required information needed for contracting purposes. Use of the enclosed proposal forms will expedite award of the research contract.

All proposals should include the information specified in this announcement in order to avoid delays in evaluation.

CDC encourages nonprofit organizations, educational institutions, small business, small disadvantaged business concerns, HubZones, Service-Disabled Veteran-Owned Small Businesses (SDVOSBS) and Woman Owned Small Businesses (WOSB) concerns to submit white papers for consideration.

This announcement is an expression of interest only and does not commit the Government to reimburse any proposal preparation cost for responding. The cost of the proposal preparation in response to this announcement is not considered an allowable expense to the normal bid and proposal indirect costs as specified in FAR 31.205-18. Any request for white paper or submission of a full proposal does not guarantee award. The Government reserves the right to cancel this requirement at any time and shall not be liable for any cost of proposal preparation or submission.

Any contractual questions concerning the preparation or content of the research proposal should be directed to:

Name	Research Topic Area	Email
Mr. Timothy Barnes	1	krz3@cdc.gov
Mr. Tray Burch	5, 6	vwa8@cdc.gov
Elizabeth Cole Greenblatt William O'Bryan	3	qst7@cdc.gov rvq0@cdc.gov
Ms. Latoya Hill	7, 8, 9	mdx7@cdc.gov
Mr. Kristopher Lemaster	10	ene3@cdc.gov
Ms. Marva D. Lewis	2	knn5@cdc.gov
Mr. Marty Nemec	18, 19	oga2@cdc.gov
Ms. Jasmine Powell	11, 12, 13	qes1@cdc.gov
Ms. Denedra Threatt	4	qfa5@cdc.gov
Mr. Ronnie Williams	14, 15, 16, 17	oga3@cdc.gov
Mr. Tim Williams	20, 21, 22	tpw8@cdc.gov

Eligibility

To be eligible for award of a contract, a prospective contractor (except other Governments, including State and Local Governments) must meet certain minimum standards pertaining to financial resources, ability to comply with the performance schedule, prior record of performance, integrity, organization, experience, operational controls, technical skills, facilities, and equipment.

Post-Employment Conflict of Interest

There are certain post-employment restrictions on former federal officers and employees, including special Government employees (Section 207 of Title 18, United States Code). If a prospective offeror believes that a

conflict of interest may exist, the situation should be brought to the attention of the Contracting Officer before time and effort is expended in preparing a proposal.

Restrictive Markings on Proposals

Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes shall:

(a) Mark the title page with the following legend: "This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed -- in whole or in part -- for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of -- or in connection with -- the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets];" and

(b) Mark each sheet of data it wishes to restrict with the following legend: "Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal."

All offerors should also complete the Research Proposal Cover Page Attachment (1) and should complete the statements of Attachment (2) indicating their preference for release of information contained in proposals and their understanding of the policy regarding evaluation of the proposals.

The offeror is cautioned, however, that portions of the proposal may be subject to release pursuant to the Freedom of Information Act, 5 U.S.C. 552, as amended.

Reporting Requirements

The contractor will provide a quarterly summary of monthly conference calls. Quarterly Progress reports should include detailed descriptions of activities conducted during the previous quarter, planned activities for the upcoming next three months, and a section on challenges or barriers to meeting timelines and completing tasks, and how the contractor has already or plans to overcome these challenges.

Non-U.S. Citizen Participation

If the proposed research (or a portion of the proposed research) requires access to critical technology, sensitive unclassified information, For Official Use Only material, or intelligence material, non-U.S. citizens may participate in the resultant contract (or portion of the resultant contract) **only** if special written permission is granted by the Contracting Officer. The Contracting Officer will require the review and concurrence of the CDC Foreign Disclosure Officer (FDO) before granting this permission.

If the proposed research (or a portion of the proposed research) requires access to classified information (i.e., confidential or secret), non-U.S. citizens may participate in the resultant contract (or portion of the resultant contract) only if a Limited Access Authorization (LAA) is granted. A LAA can be granted only in the event that there are no U.S. citizens that can perform the effort. Granting of LAAs is not anticipated under this Broad Agency Announcement.

If any non-U.S. citizen requires access to CDC buildings, or other Government facilities, special written permission must be requested and obtained from the Contracting Officer and Security Officer through the resultant contract's Technical Point of Contact. Requests shall specify purpose, duration, frequency, and location (specific room, lab, etc.).

Period of Performance

The period of performance will be based on the research project. This BAA will include a proposed period of performance which may be negotiated later. In the past, projects have had a period of performance of 12- 24 months or have included options.

Contract Types

For this BAA, offerors can propose firm-fixed price or cost reimbursement [cost plus fixed fee, cost (no fee)].

The contract type should be based on the offerors risk associated with performing the research. As a reminder, per FAR 16.301-3(a)(3), offerors proposing a cost type contracts must have an approved accounting and purchasing system in order to receive a cost contract award. As a result, if proposing a cost type contract, please submit documentation of the approved accounting system along with the proposal.

Cost Certification

Per FAR 15.403-4, certified cost and pricing data are required for offers exceeding $750,000.00 total value. As a result, a Certificate of Current Cost or Pricing Data, in the format specified in FAR 15406-2, shall be submitted along with the offeror's proposal if the work is projected to exceed $750,000.00.

Funding

- Fiscal Year Funds: 2022
- Approximate Total Funding: $75,000,000.00 (This amount is an estimate, it is not intended to be a ceiling, and is subject to availability of funds.)
- Anticipated Award Date: July/August, 2021
- Period of Performance: TBD (Based on the research project)
- Estimated number of awards: Multiple

Proposal Submission

To be considered for award, an offeror must have submitted a white paper which was favorably reviewed by CDC. Offeror will then be formally notified by the Contracting Officer to submit a formal proposal. The Request for Proposal (RFP) will identify a due date for submitting the proposal. The offeror must follow the proposal submission guideline as identified in this section and the Request for Proposal (RFP) letter.

Follow-On Contracts

A proposal for continuation of a given research project will be considered on the same basis as proposals for new research. The proposal should be submitted sufficiently in advance of the termination of the existing contract so that if it is accepted, contract performance may be continued without interruption.

Proposal Copies

Offerors shall submit copies of their proposal as follows:

Proposal Section	Electronic
Technical Proposal	One
Administrative Proposal	One
Timeline and Cost Proposal	One

All electronic documents electronic must be in a format compatible with Microsoft Office 2016.

PROPOSAL PREPARATION INSTRUCTIONS

The proposal is the only vehicle available to the offeror for receiving consideration for award. The proposal must stand on its own merit; only information provided in the proposal can be used in the evaluation process leading to an award. The proposal shall be prepared simply and economically, providing straightforward, concise delineation of capabilities necessary to perform the proposed work. The technical proposal must be accompanied by a fully supported cost proposal as cost and technical considerations are reviewed simultaneously.

Each proposal shall be submitted under cover of Attachment (1) and shall contain three distinct sections. The first section shall contain the technical approach. The second section shall contain contractual information, certifications, and other documentation. The last section shall contain a breakdown of the anticipated costs.

Section I - Technical Section Contents

The nature of the effort to be performed will determine its acceptability for award under this BAA. Proposed efforts shall be scientific in nature and explore innovative public health practicing concepts. The Technical Section shall contain the following:

Technical Proposal – Limited to 10 Pages

a. **Cover Page**: The cover page shall include the BAA Number, research topic and reference number, name and telephone number for the principal points of contact (both technical and contractual), and any other information that identifies the proposal. The cover page shall also contain the proprietary data disclosure statement, if applicable. **The cover page shall not count as part of your technical proposal page limit.**

b. **Table of Content:** It is highly recommended that the Offeror prepares a table of contents and use it for a final quality-control checklist. **The table of content shall not count as part of your technical proposal page limit.**

c. **List of Illustrations/Tables:** This list is a quick reference of charts, graphs, and other important information. A separate list of Tables is recommended. **List of illustrations/tables shall not count as part of your technical proposal page limit.**

d. **Executive Summary:** The executive summary allows the offeror to present briefly and concisely the important aspects of its proposal to key management personnel. The summary shall present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core issues of the proposed program. **The Executive Summary shall not exceed two pages and shall not count as a part of your technical proposal page limit**.

e. **Technical Approach:** In this section, the Offeror shall provide as much technical detail and analysis as is necessary or useful to support the technical approach they are proposing. One must clearly identify the core of the intended approach. It is not effective to address a variety of possible solutions to the technology methodological problems.

(1) **Technical Discussion:** No technical approach is without its limitations or shortcomings. Every issue shall be identified and compared with the successes/failures of previous approaches. A tradeoff analysis is a good way to make this comparison and shall be supported by theory, modeling, experimental data, or other sound scientific practices. If the offeror has a "new and creative" solution to the problem(s), that solution shall be developed and analyzed in this section. The preferred technical

approach shall be described in as much detail as is necessary or useful to establish confidence in the approach.

(2) **Technical Program Summary:** This section summarizes the above technical discussion in an orderly progression through the program, emphasizing the strong points of the proposed technical approach.

(3) **Potential Contribution:** Discuss the potential contribution to research programs relating to CDC initiatives, including the topic areas of interest

***In addition to the information above, your response in this area shall also focus on the information provided in Part II of this BAA.**

(4) **Risk Analysis and Alternatives:** Every technical approach has its limitations and shortcomings. The proposal evaluator(s) will formulate a risk assessment and it is in the best interest of the Offeror to have its own understanding of the risk factors presented. Critical approaches shall be identified along with their impact on the overall program as well as fallback positions that could still improve on existing approaches.

(5) **References**: Any good technical discussion must present the basis for and reference the findings cited in the literature.

f. **Special Technical Factors:** In this section, the Offeror shall describe any capabilities it has that are uniquely supportive of the topic areas described in Part II of this BAA. The following subparagraphs are offered as possible areas to be addressed:

(1) Capabilities and Relevant Experience of the staff
(2) Previous or Current Relevant Public Health Practices
(3) Identification of well-defined statistical principles and methods as applied to prediction and modeling techniques for public health, and
(4) Information on facilities/resources that will be used to accomplish the proposed effort and an explanation of why they are adequate to conduct a successful program.

g. **Schedule**: The schedule represents the Offeror' s commitment to perform the program tasks in an orderly, timely manner.

(1) **Time Line Chart by Task:** Each major task identified in the SOW must appear as a separate line on the program schedule. Planned meetings, such as kick-off, presentations (including final), Technical Interchange Meetings, etc., must be included in the time line. The time line must also indicate the anticipated meeting site.

h. **Program Organization:** In this paragraph, the Offeror shall present its organization's ability to conduct difficult technical programs. Any pertinent or useful information may be included in this paragraph, but a minimum recommended response shall address the following subparagraphs:

(1) **Organizational Chart(s) with Key Personnel**: Include prime contractor and subcontractor organization charts, principal investigator (PI), and additional key staff who are involved in this project

(2) **Management and Technical Team:** This shall specifically identify what tasks will be performed by which party and why each subcontractor, if any, was selected to perform its task(s).

(a) Prime Contractor Responsibilities
(b) Subcontractor(s) Responsibilities
(c) Consultant(s) Responsibilities

(3) **Resumes of Key Personnel:** Key personnel are those skilled, experienced, professional and technical personnel essential for successful accomplishment of the proposal objectives, such as the principal investigator, team leader, etc. Information regarding the qualifications, capabilities, and experience of the proposed key personnel shall be addressed. Include the resumes of the prime contractor, subcontractor, and consultant personnel to include the names, brief biography, and list of recent publications of the offeror's key personnel. Documentation of previous work or experience in the field of the proposer is especially important. **Resumes shall not exceed 2 pages and shall not count as a part of your technical proposal page limit**

i. **Appendix(es):** Appendices may include technical reports, published papers, and referenced material. A listing of these reports/papers with short descriptions of the subject matter is usually adequate. Do not provide commercial product advertising brochures; these are unwanted.

Offeror's Statement of Work (SOW)- No page limit

a. It is the intent of the Government to use the Offeror' s SOW, as written, provided that the Offeror' s SOW accurately describes the work to be performed, is enforceable, and is void of inconsistencies. If, in the Government's opinion, the Offeror's SOW does not reflect these requirements, the Government will prepare a SOW using information available in the offeror's proposal; this process may delay the award.

b. **The SOW shall be a separate word document that is a distinct part of the proposal. Do not include any proprietary information in the SOW. To ensure all technical proposals receive proper consideration, the Government requires that the SOW format below be strictly adhered to.**

c. Below is the required format for the SOW. Begin this section on a new page with the Title of the Project at the top of the page. Start your SOW at Paragraph C.1.

STATEMENT OF WORK

C.1 Background and Need – (*Describes the requirements in general, non-technical terms. This section should explain why the acquisition is being pursued and how it relates to past, current, or future projects. Include a summary of statutory program authority and any regulations that are applicable. If any of the techniques have been found to be tried and been found to be effective, they should be included here.)*

C.2 Project Objective – (*A succinct statement of the purpose of the acquisition. It should outline results that the Government expects and may also identify the benefits to the program that is contemplated.)*

C.3 Scope of Work – (*An overall, non-technical description of the work to be performed. It expands on the projected objectives, but does not attempt to detail all of the work required. It must be consistent with the detailed requirements.)*

C.4 Technical Requirements – (*Spells out precisely what is expected of the contractor in the performance of the work.*

- *Describes the specific tasks and phases of the work*
- *Deliverables to be generated from the described tasks must be clearly defined*
- *Specifies the total effort each task or phase is to receive*
- *Considerations that may guide the contractor in its analysis, design, or experimentation on the designated problems*
- *Identifies the requirements and indicates the scope of each)*

C.5 Reporting Schedule – *(Describes any reporting requirements including content and format.)*

C.6 Special Considerations – *(Information that does not fit neatly or logically into one of the other sections. For example, it may be used to explain any special relationships between the contractor and other contractors working for the government.)*

C.7 Government Furnished Property – *Issuance of GFP shall be determined by the CDC Contracting Officer Representative (COR). Access to CDC IT systems and facilities is not anticipated. If it is determined that GFP or access is required, it will be controlled through use of CDC-issued HSPD-12 compliant ID badge.*

C.8 Travel – *Describes any travel that is projected to take place during the period of performance. Travel may include in-person kick-off meetings or final meetings, attendance at conferences, travel to present deliverables, etc.*

C.9 References – *(Describes any reference materials that may be relevant to the work being performed.)*

Deliverables – *(Defines and describes the deliverables, the quantity required, the recipient(s), and the schedule should be attached to the SOW. A sample of the tabs that should be included in the deliverable table are included below.*
NOTE: Deliverables included in Deliverables table must correspond to the tasks outlined under "Technical Requirements"

Task/Subtask	**Purpose**	**Deliverable Description**	**Quantity / Frequency**	**Deliverable Due Date**	**Deliver To Whom**

Section II - Administrative Section Contents – No page limit

This portion of the proposal shall contain the completed certifications and applicable forms contained in this BAA and shall include the following:

Contract Type

Identify the type of completion contract proposed. (**Note**: Offers proposed on a cost-reimbursement basis **MUST** contain evidence that the offeror' s accounting system is approved for such type contracting; i.e., provide identification of audit agency and dates last accounting and estimating system audits were performed. If approval was not obtained before submission of the proposal, the proposal shall address how the offeror will obtain the required approvals. Evidence of an approved accounting system **MUST** be obtained prior to contract award.)

Environmental Considerations

Discuss all applicable environmental and energy conservation objectives associated with the acquisition (see FAR Part 23), the applicability of an environmental assessment or environmental impact statement (see 40 CFR 1502), the proposed resolution of environmental issues, and any environmentally-related requirements to be included in the resultant contract.

Organizational Conflicts of Interest

Identify any members of the offeror's organization or team with potential conflicts of interest. Possible conflicts of interest include any people with prior federal employment, including employment of the Principal Investigator as a special Government employee (duties, agency with whom employed, dates of employment) within two years from the date of proposal submission. If none, so state.

Disclosure Requirement

Completion of Attachment (2) is prerequisite for evaluation of the proposal under this BAA.

Understanding of Evaluation Policy

Completion of Attachment (2) is prerequisite for evaluation of the proposal under this BAA.

Representations, Certifications and Other Statements of Offerors

Attachment (3) is provided for **information only**. Each offeror is required to complete the Online Representations and Certifications prior to submission of proposal and verification/validation is a prerequisite to award under this BAA. (**Note**: Online Representations and Certifications Applications (ORCA), an e-Government initiative has replaced the paper based Representations and Certifications (Reps and Certs) process. The ORCA site can be found by going to http://www.sam.gov/SAM and clicking on "Online Reps and Certs Application" on the left side of the screen.)

Contractors' Performance Assessment Reporting System (CPARS) Ratings

Completion of Attachment (4) is prerequisite for evaluation of the proposal under this BAA.

Past/Present Performance Reference Questionnaire

Completion of Attachment (5) is prerequisite for evaluation of the proposal under this BAA.

Subcontracting Plan (Only Applicable to Large Businesses)

In accordance with FAR 19.702, if the total amount of the proposal exceeds $750,000 and the offeror is a large business, the offeror shall prepare and submit a Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan. A mutually agreeable Subcontracting Plan will be included in and made a part of the resultant contract. The contract cannot be executed unless the Contracting Officer determines that the Subcontracting Plan provides the maximum practicable opportunity for small, small disadvantaged and women-owned small business concerns to participate in the performance of the contract.

As stated in 15 U.S.C. 637(d) (8), any contractor or subcontractor failing to comply in good faith with the requirements of the subcontracting plan is in material breach of its contract. Further, 15 U.S.C. 637(d) (4) (f) directs that a contractor's failure to make a good faith effort to comply with the requirements of the subcontracting plan shall result in the imposition of liquidated damages.

Title to Equipment

Title to equipment or other tangible property purchased with contract funds will be disposed of in accordance with Contracting Officer instructions at the time of contract completion.

Section III - Cost Section Contents – No page limit

In accordance with FAR 15.403-3 (under FAR 15.408 Table 15.2 when submission of Cost or Pricing Data is required), a detailed cost proposal shall be submitted with the research proposal and shall include, as a minimum, the following information (contractor's format is acceptable):

Period of Performance

Identify the proposed duration of the effort.

Direct Labor

Provide a list of participants, by category (and name, if appropriate), showing the hours and labor rates to be charged for each and the total amount per year proposed to be paid for each. Do not propose labor costs as percentages of time over the duration of the period of performance. Labor costs should be calculated by multiplying each proposed employee's labor rate by the amount of labor hours that they will work. Please disclose and explain the basis of any potential escalation factors utilized. Please refer to Attachment 9 for clarity.

Materials

Provide an itemized list of permanent equipment showing the cost of each item and the basis for the proposed cost. Provide a general description and total estimated cost of expendable equipment and supplies. Permanent equipment is any article of non-expendable tangible personal property having a useful life of more than two (2) years and an acquisition cost of $500 or more per unit. Permanent equipment costs shall not be fee/profit bearing.

Other Direct Costs

Travel

Include contemplated expenditures for travel with explanations for each trip and its proposed length and number of participants. The breakdown of these costs shall show the airfare, per diem rates, car rental rate, and any other travel expenses (such as parking fees, etc.) and shall be in accordance with the Joint Travel Regulations (JTR).

Subcontracts

Subcontractor cost proposals shall meet all of the requirements stated herein for the prime contractor. Subcontractor cost breakdowns may be submitted under separate cover.

Consultants

Provide a breakdown of any costs for consulting services showing number of days, daily rates, and estimated travel/per diem costs to the level of detail described in the travel narrative above. The need for consulting services must be explained and the basis for the daily rates must be provided.

Miscellaneous

Miscellaneous costs may include such items as publication charges, copying, subscriptions, photography, graphics, etc., only if they are consistent with and allowable under the offeror' s cost accounting system.

Indirect Costs

Indirect rates (overhead, G&A, etc.) utilized must be disclosed. Indicate whether any indirect rates used are fixed or provisional and the time frames to which they are applicable (e.g., a fixed rate may apply until a specified date, after which the rate becomes provisional). Proposals for contracts subject to FAR Subpart 31.2 shall complete Attachment (4). Facilities capital cost of money (FCCM) will not be an allowable cost in any resulting contract if the offeror's proposal fails to identify or propose FCCM (see FAR 15.408(i)).

Fee/Profit

The offeror must explain their proposed fee or profit, if any, which the organization proposes to assess the research project and how the fee/profit was derived. Reminder: Permanent equipment costs and the cost of facilities when purchased for the account of the Government (i.e., charged as a direct cost) shall not be fee/profit bearing.

PART V - PROPOSAL EVALUATION

INITIAL REVIEW

Upon receipt of a proposal, the Government will perform an initial review of the proposal's scientific/technical merit and potential contribution to CDC's mission. The Government will also determine if funds are expected to be available based on the proposed cost for the effort. Proposals not considered having sufficient scientific/technical merit or relevance to the CDC's mission or those in areas for which funds are not expected to be available, may be declined without being subject to the detailed scientific review described below. Scientific/technical merit, relevance to the research to CDC's mission, and availability of funding are of equal importance.

SCIENTIFIC REVIEW

Formal proposals not declined as a result of the initial review will be subject to a detailed extensive scientific review by highly qualified personnel.

Proposals submitted in response to this BAA will be evaluated in accordance with the following criteria:

Proposed Research

The overall scientific and/or technical merits of the proposed research, including the adequacy and effectiveness of any analysis and/or testing required to substantiate the methodology being developed.

Potential Contribution

The potential contributions of the effort to the CDC's mission and the extent to which the research effort will contribute to balancing the overall CDC's Research.

Offeror's Qualifications

The offeror's capabilities, related experience, facilities, techniques, or the unique combinations of any of these qualifications are integral factors for achieving the proposal objectives.

Personnel

The qualifications, capabilities, and experience of the proposed key personnel, such as the contractor manager, team leader, etc. Key personnel are those skilled, experienced, professional and technical personnel essential for successful accomplishment of the proposal objectives.

Cost Realism

In accordance with FAR 15.404-1 Proposal analysis techniques, the Government will evaluate the reasonableness and realism of proposed costs.

Administrative Proposal

The Contracting Officer will review the administrative section of the proposal for compliance.

PROPOSAL COMPARISONS

Each proposal will be evaluated based on the merit and relevance of the specific research proposed as it relates to the overall CDC mission rather than against other proposals for research in the same general area.

PART VI - FORMS & ATTACHMENTS

(See Attached Document)

PART VI - FORMS AND ATTACHMENTS

The following forms are required for all White Paper submissions:

	Page Number	Page Qty
FORM 1: White Paper Cover Page and Checklist	**2**	**1**

The following forms are required for all Proposal submissions:

FORM 2: Research Proposal Cover Page and Checklist	**3**	**1**
FORM 3: Representations, Certifications and Statements of Understanding	**4**	**17**
FORM 4: Contract Clearances	**21**	**1**
FORM 5: Past /Present Performance Questionnaire	**22**	**3**
FORM 6: ACH Vendor /Miscellaneous Payment Enrollment Form _ CDC 0.4433	**25**	**1**

The following attachments are for informational purposes only:

ATTACHMENT 1: Contract Clauses	**26**	**10**
ATTACHMENT 2: Contractor Performance Assessment Reporting System (CPARS)	**36**	**4**
ATTACHMENT 3: SAMPLE Statement ofWork (SOW)	**40**	**1**
ATTACHMENT 4: SAMPLE Cost Proposal Format	**41**	**1**

FORM 1: WHITE PAPER COVER PAGE and CHECKLIST

This document must accompany all white paper submissions.

1. Attention To:

CDC Office of Acquisition Services (OAS),
2900 Woodcock Blvd, Atlanta, GA 30341

2. From (Name and Address of Offeror Organization):

3. Government Point of Contact *(During Technical Dialogue)*

4. Offeror Technical Point of Contact *(During Technical Dialogue)*

5. Offeror Business Type and Size:

- ☐ Small Business
- ☐ Women Owned Small Business
- ☐ Small Disadvantaged Business 8(a)
- ☐ HUBZone
- ☐ Service Disabled Veteran Owned Small Business
- ☐ Large
- ☐ Individual
- ☐ Partnership
- ☐ Corporation: *Incorporated state:*
- ☐ Other

6. DUNS:

7. CAGE:

8. TIN:

9. CDC Research Topic Area:

- ☐ Research Topic 1
- ☐ Research Topic 2
- ☐ Research Topic 3
- ☐ Research Topic 4
- ☐ Research Topic 5
- ☐ Research Topic 6
- ☐ Research Topic 7
- ☐ Research Topic 8
- ☐ Research Topic 9
- ☐ Research Topic 10
- ☐ Research Topic 11
- ☐ Research Topic 12
- ☐ Research Topic 13
- ☐ Research Topic 14
- ☐ Research Topic 15
- ☐ Research Topic 16
- ☐ Research Topic 17
- ☐ Research Topic 18
- ☐ Research Topic 19
- ☐ Research Topic 20
- ☐ Research Topic 21
- ☐ Research Topic 22

Offerors may submit multiple White Papers and/or address more than one topic in a single paper

10. White Paper Title:

11. Estimated Timeline:

12. ROM:

13. White Paper Contents: White papers must include ALL of the following information, document and requirements in order to be evaluated

- ☐ Paper size: 8.5 by 11 inches
- ☐ Page Margin Size: One inch
- ☐ Single-spaced
- ☐ Printed only on one side of page
- ☐ Font size: 12-point, unreduced
- ☐ Shall be unclassified
- ☐ Shall not exceed four (4) pages in length (in addition to this Cover Page)

14. White Paper Inclusions: Identify if the research involves ANY of the following activities *(check all that apply)*

- ☐ Human Subjects
- ☐ Travel
- ☐ Data purchase, collection or creation
- ☐ Live Vertebrate Animals
- ☐ Conference(s) or Training
- ☐ Development of IT (including mobile app) or IT solution
- ☐ Hazardous Material /Select Agents
- ☐ Printing
- ☐ Purchase of equipment that directly interfaces with IT or collects data

FORM 2: RESEARCH PROPOSAL COVER PAGE and CHECKLIST

1. Attention To:

CDC Office of Acquisition Services (OAS),
2900 Woodcock Blvd, Atlanta, GA 30341

2. From: (Name and Address of Offeror Organization)

3. Offeror Business Type and Size:

- ☐ Small Business
- ☐ Women Owned Small Business
- ☐ Small Disadvantaged Business 8(a)
- ☐ HUBZone
- ☐ Service Disabled Verteran Owned Small Business
- ☐ Large
- ☐ Individual
- ☐ Partnership
- ☐ Corporation: *Incorported state:* _____
- ☐ Other _____

4. DUNS:

5. CAGE:

6. TIN:

7. Proposal Title:

8. Project ID:

Provided in CDC's Invitation Letter

9. CDC Research Topic Area:

- ☐ Research Topic 1
- ☐ Research Topic 2
- ☐ Research Topic 3
- ☐ Research Topic 4
- ☐ Research Topic 5
- ☐ Research Topic 6
- ☐ Research Topic 7
- ☐ Research Topic 8
- ☐ Research Topic 9
- ☐ Research Topic 10
- ☐ Research Topic 11
- ☐ Research Topic 12
- ☐ Research Topic 13
- ☐ Research Topic 14
- ☐ Research Topic 15
- ☐ Research Topic 16
- ☐ Research Topic 17
- ☐ Research Topic 18
- ☐ Research Topic 19
- ☐ Research Topic 20
- ☐ Research Topic 21
- ☐ Research Topic 22

10. Type of Contract Proposed:

- ☐ Firm Fixed Price
- ☐ Cost Plus Fee
- ☐ Cost No Fee

11. Requested Start Date:

12. Proposed Contract Value:

13. Proposal Valid Until:

Minimum 9 months from submission

14. Requested End Date:

15. Payment Mailing Address:

16. Contents: (Proposals must include ALL of the following information)

☐ Table of Contents	No page limit
☐ List of Illustrations/Tables	No page limit
☐ Executive Summary	NTE two (2) pages
☐ Technical Proposal	NTE ten (10) pages
☐ Resumes of Key Personnel	NTE two (2) pages each
☐ Appendix(es)	No page limit
☐ Cost Proposal	No page limit
☐ Offeror's Statement of Work (SOW)	No page limit

17. Attachments: (Proposals Forms are provided in PART VI of the BAA)

- ☐ FORM 2: Research Proposal Cover Page and Checklist
- ☐ FORM 3: Representations, Certifications and Statement of Understanding
- ☐ FORM 4: Contract Clearances
- ☐ FORM 5: Past/Present Performance Reference Questionnaire
- ☐ FORM 6: ACH Vendor /Miscellaneous Payment Form_CDC 0.4433

18. Inclusions: (Indicate if the proposed research involves any of the following activities)

- ☐ Live Vertebrate Animals
- ☐ Hazardous Material /Select Agents
- ☐ Data Collection
- ☐ Development of IT or IT solutions

19. Offeror's Administrative Representative:

Name (Individual Authorized to Conduct Negotiations)	*Phone*	*Email*

20. Offeror's Principal Investigator:

Name (Offeror's Technical Subject Matter Expert)	*Phone*	*Email*

FORM 3: REPRESENTATIONS, CERTIFICATIONS AND STATEMENTS OF UNDERSTANDING

This form must be completed by offerors and attached to all research proposal submissions.

SECTION		PAGE
2.1 STATEMENT OF DISCLOSURE PREFERENCE		2
2.2 STATEMENT OF UNDERSTANDING OF EVALUATION POLICY		2
2.3 FAR PROVISIONS		3
The following provisions must be completed by ALL offerors		
52.203-11	CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEP 2007)	3
52.204-3	TAXPAYER IDENTIFICATION (OCT 1998)	3
52.204-5	WOMEN-OWNED BUSINESS (Other Than Small Business) (OCT 2014)	4
52.204-6	UNIQUE ENTITY IDENTIFIER (OCT 2016)	4
52.204-24	REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT.	5
52.204-25	PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT.	6
52.209-5	CERTIFICATION REGARDING OTHER RESPONSIBILITY MATTERS	8
52.209-11	REPRESENTATION BY CORPORATIONS REGARDING DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW. (FEB 2016)	10
52.215-6	PLACE OF PERFORMANCE (OCT 1997)	10
52.219-1	SMALL BUSINESS PROGRAM REPRESENTATIONS	11
52.222-22	PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (Feb 1999)	13
52.222-25	AFFIRMATIVE ACTION COMPLIANCE (Apr 1984)	14
52.226-2	HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION (OCT 2014)	14
52.227-6	ROYALTY INFORMATION (APR 1984)	14
52.230-1	COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION	14
The following provisions must be completed ONLY if the proposed contract type is FIRM FIXED PRICE		
52.203-2	Certificate of Independent Price Determination(APR 1985)	16
2.4 CONCURRENCE AND SIGNATURE		**17**

STATEMENTS, CERTIFICATIONS AND STATEMENT OF DISCLOSURE PREFERENCE AND UNDERSTANDING OF EVALUATION POLICY

CDC has a continuing interest in receiving and evaluating proposals containing new ideas, suggestions for researching ways to enhance the state-of-the-art in public health. However, Government personnel and contractors are constantly engaged in R&D activities, and the substance of your proposal may already be known to Government employees or contractors, or may even be in the public domain. For such reasons it is desirable, when receiving proposals for evaluation, to insure that the persons submitting them are aware of the conditions under which the CDC will consider them.

It must be understood that the receipt and evaluation of the proposal by CDC does not imply a promise to pay, recognition of novelty or originality, or any relationship, which might require the Government to pay for use of information to which it is otherwise lawfully entitled.

Due care will be exercised to ensure that, in addition to technical design or concept data submitted, administrative and cost data will not be used by the Government for any purpose other than evaluation of the proposal. Administrative and cost data will not be disclosed to non-Government participants. Additionally, such data will not be disclosed outside the Government or be duplicated, used or disclosed in whole or in part by the Government, except for tracking and record purposes or to evaluate the proposal. This restriction does not limit the Government's right to use information contained in such data if it is obtained from another source, or is in the public domain.

All research proposals will be treated as privileged information before award and contents will only be disclosed for purposes of evaluation. Your voluntary submission will be handled in accordance with established Government procedures for safeguarding such articles or information against unauthorized disclosure. All Government reviewers will be made aware that proposals sent to them are not to be duplicated, used, or disclosed in whole or in part for any purpose other than to evaluate the proposal, without the written permission of the offeror.

You should be aware that, despite all precautions, we may be able to protect the confidentiality of proposal only to the extent that it is exempt from disclosure under the Freedom of Information Act (see FAR Subpart 24.2). Upon receipt, your proposal will be submitted to the appropriate technical experts for evaluation. Your proposal will undergo initial review within one hundred and twenty (120) days after receipt. If additional time for this review is required, you will be notified in writing. Processing of proposals not declined as a result of the initial review may require as much as 180 days.

Having read and understood the above policy, please execute the following statements:

2.1 STATEMENT OF DISCLOSURE PREFERENCE

☐ This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed -- in whole or in part -- for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of – or in connection with -- the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction.

- ☐ The data subject to this restriction are contained in sheets: _____
- ☐ All data contained in this proposal are subject to this restriction.

☐ Permission is hereby granted to CDC to evaluate this proposal, which may include evaluation by evaluators both within and outside the Government, with the understanding that written agreement not to disclose this information shall be obtained from any non-Government evaluator.

2.2 STATEMENT OF UNDERSTANDING OF EVALUATION POLICY

☐ It is understood that CDC has accepted the above proposal for the purpose of evaluating it and advising of any possible interest. It is further understood that such acceptance does not imply or create a promise to pay; an obligation to give up any legal right or to assume any duty; a recognition of novelty, originality or priority; or any relationship, contractual or otherwise, such as would render the Government liable to pay for or give up any legal right or assume any obligation for disclosure or use of any information in the proposal to which the Government would otherwise lawfully be entitled.

2.3 REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS OR QUOTERS

The following FAR provisions must be completed by ALL offerors.

52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEP 2007)

(a) *Definitions.* As used in this provision—"Lobbying contact" has the meaning provided at 2 U.S.C. 1602(8). The terms "agency," "influencing or attempting to influence," "officer or employee of an agency," "person," "reasonable compensation," and "regularly employed" are defined in the FAR clause of this solicitation entitled "Limitation on Payments to Influence Certain Federal Transactions" (52.203-12).

(b) *Prohibition.* The prohibition and exceptions contained in the FAR clause of this solicitation entitled "Limitation on Payments to Influence Certain Federal Transactions" (52.203-12) are hereby incorporated by reference it his provision.

(c) *Certification.* The offeror, by signing its offer, hereby certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on its behalf in connection with the awarding of this contract.

(d) *Disclosure.* If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(e) *Penalty.* Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by 31 U.S.C. 1352. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure required to be filed or amended by this provision, shall be subject to a civil penalty of not less than $10,000, and not more than $100,000, for each such failure.

(End of Provision)

52.204-3 TAXPAYER IDENTIFICATION (OCT 1998)

(a) Definitions.
Common parent, as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.
Taxpayer Identification Number (TIN), as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

(b) All offerors must submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C.7701(c) and 3325(d), reporting requirements of 26 U.S.C.6041, 6041A, and 6050M, and implementing regulations issued by the IRS. If the resulting contract is subject to the payment reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C.7701(c) (3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror' s TIN.

(d) Taxpayer Identification Number (TIN).

☐ TIN: _____ ☐ TIN has been applied for.

☐ TIN is not required because: _____

☐ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

☐ Offeror is an agency or instrumentality of a foreign government;

☐ Offeror is an agency or instrumentality of the Federal Government.

(e) Type of organization.

☐ Sole proprietorship ☐ Partnership ☐ Corporate entity (not tax-exempt)

☐ Corporate entity (tax-exempt) ☐ Government entity (Federal, State, or local)

☐ Foreign government ☐ International organization per 26 CFR 1.6049-4

☐ Other _____

(f) Common parent.

☐ Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.

☐ Name and TIN of common parent:

Name _____ TIN _____

{End of provision}

52.204-5 WOMEN-OWNED BUSINESS (OTHER THAN SMALL BUSINESS) (OCT 2014)

a) Definition. "Women-owned business concern," as used in this provision, means a concern that is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

(b) Representation. [*Complete only if the offeror is a women-owned business concern and has not represented itself as a small business concern in paragraph (c)(1) of FAR 52.219-1, Small Business Program Representation, of this solicitation*.]

☐ The offeror represents that it is a women-owned business concern.

(End of Provision)

52.204-6 UNIQUE ENTITY IDENTIFER (OCT 2016)

(a) Definitions. As used in this provision—

"*Electronic Funds Transfer (EFT) indicator*" means a four-character suffix to the unique entity identifier. The suffix is assigned at the discretion of the commercial, nonprofit, or Government entity to establish additional System for Award Management records for identifying alternative EFT accounts (see subpart 32.11) for the same entity.

"*Unique entity identifier*" means a number or other identifier used to identify a specific commercial, nonprofit, or Government entity. See www.sam.gov for the designated entity for establishing unique entity identifiers.

(b) The Offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "Unique Entity Identifier" followed by the unique entity identifier that identifies the Offeror's name and address exactly as stated in the offer. The Offeror also shall enter its EFT indicator, if applicable.

(c) If the Offeror does not have a unique entity identifier, it should contact the entity designated at www.sam.gov for establishment of the unique entity identifier directly to obtain one. The Offeror should be prepared to provide the following information:

(1) Company legal business name.
(2) Tradestyle, doing business, or other name by which your entity is commonly recognized.
(3) Company physical street address, city, state and Zip Code.
(4) Company mailing address, city, state and Zip Code (if separate from physical).
(5) Company telephone number.
(6) Date the company was started.
(7) Number of employees at your location.
(8) Chief executive officer/key manager.
(9) Line of business (industry).
(10) Company headquarters name and address (reporting relationship within your entity).

(End of Provision)

52.204-24 REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT.

As prescribed in 4.2105(a), insert the following provision:

Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (OCT 2020)

The Offeror shall not complete the representation at paragraph (d)(1) of this provision if the Offeror has represented that it "does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument" in paragraph (c)(1) in the provision at 52.204-26, Covered Telecommunications Equipment or Services—Representation, or in paragraph (v)(2)(i) of the provision at 52.212-3, Offeror Representations and Certifications-Commercial Items. The Offeror shall not complete the representation in paragraph (d)(2) of this provision if the Offeror has represented that it "does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services" in paragraph (c)(2) of the provision at 52.204-26, or in paragraph (v)(2)(ii) of the provision at 52.212-3.

(a) **Definitions.** As used in this provision—Backhaul, covered telecommunications equipment or services, critical technology, interconnection arrangements, reasonable inquiry, roaming, and substantial or essential component have the meanings provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) **Prohibition**.
(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Nothing in the prohibition shall be construed to—
(i) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or
(ii) Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract or extending or renewing a contract with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract. Nothing in the prohibition shall be construed to—
(i) Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or
(ii) Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(c) **Procedures.** The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".

(d) **Representation.** The Offeror represents that—
(1) It ☐ will, ☐ will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation. The Offeror shall provide the additional disclosure information required at paragraph (e)(1) of this section if the Offeror responds "will" in paragraph (d)(1) of this section; and

(2) After conducting a reasonable inquiry, for purposes of this representation, the Offeror represents that—
It ☐ does, ☐ does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. The Offeror shall provide the additional disclosure information required at paragraph (e)(2) of this section if the Offeror responds "does" in paragraph (d)(2) of this section.

(e) **Disclosures.**
(1) Disclosure for the representation in paragraph (d)(1) of this provision. If the Offeror has responded "will" in the representation in paragraph (d)(1) of this provision, the Offeror shall provide the following information as part of the offer:
(i) For covered equipment—
(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the original equipment manufacturer (OEM) or a distributor, if known);
(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(ii) For covered services—
(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or
(B) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(2) Disclosure for the representation in paragraph (d)(2) of this provision. If the Offeror has responded "does" in the representation in paragraph (d)(2) of this provision, the Offeror shall provide the following information as part of the offer:
(i) For covered equipment—
(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known);
(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(ii) For covered services—
(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or
(B) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(End of provision)

52.204-25 PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT.

As prescribed in 4.2105(b), insert the following clause:

Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020)

(a) **Definitions.** As used in this clause—

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (**e.g.**, connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (**e.g.**, fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means–
(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);
(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);
(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or
(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means–
(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;
(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-
(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or
(ii) For reasons relating to regional stability or surreptitious listening;
(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);
(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);
(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or
(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (**e.g.**, connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (**e.g.**, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) **Prohibition**.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) **Exceptions.** This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) **Reporting requirement.**

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at https://dibnet.dod.mil.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) **Subcontracts.** The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

52.209-5 CERTIFICATION REGARDING OTHER RESPONSIBILITY MATTERS

As prescribed in 9.104-7(a), insert the following provision:

Certification Regarding Responsibility Matters (Aug 2020)

(a)

(1) The Offeror certifies, to the best of its knowledge and belief, that—

(i) The Offeror and/or any of its Principals–

(A) Are ☐ are not ☐ presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have ☐ have not ☐ within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property (if offeror checks "have", the offeror shall also see 52.209-7, if included in this solicitation);

(C) Are ☐ are not ☐ presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision;

(D) Have ☐ have not ☐ within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds the threshold at 9.104-5(a)(2) for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) **The tax liability is finally determined**. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) **The taxpayer is delinquent in making payment**. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) **Examples**.

(i) The taxpayer has received a statutory notice of deficiency, under I.R.C. § 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. § 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. § 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has □ has not □, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principal," for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (**e.g.**, general manager; plant manager; head of a division or business segment; and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

52.209-11 REPRESENTATION BY CORPORATIONS REGARDING DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW. (FEB 2016)

As prescribed in 9.104-7 (d), insert the following provision:

Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law (Feb 2016)

(a) As required by sections 744 and 745 of Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), and similar provisions, if contained in subsequent appropriations acts, the Government will not enter into a contract with any corporation that–
   (1) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless an agency has considered suspension or debarment of the corporation and made a determination that suspension or debarment is not necessary to protect the interests of the Government; or
   (2) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless an agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(b) The Offeror represents that–

   (1) It is ☐ is not ☐ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; and
   (2) It is ☐ is not ☐ a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

(End of provision)

52.215-6 PLACE OF PERFORMANCE (OCT 1997)

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, ☐ intends, ☐ does not intend [check applicable block] to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of performance (Street address, City, County, State, Zip code)	Name and address of owner and operator of the plant or facility if other than offeror or quoter

(End of provision)

52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS

As prescribed in 19.309(a)(1), insert the following provision:

Small Business Program Representations (Nov 2020)

(a) **Definitions**. As used in this provision- "Economically disadvantaged women-owned small business (EDWOSB) concern" means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

Service-disabled veteran-owned small business concern-
(1) Means a small business concern-
(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and
(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.
(2) "Service-disabled veteran" means a veteran, as defined in 38 U.S.C.101(2), with a disability that is service-connected, as defined in 38 U.S.C.101(16).

Small business concern—
(1) Means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (b) of this provision.
(2) Affiliates**,** as used in this definition, means business concerns, one of whom directly or indirectly controls or has the power to control the others, or a third party or parties control or have the power to control the others. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships. SBA determines affiliation based on the factors set forth at 13 CFR 121.103.

Small disadvantaged business concern, consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that-
(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by-
(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States, and
(ii) Each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and
(2) The management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

"Veteran-owned small business concern" means a small business concern-
(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C.101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and
(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern" means a small business concern-

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and
(2) Whose management and daily business operations are controlled by one or more women.

"Women-owned small business (WOSB) concern eligible under the WOSB Program" (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(b)
(1) The North American Industry Classification System (NAICS) code for this acquisition is– ***541715***.
(2) The small business size standard is ***1000***.
(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture (i.e., nonmanufacturer), is 500 employees.

(c) Representations.
(1) The offeror represents as part of its offer that it □ is, □ is not a small business concern.

(2) [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]*

The offeror represents that It ☐ is, ☐ is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]*

The offeror represents as part of its offer that It ☐ is, ☐ is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [*Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(3) of this provision.]*

The offeror represents as part of its offer that-
(i) It ☐ is, ☐ is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(4)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [*The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.]* Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. [*Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (c)(4) of this provision.*] The offeror represents as part of its offer that-
(i) It ☐ is, ☐ is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(5)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [*The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.]* Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]*

The offeror represents as part of its offer that it It ☐ is, ☐ is not a veteran-owned small business concern.

(7) [*Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(6) of this provision.]*

The offeror represents as part of its offer that It ☐ is, ☐ is not a service-disabled veteran-owned small business concern.

(8) [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]*

The offeror represents, as part of its offer, that-

(i) It ☐ is, ☐ is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR Part 126; and

(ii) It ☐ is, ☐ is not a HUBZone joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(8)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [*The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.]* Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Under 15 U.S.C.645(d), any person who misrepresents a firm's status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall-

(1) Be punished by imposition of fine, imprisonment, or both;

(2) Be subject to administrative remedies, including suspension and debarment; and

(3) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

Alternate I (Sep 2015). As prescribed in **19.309**(a)(2), add the following paragraph (c)(9) to the basic provision:

(9) [*Complete if offeror represented itself as disadvantaged in paragraph (c)(2) of this provision.*] The offeror shall check the category in which its ownership falls:

☐ Black American ☐ Hispanic American

☐ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians)

☐ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, The Philippines, Republic of Palau, Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru)

☐ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal)

☐ Individual/concern, other than one of the preceding

52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FEB 1999)

The offeror represents that –

(a) It ☐ has, ☐ has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation;

(b) It ☐ has, ☐ has not filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.16.

(End of provision)

52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APR 1984)

The offeror represents that (a) it ☐ has developed and has on file, ☐ has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or (b) it ☐ has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(End of provision)

52.226-2 HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION (OCT 2014)

(a) *Definitions*. As used in this provision --

"Historically Black College or University" means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2.

"Minority Institution" means an institution of higher education meeting the requirements of Section 365(3) of the Higher Education Act of 1965 (20 U.S.C. 1067k, including a Hispanic-serving institution of higher education, as defined in Section 502(a) of the Act (20 U.S.C. 1101a).

(b) *Representation*. The offeror represents that it --

It ☐ is, ☐ is not a historically black college or university;

It ☐ is, ☐ is not a minority institution.

(End of Provision)

52.227-6 ROYALTY INFORMATION (APR 1984)

(a) *Cost or charges for royalties.* When the response to this solicitation contains costs or charges for royalties totaling more than $250, the following information shall be included in the response relating to each separate item of royalty or license fee:
(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers, patent application serial numbers, or other basis on which the royalty is payable.
(4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable.
(5) Percentage or dollar rate of royalty per unit.
(6) Unit price of contract item.
(7) Number of units.
(8) Total dollar amount of royalties.

(b) *Copies of current licenses.* In addition, if specifically requested by the Contracting Officer before execution of the contract, the offeror shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents.

(End of Provision)

52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION

As prescribed in 30.201-3 (a), insert the following provision:

Cost Accounting Standards Notices and Certification (Jun 2020)

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III. Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS coverage pursuant to 48 CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement-Cost Accounting Practices and Certification

(a) Any contract in excess of the lower CAS threshold specified in Federal Acquisition Regulation (FAR) 30.201-4(b) resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR chapter 99must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

Caution: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) ☐ **Certificate of Concurrent Submission of Disclosure Statement**. The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) Original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable; and

(ii) One copy to the cognizant Federal auditor.
(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official.)

Date of Disclosure Statement: _____

Name and Address of Cognizant ACO or Federal Official Where Filed:
_____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) ☐ **Certificate of Previously Submitted Disclosure Statement**. The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: _____

Name and Address of Cognizant ACO or Federal Official Where Filed:
_____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) ☐ **Certificate of Monetary Exemption**. The offeror hereby certifies that the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling $50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) ☐ **Certificate of Interim Exemption**. The offeror hereby certifies that (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and (ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under paragraph (c)(1) or (c)(2) of PartI of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

Caution: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of $50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

II. Cost Accounting Standards-Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

☐ The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than $50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

Caution: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of $50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of $50 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with paragraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

☐ Yes ☐ No

(End of provision)

A. The following FAR provision must be completed ONLY if the proposed contract type is Firm Fixed Price:

52.203-2 <u>CERTIFICATE OF INDEPENDENT PRICE DETERMINATION (APR 1985)</u>

(a) The offeror certifies that
  (1) The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to (i) those prices, (ii) the intention to submit an offer, or (iii) the methods or factors used to calculate the prices offered;
  (2) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award (in the case of a negotiated solicitation) unless otherwise required by law; and
  (3) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory
  (1) Is the person in the offeror' s organization responsible for determining the prices being offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above; or

(2) (i) Has been authorized, in writing, to act as agent for the following principals in certifying that those principals have not participated, and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above (*insert full name of person(s) in the offeror's organization responsible for determining the prices offered in this bid or proposal, and the title of his or her position in the offeror's organization*); (ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) above have not participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above; and (iii) As an agent, has not personally participated, and will not participate, in any action contrary to subparagraphs (a) (1) through (a) (3) above.

(c) If the offeror deletes or modifies subparagraph (a) (2) above, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure.

{End of provision}

2.4 CONCURRENCE AND SIGNATURE

By signing below, the offeror hereby certifies the information provided, including the offerors response(s) to the *STATEMENT OF DISCLOSURE PREFERENCE* under section 2.1, the *STATEMENT OF UNDERSTANDING OF EVALUATION POLICY* under section 2.2 and each of the *FAR PROVISIONS* under section 2.3.

BAA Number | Topic Number

Proposal Title

Offeror /Organization (Company or Corporation Name)

DUNS | NAIC | Name of Authorized Representative Signing

Title

Signature | Date

FORM 4: CONTRACT CLEARANCE

Please check the box(es) below to assist CDC in determining clearance requirements for the proposed research. (check all that apply):

☐ The proposed research includes activities involving the use of hazardous materials or select agents.

☐ The proposed research includes activities involving the use of live vertebrate animals.

☐ The proposed research involves the collection or creation of data; purchase of data, information or samples; development of IT (including mobile apps) or IT solutions; and/or equipment that directly interface with IT or collects data.

COMMON CLEARANCES: The most common required clearance for procurement of services and supplies, as set forth in the Federal Acquisitions Regulations (FAR), Code of Federal Regulations (CFR) and Department of Health and Human Services (HHS) policies, are listed below.

1. **Human Subjects:** This clearance is required all service contracts and contracts for the procurement of data, information or samples (Reference HHSAR 370.301 and 45 CFR 46.103).

   The purpose of this clearance is to make sure that Center for Disease Control and Prevention is in compliance with the Department of Health and Human Services (HHS) policy. The policy is that the contracting officer shall not award a contract involving human subjects until the prospective contractor provides assurance that the activity will undergo initial and continuing review by an appropriate Institutional Review Board (IRB) in accordance with HHS regulations at 45 CFR 46.103. The contracting officer shall require a Federal-wide assurance (FWA), approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or institution engaged in human subjects research in performance of a contract. OHRP administers the assurance covering all HHS-supported or HHS-conducted activities involving human subjects.

2. **Regulatory Compliance for proposals involving vertebrate animals:** Animal use conducted under this contract shall be in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the current edition of the "Guide for the Care and Use of Laboratory Animals (the Guide), the Animal Welfare Act and Regulations (Title 9 Code of Federal Regulations part 1), and all applicable local, state, or other federal regulations.

   The Offeror and any subcontractors shall have an approved, current Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), at the time of contract award.

   Accreditation of the Offeror and any subcontractors by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) is preferred.

   If animal species regulated by the United States Department of Agriculture (USDA) are involved in a contract, the Offeror and any subcontractors shall be registered with the Secretary of Agriculture of the United States in accordance with the following Federal regulations 7 U.S.C 2136 and 9 CFR sections 2.25-2.28 respectively.

   The Offeror and/or subcontractors must address the following items in their submitted proposal as required by the Public Health Service Policy on Humane Care and Use of Laboratory Animals (section IV.D.1.):
   a. identification of the species and approximate number of animals to be used;
   b. rationale for involving animals, and for the appropriateness of the species and numbers used;
   c. a complete description of the proposed use of the animals;
   d. a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
   e. a description of any euthanasia method to be used.

3. **Paperwork Reduction**: This clearance is required for all service contracts and contracts for the procurement of data, information or samples (Reference HHSAR 352.211-3 and 5 CFR 1320).

   The purpose of this clearance is to ensure that the Center for Disease Control and Prevention (CDC) is in compliance with the Paperwork Reduction Act of 1995. In addition, it helps determines the applicability for proposed projects.

4. **Section 508**: This clearance is required for all information, communication and technology (ICT) contracts. (Reference HHSAR 339.2) In compliance with the Department of Health and Human Services (HHS) policy. (a) Electronic and information technology (EIT) supplies and services must comply with Section 508 of the Rehabilitation Act (the Act) of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board (Access Board) Electronic and Information Accessibility Standards (36 CFR part 1194). Requiring activities must consult with their Section 508 Official or designee to determine if the contractor should be responsible for compliance with EIT accessibility standards which apply to website content and communications material.
   (1) When conducting a procurement and employing the best value continuum, the solicitation shall include a separate technical evaluation factor developed by the contracting officer, requiring activity, and the Operating Division (OPDIV) Section 508 Official or designee.
   (2) At a minimum, solicitations for supplies and services shall require the submission of a Section 508 Product Assessment Template (See http://www.hhs.gov/web/508 for the template). Solicitations for services shall include any other pertinent information that the contracting officer deems necessary to evaluate the offeror's ability to meet the applicable Section 508 accessibility standards.

5. **Information Security and Privacy:** This clearance is required for all contracts (Reference FAR 39.101(d)) The purpose of this clearance is to determine if the acquisition requires information security, involves personal identifiable information, and is subject to the privacy act.

6. **Safety and Health:** This clearance is required for all contracts that involve hazardous materials or hazardous operations, including services or products; research, development or test projects; transportation of hazardous materials; and construction. (Reference FAR 36.513 and 52.236-13)

FORM 5: PAST /PRESENT PERFORMANCE REFERENCE INSTRUCTIONS

Reference Information Table: OFFEROR should complete the Reference Information Table BEFORE sending this questionnaire to the customers to ensure the accuracy of the information being provided. Send the completed Reference Information Table and blank questionnaire to each customer with a cover letter that 1) authorizes the selected customers to discuss the offeror' s performance under the applicable contract with the contracting officer; 2) requests the customer complete the questionnaire; and 3) instructs the customer to return the completed questionnaire by email to: oadsbaaprojects@cdc.gov. Submit a copy of the customer's cover letter with your business proposal to ensure receipt of questionnaires' responses.

Past /Present Performance Questionnaire: Customer /reference responses will be rated using the following scale:

Rating	**Rating Code**	**Description**
Unsatisfactory	P/U	Does not meet minimum acceptable standards in one or more areas; remedial action required in one or more areas; deficiencies in one or more areas which adversely affect overall performance.
Satisfactory	S	Meets or slightly exceeds minimum acceptable standards; adequate results; reportable deficiencies with identifiable, but not substantial, effects on overall performance.
Good	G	Effective performance; fully responsive to contract requirements; reportable deficiencies, but with little identifiable effect on overall performance.
Very Good	VG	Very effective performance; fully responsive to contract requirements; contract requirements accomplished in a timely, efficient, and economical manner for the most part; only minor deficiencies with minimal effect on overall performance.
Excellent	E	Of exceptional merit; exemplary performance in a timely, efficient, and economical manner; very minor (if any) deficiencies with no adverse effect on overall performance.
Neutral	N	No record of relevant past performance or past performance information is not available

Reference Information Table (to be completed by the Offeror): Send the completed Table and blank questionnaire to each customer with a cover letter that 1) authorizes the selected customers to discuss the offeror's performance under the applicable contract with the contracting officer; 2) requests the customer complete the questionnaire; and 3) instructs the customer to return the completed questionnaire by email to: oadsbaaprojects@cdc.gov

Offeror /Organization Name	
BAA Number	
Reference Business Name	
Reference Business Address	
Point of Contact	
Phone number	
E-mail address	
Contract Number	
Dollar Value	
Period of Performance	
Description of Services Performed	
Explain any problems and resolutions	

Past /Present Performance Questionnaire: By receipt of this request, Offeror authorizes the selected customers to discuss their performance under the applicable contract with the contracting officer. Please return the completed questionnaire by email to: oadsbaaprojects@cdc.gov

1 How would you rate the contractor's compliance with the delivery schedule / performance milestones?

Rating	Comments

2 How would you rate the contractor's business practices (e.g. maintaining a positive working relationship, business ethics, timely and effectively resolution of any problems etc.)?

Rating	Comments

3 How would you rate the contractor's record of conforming to contract requirements and to standards of good workmanship/quality of the product or service?

Rating	Comments

4 How would you rate the contractor's overall compliance with the terms and conditions of your purchase order /contract?

Rating	Comments

5 How would you rate the contractor's history of reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the contractor's business-like concern for the interest of the customer?

Rating	Comments

6 How would you rate the contractor's overall performance?

Rating	Comments

Would you purchase services from this contractor again?

☐ Yes ☐ No

Please provide any additional comments applicable to the contractor's past performance

Reference Businesss Name **Reference Name** **Signature**

FORM 6:

ACH VENDOR/MISCELLANEOUS PAYMENT ENROLLMENT FORM

CDC FMO
REVISED 01/29/04

This form is used for Automated Clearing House (ACH) payments with an addendum record that contains payment-related information processed through the Vendor Express Program.

PRIVACY ACT STATEMENT

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor's financial institution. Failure to provide the requested information may delay or prevent the receipt of payments.

AGENCY INFORMATION

FEDERAL PROGRAM AGENCY Centers for Disease Control & Prevention		
AGENCY IDENTIFIER: CDC	AGENCY LOCATION CODE (ALC): 7509-0421	ACH FORMAT: ☒ CCD+ ☐ CTX ☐ CTP
ADDRESS P. O. Box 15580, MS D06		
Atlanta, GA 30333		
CONTACT PERSON NAME: Customer Service		TELEPHONE NUMBER: (404) 718-8100
ADDITIONAL INFORMATION		FAX: (404) 638-5342

PAYEE/COMPANY INFORMATION

PAYEE/COMPANY NAME:		SSN or TAXPAYER ID NO.
ADDRESS:		DUNS+4 NUMBER
CITY	STATE	ZIP
CONTACT PERSON NAME:		TELEPHONE NUMBER:

FINANCIAL INSTITUTION INFORMATION

FINANCIAL INSTITUTION NAME:		
ADDRESS (OR BRANCH):		
CITY:	STATE:	ZIP:
NINE-DIGIT ROUTING TRANSIT NUMBER: ☐☐☐☐☐☐☐☐☐		
DEPOSITOR ACCOUNT NUMBER:		
TYPE OF ACCOUNT: ☐ CHECKING ☐ SAVINGS		
ACH COORDINATOR NAME OR AUTHORIZED OFFICIAL AT FINANCIAL INSTITUTION (NOT REQUIRED):		TELEPHONE NUMBER:

ATTACHMENT 1: CONTRACT CLAUSES

Section H- Special Requirement Clauses

H.1 PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM CDC FUNDED RESEARCH (Nov 2018)

All CDC-funded investigators shall submit to the National Institutes of Health Manuscript Submission System the electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services, Centers for Disease Control and Prevention. CDC defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The CDC Stacks and National Library of Medicine's (NLM) PubMed Central (PMC) archives will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and CDC.

H.2 Certificates of Confidentiality (Nov 2018)
Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. Consistent with the statute, research commenced or ongoing after December 13, 2016 and in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate.

Consistent with the statute, CDC considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

For research covered by a Certificate and consistent with the statute, Contractor shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Consistent with the statute, disclosure is permitted only in the below circumstances:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

Contractor shall keep records of when such disclosures are made and, upon request by CDC, shall make such information available to CDC.

Contractor shall comply with FAR Part 31, Contract Cost Principles and Procedures, as applicable, and maintain effective internal controls that provide reasonable assurance that the contract is managed in compliance with Federal statutes and regulations. Contractors conducting research covered by a Certificate shall ensure that any company/institution/individual not funded by CDC who receives a copy of identifiable, sensitive information protected by a Certificate is aware of the requirements of subsection 301(d) of the Public Health Service Act with respect to such information. The Contractor will secure an agreement with such company/institution/individual to ensure compliance with the requirements of the Certificate. In addition, Contractor shall ensure that all its employees and subcontractor employees working on this contract are informed of the substance of the abovementioned requirements and agree to comply with subsection 301(d) of the Public Health Service Act.

H.3 PUBLIC ACCESS TO CDC FUNDED DIGITAL PUBLIC HEALTH DATA (Nov 2018)
Public Health Data

Definition: Public Health data means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation

When CDC is funding, in whole or in part, via a contract as defined in FAR 2.101, with respect to public health data, a CDC-approved Data Management Plan (DMP) – a plan for digital data management, sharing, and preservation is required prior to commencing any related services or work. For contracts where public health data collection or generation activities may become necessary during the period of performance (e.g. via contract modification), a DMP will be required to be submitted and evaluated during the period of performance. The DMP is a deliverable and a living document that should be updated throughout the life cycle of data. A final DMP is required at the end of the contract performance that shows where the data are deposited and how they are being made accessible or justification provided for not doing so.

Data Management Plan
A DMP for each collection and/or generation of public health data should include the following information:

- A description of the public health data to be collected or generated in the contract period of performance;
- Standards to be used for the collected or generated public health data;
- Mechanisms for or limitations to providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights) or justification for why data cannot be made accessible. This section should address access to identifiable and de-identified data (see below for additional information about access);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explanation of why long-term preservation and access are not justified. This section should address archiving and preservation of identifiable and de-identified data (see below for additional information regarding archiving).

  Examples of Data Management Plan Templates and Tools:
  University of California: https://www.cdlib.org/services/uc3/dmpt.html
  USGS: http://www.usgs.gov/datamanagement/plan/dmplans.php

Access to and Archiving of the Data
To the extent that is feasible, contractors should make public health data accessible. Rights in Data clauses (FAR 52.227-14 Rights in Data – General, 52.227-16, Additional Data Requirements, FAR 52.227-17 Rights in Data – Special Works, or FAR 52.227-18 Rights in Data-Existing Works), may be applicable and incorporated into contracts, depending on the Statement of Work involved. The data rights clauses give the government "unlimited rights" in data first produced (when funded by government solely) in the performance of a contract. "Unlimited rights" is an unlimited license to use, disclose or reproduce the data; it does not give the government ownership of the data. Unlimited rights in data would allow the government to archive and make public non-proprietary data first produced in contract performance.

Contracts that do not include terms for submittal of public health data to CDC, are expected to plan and prepare for providing access to, and archiving/long-term preservation of, collected and/or generated data within the contract period of performance, as set forth below. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data, which should be made accessible within a year of the end of a collection cycle. For public use de-identified (removal of sensitive identifiable or potentially identifiable information) datasets, an accompanying data dictionary, and other documentation relevant to use of the data set should be deposited in a sustainable repository to provide access to the data. Data that cannot be de-identified can be provided as restricted data upon request under a data-use agreement or onsite controlled use.

For data underlying a scientific publication, the contractor shall make the data available coincident with publication of the paper, at a minimum a machine-readable version of the data tables shown in the paper, unless the data set is already available via a release or sharing mechanism. In addition, contractors should ensure the quality of data they make accessible and seek to provide the data in a machine readable and nonproprietary format. Contractors who fail to release public health data in a timely fashion may be subject to procedures normally used to address failure to comply with the terms and conditions of the contract and may be grounds for the Contracting Officer to terminate the contract for default. Irrespective of whether the data are made accessible or not, Public health data of value should be preserved long-term.

A final DMP is required at the end of the contract performance. The final DMP will indicate the location of the deposited data and the manner of access granted to the data. There needs to be an adequate justification for not making data accessible and this justification must be documented in the DMP and approved by the Contracting Officer's Representative.

Additional information is available at https://www.hhs.gov/open/publicaccess/index.html

Section I Clauses

CLAUSES INCORPORATED BY REFERENCE FAR 52.252-2 (FEB 1998): This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The full text of a clause may be accessed electronically at http://farsite.hill.af.mil/

The following clauses pertain to ALL contract types

NUMBER	TITLE	DATE
52.202-1	Definitions	NOV 2013
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	SEP 2006
52.203-7	Anti-Kickback Procedures	MAY 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	MAY 2014
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	MAY 2014
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	OCT 2010
52.203-13	Contractor Code of Business Ethics and Conduct	OCT 2015
52.203-14	Display of Hotline Poster(s)	OCT 2015
52.203-15	Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009	JUN 2010
52.203-16	Preventing Personal Conflicts of Interest	DEC 2011
52.203-17	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights	APR 2014
52.204-2	Security Requirements	AUG 1996
52.204-4	Printed or Copied Double-Sided on Recycled Paper	MAY 2011
52.204-7	System for Award Management	JUL 2013
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-19	Incorporation by Reference of Representations and Certifications	DEC 2014
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	OCT 2015

52.204-13	System for Award Management Maintenance	JUL 2013
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	OCT 2015
52.209-10	Prohibition on Contracting with Inverted Domestic Corporation	NOV 2015
52.210-1	Market Research	APR 2011
52.211-11	Liquidated Damages – Supplies, Services, or Research and Development	SEP 2000
52.215-2	Audit and Records – Negotiation	OCT 2010
52.215-8	Order of Precedence – Uniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Cost or Pricing Data – Modifications	AUG 2011
52.215-13	Subcontractor Cost or Pricing Data – Modifications	OCT 2010
52.215-14	Integrity of Unit Prices	OCT 2010
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications – Alternate IV	OCT 2010
52.215-22	Limitations on Pass-Through Charges—Identification of Subcontract Effort	OCT 2009
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.217-8	Option to Extend Services	NOV 1999
52.219-1	Small Business Program Representations	OCT 2014
52.219-8	Utilization of Small Business Concerns	OCT 2014
52.219-9	Small Business Subcontracting Plan	JAN 2017
52.219-16	Liquidated Damages – Subcontracting Plan	JAN 1999
52,219-28	Post Award Small Business Program Representation	JUL 2013
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition of Segregated Facilities	APR 2015
52.222-26	Equal Opportunity	APR 2015
52.222-35	Equal Opportunity for Veterans	OCT 2015
52.222-36	Affirmative Action for Workers with Disabilities	JUL 2014
52.222-37	Employment Reports Veterans	FEB 2016
52.222-38	Compliance with Veterans' Employment Reporting Requirements	FEB 2016
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	MAR 2015
52.222-54	Employment Eligibility Verification	OCT 2015
52.223-6	Drug-Free Workplace	MAY 2001
52.223-18	Encouraging Contractor Policies to Ban Text Messaging While Driving	AUG 2011
52.224-1	Privacy Act Notification	APR 1984
52.224-2	Privacy Act	APR 1984
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.225-25	Prohibition on Contracting with Entities in Certain Activities or Transactions Relating to Iran – Representations and Certifications	Oct 2015
52.226-1	Utilization of Indian Organizations and Indian-Owned Economic Enterprises	JUN 2000
52.227-1	Authorization and Consent – Alternate I	APR 1984
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	DEC 2007
52.227-11	Patent Rights-Ownership by The Contractor	MAY 2014
52.227-14	Rights in Data – General	MAY 2014
52.227-14	Rights in Data – General *Alternative IV*	DEC 2007
52.227-17	Rights in Data – Special Works	DEC 2007
52.232-17	Interest	MAY 2014
52.232-18	Availability of Funds	APR 1984
52.232-19	Availability of Funds for the Next Fiscal Year	APR 1984
52.232-23	Assignment of Claims	MAY 2014
52.232-25	Prompt payment	JUL 2013

52.232-33	Payment by Electronic Funds Transfer – System for Award Management	JUL 2013
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014
52.233-2	Service of Protest	SEP 2006
52.233-3	Protest after Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.239-1	Privacy or Security Safeguards	AUG 1996
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-13	Bankruptcy	JUL 1995
52.243-7	Notification of Changes	APR 1984
52.244-2	Subcontracts	OCT 2010
52.244-5	Competition in Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	JUN 2016
52.246-25	Limitation of Liability - Services	FEB 1997
52.249-5	Termination For Convenience of the Government (Educational & Other Nonprofit Institutions	AUG 2016
52.252-4	Alterations in Contract	APR 1984
52.253-1	Computer Generated Forms	JAN 1991

The following clauses pertain to FIRM-FIXED PRICE Contracts only (as applicable):

NUMBER	TITLE	DATE
52.203-6	Restrictions on Subcontractor Sales to the Government	SEP 2006
52.228-5	Insurance - Work on a Government Installation	JAN 1997
52.229-3	Federal, State, and Local Taxes	FEB 2013
52.230-3	Disclosure and Consistency of Cost Accounting Practices	OCT 2015
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.232-1	Payments	APR 1984
52.232-8	Discount for Prompt Payment	FEB 2002
52.232-11	Extras	APR 1984
52.232-28	Invitation to Propose Performance-Based Payments	MAR 2000
52.232-32	Performance-Based Payments	APR 2012
52.233-3	Protest after Award	AUG 1996
52.243-1	Changes - Fixed-Price – Alternate V	AUG 1984
52.249-9	Default (Research and Development)	APR 1984

The following clauses pertain to COST-REIMBURSABLE Contracts only (as applicable):

NUMBER	TITLE	DATE
52.216-7	Allowable Cost and Payment	AUG 2018
52.233-3	Protest after Award	AUG 1996
52.242-3	Penalties for Unallowable Costs	MAY 2014
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.243-2	Changes—Cost Reimbursement.	AUG 1987
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984

DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATIONS (HHSAR)

NUMBER	TITLE	DATE
352.211-2	Conference Sponsorship Requests and Conference Materials Disclaimer	DEC 2015
352.215-70	Late Proposals and Revisions	DEC 2015
352.216-70	Additional Cost Principles	DEC 2015
352.223-70	Safety and Health	DEC 2015
352.232-70	Incremental Funding	DEC 2015
352.233-71	Litigation and Claims	DEC 2015
352.239-73	Electronic and Information Technology Accessibility	DEC 2015

Section K Clauses

K.1 52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998): This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. The full text of a solicitation provision may be accessed electronically at http://www.acquisition.gov and http://farsite.hill.af.mil

(End of Provision)

FAR SOURCE	TITLE AND DATE
52.204-17	Ownership or Control of Offeror (Nov 2014)
52.204-19	Incorporation by Reference of Representations and Certifications (Dec 2014)

K.2 FAR 52.204-8 Annual Representations and Certifications (MAR 2020)

(a)

(1) The North American Industry classification System (NAICS) code for this acquisition is **541715**.
(2) The small business size standard is **1000**.
(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)

(1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.
(2) If the provision at 52.204-7, System for Award Management, is not included in this solicitation, and the Offeror has an active registration in the System for Award Management (SAM), the Offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The Offeror shall indicate which option applies by checking one of the following boxes:

☐ (i) Paragraph (d) applies.

☐ (ii) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c)

(1) The following representations or certifications in SAM are applicable to this solicitation as indicated:
(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—
(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;
(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or
(C) The solicitation is for utility services for which rates are set by law or regulation.
(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.
(iii) 52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements—Representation. This provision applies to all solicitations.
(iv) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.
(v) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—
(A) Are not set aside for small business concerns;
(B) Exceed the simplified acquisition threshold; and
(C) Are for contracts that will be performed in the United States or its outlying areas.
(vi) 52.204-6, Covered Telecommunications Equipment or Services-Representation. This provision applies to all solicitations.
(vii) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation.
(viii) 52.209-5; Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(ix) 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law. This provision applies to all solicitations.
(x) 52.214-14, Place of Performance--Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.
(xi) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.
(xii) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.
(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.
(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.
(C) The provision with its Alternate II applies to solicitations that will result in a multiple-award contract with more than one NAICS code assigned.
(xiii) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.
(xiv) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.
(xv) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.
(xvi) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.
(xvii) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.
(xviii) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA- designated items.
(xix) 52.223-22, Public Disclosure of Greenhouse Gas Emissions and Reduction Goals—Representation. This provision applies to solicitations that include the clause at 52.204-7.
(xx) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.
(xxi) 52.225-4, Buy American--Free Trade Agreements--Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225- 3.
(A) If the acquisition value is less than $25,000, the basic provision applies.
(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.
(C) If the acquisition value is $50,000 or more but is less than $83,099, the provision with its Alternate II applies.
(D) If the acquisition value is $83,099 or more but is less than $100,000, the provision with its Alternate III applies.
(xxii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.
(xxiii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification. This provision applies to all solicitations.
(xxiv) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certification. This provision applies to all solicitations.
(xxv) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.

(2) The following representations or certifications are applicable as indicated by the Contracting Officer: [Contracting Officer check as appropriate.]

☐ (i) 52.204-17, Ownership or Control of Offeror.
☐ (ii) 52.204-20, Predecessor of Offeror.
☐ (iii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.
☐ (iv) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Certification.

☐ (v) 52.222-52 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Certification.
☐ (vi) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).
☐ (vii) 52.227-6, Royalty Information.
☐ (A) Basic.
☐ (B) Alternate I.
☐ (viii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The Offeror has completed the annual representations and certifications electronically in SAM accessed through https://www.sam.gov. After reviewing the SAM information, the Offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.

(End of Provision)

K.3 FAR 52.209-7 Information Regarding Responsibility Matters (OCT 2018)

(a) *Definitions*. As used in this provision—

"Administrative proceeding" means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (*e.g.*, Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceeding at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

"Federal contracts and grants with total value greater than $10,000,000" means—
(1) The total value of all current, active contracts and grants, including all priced options; and
(2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

"Principal" means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (*e.g.*, general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror ☐ has ☐ does not have current active Federal contracts and grants with total value greater than $10,000,000.

(c) If the offeror checked "has" in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

(1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:
(i) In a criminal proceeding, a conviction.
(ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more.
(iii) In an administrative proceeding, a finding of fault and liability that results in—
(A) The payment of a monetary fine or penalty of $5,000 or more; or
(B) The payment of a reimbursement, restitution, or damages in excess of $100,000.
(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.
(2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.
(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management via https://www.sam.gov (see 52.204-7).

(End of provision)

K.4 Implementation of Executive Order (EO) 13224 Terrorist Financing: The Contractor is reminded that US Executive Orders and US law prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility to ensure compliance with these Executive Orders.

(End of Provision)

K.5 Contact for Negotiation/Administration (May 1998): Designate a person we may contact for contract administration in the event your firm receives a contract as a result of this solicitation:

Name: _____ Title: _____

Address: (Street) _____ (City) _____ (State) _____ (Zip Code)

Area Code: _____ Telephone: _____

Bidder/Offeror is located in Congressional District:

(Street) _____ (City) _____ (State) _____ (Zip Code)

Contract will be performed in Congressional District:

(Street) _____ (City) _____ (State) _____ (Zip Code)

(End of Provision)

K.6 Certification (May 1998): TO BE COMPLETED BY THE OFFEROR: (The Offeror must check or complete all appropriate boxes or blanks in the Representations and Certifications contained herein). The Representations and Certifications must be executed below, by an individual authorized to bind the offeror.

The offeror makes the forgoing Representations and Certifications as a part of its proposal.

_____ _____
(Name of offeror) (Solicitation Number)

_____ _____
(Signature of Authorized Individual) (Date)

_____
(Typed Name of Authorized Individual)

Note: The penalty for making false statements in offerors is prescribed in 18 U.S.C. 1001.

(End of Provision)

K.7 Contractor Performance Assessment Reporting System (CPARS) Requirements (Apr 2013): In accordance with FAR 42.15, the Centers for Disease Control and Prevention (CDC) will review and evaluate contract performance. FAR 42.1502 and 42.1503 requires agencies to prepare evaluations of contractor performance and submit them to the Past Performance Information Retrieval System (PPIRS). The CDC utilizes the Department of Defense (DOD) web-based Contractor Performance Assessment Reporting System (CPARS) to prepare and report these contractor performance evaluations. All information contained in these assessments may be used by the Government, within the limitations of FAR 42.15, for future source selections in accordance with FAR 15.304 where past performance is an evaluation factor.

The CPARS system requires a contractor representative to be assigned so that the contractor has appropriate input into the performance evaluation process. The CPARS contractor representative will be given access to CPARS and will be given the opportunity to concur or not-concur with performance evaluations before the evaluations are complete. The CPARS contractor representative will also have the opportunity to add comments to performance evaluations.

The assessment is not subject to the Disputes clause of the contract, nor is it subject to appeal beyond the review and comment procedures described in the guides on the CPARS website. Refer to: www.cpars.gov for details and additional information related to CPARS, CPARS user access, how contract performance assessments are conducted, and how Contractors participate. Access and training for all persons responsible for the preparation and review of performance assessments is also available at the CPARS website.

The contractor must provide the CDC contracting office with the name, e-mail address, and phone number of their designated CPARS representative who will be responsible for logging into CPARS and reviewing and commenting on performance evaluations. The contractor must maintain a current representative to serve as the contractor representative in CPARS. It is the contractor's responsibility to notify the CDC contracting office, in writing (letter or email), when their CPARS representative information needs to be changed or updated. Failure to maintain current CPARS contractor representative information will result in the loss of an opportunity to review and comment on performance evaluations.

Provide the current CPARS representative information below.

_____	_____
PRINT OR TYPE NAME	EMAIL ADDRESS AND PHONE NUMBER

(End of Provision)

K.8 Point of Contact: The Contractor shall designate a senior person from the key personnel as the point of contact during normal business hours. This person shall be available for on-site meetings during normal business hours. Should the person be unavailable when scheduled to be on-site, the Contractor shall notify the COR of the name of the designated alternate point of contact. The designated person shall have the authority of the Program Manager to direct personnel and shall be accountable to the directions of the COR. The Contractor shall provide to the COR a contact and backup contact who shall be on-call to make decisions as required during non-business hours.

Name: _____ Title: _____

Address: (Street) _____ (City) _____ (State) _____ (Zip Code)

Area Code: _____ Telephone: _____

(End of Provision)

ATTACHMENT 2: CONTRACTORS' PERFORMANCE ASSESSMENT REPORTING SYSTEM (CPARS)

This assessment will be performed electronically at least annually or as required by www.cpars.gov

Block 18a Quality of Product or Service: Assess the contractor's conformance to contract requirements, specifications and standards of good workmanship (e.g. commonly accepted technical, professional, environmental, or safety and health standards).

For example: Are reports/data accurate? Does the product or service provided meet the specifications of the contract? Does the contractor's work measure up to commonly accepted technical or professional standards? Assess the degree of Government technical direction required to solve problems that arise during performance.

For Operations Support: Assess how successfully the contractor meets program quality objectives such as ability to produce, reliability, maintainability and ability to inspect. The Assessing Official must be flexible in how contractor success is measured (e.g. using data from field reliability and maintainability and failure reports, user comments and acceptance rates, and scrap and rework rates). These quantitative indicators may be useful later, for example, in source selection evaluations, in demonstrating continuous improvement, quality and reliability leadership that reflects progress in total quality management. Assess the contractor's control of the overall production process to include material control, shop planning and control, and status.

Block 18b Schedule: Assess the timeliness of the contractor against the completion of the contract, task orders, milestones, delivery schedules, and administrative requirements (e.g. efforts that contribute to or effect the schedule variance). This assessment of the contractor's adherence to the required delivery schedule should include the contractor's efforts during the assessment period that contributes to or effect the schedule variance. This element applies to contract closeout activities as well as contract performance. Instances of adverse actions such as the assessment of liquidated damages, or issuance of Cure Notices, Show Cause Notices, and Delinquency Notices are indicators of problems which may have resulted in variance to the contract schedule and should therefore be noted in the evaluation.

Block 18c Cost Control *Not required for Firm Fixed Price or Firm Fixed Price with Economic Price Adjustment*

Block 18d Business Relations: Assess the integration and coordination of all activity needed to execute the contract, specifically the timeliness, completeness and quality of problem identification, corrective action plans, proposal submittals, the contractor's history of reasonable and cooperative behavior (to include timely identification of issues in controversy), customer satisfaction, timely award and management of subcontracts. Include, as applicable, information on the following:

- Is the contractor oriented toward the customer?
- Is interaction between the contractor and the government satisfactory or does it need improvement?
- Include the adequacy of the contractor's accounting, billing, and estimating systems and the contractor's management of Government Property (GFP) if a substantial amount of GFP has been provided to the contractor under the contract.
- Address the timeliness of awards to subcontractors and management of subcontractors, including subcontract costs. Consider efforts taken to ensure early identification of subcontract problems and the timely application of corporate resources to preclude subcontract problems from impacting overall prime contractor performance.
- Assess the prime contractor's effort devoted to managing subcontracts and whether subcontractors were an integral part of the contractor's team.

Block 18e Management of Key Personnel *For Services and Information Technology Business Sectors only: A*ssess the contractor's performance in selecting, retaining, supporting, and replacing, when necessary, key personnel.

For example: How well did the contractor match the qualifications of the key position, as described in the contract, with the person who filled the key position? Did the contractor support key personnel so they were able to work effectively? If a key person did not perform well, what action was taken by the contractor to correct this? If a replacement of a key person was necessary, did the replacement meet or exceed the qualifications of the position as described in the contract schedule?

Block 18f Utilization of Small Business: FAR Subpart 19.7 and 15 U.S.C. 637 contains statutory requirements for complying with the Small Business Subcontracting Program. Assess whether the contractor provided maximum practicable opportunity for Small Business (including Alaska Native Corporations (ANCs) and Indian Tribes) (including Small Disadvantaged Businesses (which also includes ANCs and Indian Tribes), Women Owned Small Businesses, HUBZone, Veteran Owned, Service Disabled Veteran Owned Small Business, Historically Black Colleges and Minority Institutions and ANCs and Indian Tribes that are not Small Disadvantaged Businesses or Small Businesses) to participate in contract performance consistent with efficient performance of the contract.

Assess compliance with all terms and conditions in the contract relating to Small Business participation (including FAR 52.219-8, Utilization of Small Businesses and FAR 52.219-9, Small Business Subcontracting Plan (when required)). Assess any small business participation goals which are stated separately in the contract. Assess achievement on each individual goal stated within the contract or subcontracting plan including good faith effort if the goal was not achieved.

It may be necessary to seek input from the Small Business specialist, ACO or PCO in regards to the contractor's compliance with these criteria. For contracts subject to a commercial subcontracting plan, the Utilization of Small Business factor should be rated "satisfactory" as long as an approved plan remains in place, unless liquidated damages have been assessed by the contracting officer who approved the commercial plan (see FAR 19.705-7(h)). In such case, the Utilization of Small Business area must be rated "unsatisfactory." This area must be rated for all contracts and task orders that contain a small business subcontracting goal. Ratings for the Utilization of Small Business evaluation area will be in accordance with the definitions described below. Ratings for the other CPAR evaluation areas will be in accordance with the ratings described in Block 18 Evaluation Areas.

In accordance FAR 19.705-2(e) a contract may have no more than one subcontracting plan. Evaluations of the Utilization of Small Business are required for contracts and orders placed against basic ordering agreement (BOA) and blanket purchase agreement (BPA) if a subcontracting plan is required. Evaluations of Utilization of Small Business for single-agency task orders and delivery orders (to include FSS) are not required and shall not be accomplished unless the contracting officer determines that such evaluations would produce more useful past performance information for source selection officials than that contained in the overall contract evaluation. Execution of any subcontracting plan may be addressed in block 20.

Block 18g Other Areas: Specify additional evaluation areas that are unique to the contract, or that cannot be captured elsewhere on the form. More than one type of entry may be included, but should be separately labeled. If extra space is needed, use Block 20. If the contract contains an award fee provision, enter "award fee" in the "Other Areas" block (18g). The Assessing Official should translate the award fee earned to adjective ratings, which could prove more useful for using past performance to assess future performance risk in upcoming source selections. If award fee information is included in the CPAR, use block 20 to provide a description for each award fee. Include the scope of the award fee by describing the extent to which it covers the total range of contract performance activities, or is restricted to certain elements of the contract. If any other type of contract incentive is included in the contract (excluding contract shareline incentives on fixed price or cost-type contracts), it should be reported in a manner similar to the procedures described above for award fee. Use Block 18g in those instances where the Assessing Official believes strongly, either positively or negatively, regarding an aspect of the contractor's performance, but cannot fit that aspect into any of the other blocks on the form.

CPARS RATINGS

Exceptional: Exceeded all negotiated subcontracting goals or exceeded at least one goal and met all of the other negotiated subcontracting goals for the current period. Had exceptional success with initiatives to assist, promote, and utilize small business (SB), small disadvantaged business (SDB), women-owned small business (WOSB), HUBZone small business, veteran-owned small business (VOSB) and service disabled veteran owned small business (SDVOSB). Complied with FAR 52.219-8, Utilization of Small Business Concerns. Exceeded any other small business participation requirements incorporated in the contract, including the use of small businesses in mission critical aspects of the program. Went above and beyond the required elements of the subcontracting plan and other small business requirements of the contract. Completed and submitted Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate and timely manner.

NOTE: To justify an Exceptional rating, identify multiple significant events and state how they were a benefit to small business utilization. A singular benefit, however, could be of such magnitude that it constitutes an Exceptional rating. Ensure that small businesses are given meaningful, innovative work directly related to the project, rather than peripheral work, such as cleaning offices, supplies, landscaping, etc. Also, there should have been no significant weaknesses identified.

Very Good: Met all of the negotiated subcontracting goals in the traditional socio-economic categories (SB, SDB and WOSB) and met at least one of the other socio-economic goals (HUBZone, VOSB, SDVOSB) for the current period. Had significant success with initiatives to assist, promote and utilize SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB. Complied with FAR 52.219-8, Utilization of Small Business Concerns. Met or exceeded any other small business participation requirements incorporated in the contract, including the use of small businesses in mission critical aspects of the program. Endeavored to go above and beyond the required elements of the subcontracting plan. Completed and submitted Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate and timely manner.

NOTE: To justify a Very Good rating, identify a significant event and state how they were a benefit to small business utilization. Ensure that small businesses are given meaningful, innovative work directly related to the project, rather than peripheral work, such as cleaning offices, supplies, landscaping, etc. There should be no significant weaknesses identified.

Satisfactory: Demonstrated a good faith effort to meet all of the negotiated subcontracting goals in the various socio-economic categories for the current period. Complied with FAR 52.219-8, Utilization of Small Business Concerns. Met any other small business participation requirements included in the contract. Fulfilled the requirements of the subcontracting plan included in the contract. Completed and submitted Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate and timely manner.

NOTE: To justify a Satisfactory rating, there should have been only minor problems, or major problems the contractor has addressed or taken corrective action. There should have been no significant weaknesses identified. A fundamental principle of assigning ratings is that contractors will not be assessed a rating lower than Satisfactory solely for not performing beyond the requirements of the contract.

Marginal: Deficient in meeting key subcontracting plan elements. Deficient in complying with FAR 52.219-8, Utilization of Small Business Concerns, and any other small business participation requirements in the contract. Did not submit Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate or timely manner. Failed to satisfy one or more requirements of a corrective action plan currently in place; however, does show an interest in bringing performance to a satisfactory level and has demonstrated a commitment to apply the necessary resources to do so. Required a corrective action plan.

NOTE: To justify Marginal performance, identify a significant event that the contractor had trouble overcoming and how it impacted small business utilization. A Marginal rating should be supported by referencing the actions taken by the government that notified the contractor of the contractual deficiency.

Unsatisfactory: Noncompliant with FAR 52.219-8 and 52.219-9 and any other small business participation requirements in the contract. Did not submit Individual Subcontract Reports and/or Summary Subcontract Reports in an accurate or timely manner. Showed little interest in bringing performance to a satisfactory level or is generally uncooperative. Required a corrective action plan.

NOTE: To justify an Unsatisfactory rating, identify multiple significant events that the contractor had trouble overcoming and state how it impacted small business utilization. A singular problem, however, could be of such serious magnitude that it alone constitutes an Unsatisfactory rating. An Unsatisfactory rating should be supported by referencing the actions taken by the government to notify the contractor of the deficiencies. When an Unsatisfactory rating is justified, the contracting officer must consider whether the contractor made a good faith effort to comply with the requirements of the subcontracting plan required by FAR 52.219-9 and follow the procedures outlined in FAR 52.219-16, Liquidated Damages-Subcontracting Plan.

NOTE: Plus or minus signs may be used to indicate an improving (+) or worsening (-) trend insufficient to change assessment status.

NOTE: Generally, zero percent is not a goal unless the Contracting Officer determined when negotiating the subcontracting plan that no subcontracting opportunities exist in a particular socio-economic category. In such cases, the contractor shall be considered to have met the goal for any socio-economic category where the goal negotiated in the plan was zero.

ATTACHMENT 3: SAMPLE STATEMENT OF WORK (SOW)

This template is designed to provide guidance to offerors in developing a detailed statement of work.

Offeror's statement of work must follow this format

Project Title: *Enter the project title*

Project ID: *Enter the Project ID shown in your Notification Letter*

C.1 Background and Need: *Describe the requirements in general, non-technical terms. This section should explain why the acquisition is being pursued and how it relates to past, current, or future projects. Include a summary of statutory program authority and any regulations that are applicable. If any of the techniques have been found to be tried and been found to be effective, they should be included here.*

C.2 Project Objective: *Provide a succinct statement of the purpose of the acquisition. It should outline results that the Government expects and may also identify the benefits to the program that is contemplated.*

C.3 Scope of Work: *Provide an overall, non-technical description of the work to be performed. It expands on the projected objectives, but does not attempt to detail all of the work required. It must be consistent with the detailed requirements.*

C.4 Technical Requirements: *Spell out precisely what is expected of the contractor in the performance of the work.*

- *Describe the specific tasks and phases of the work*
- *Deliverables to be generated from the described tasks must be clearly defined*
- *Specify the total effort each task or phase is to receive*
- *Considerations that may guide the contractor in its analysis and design on the designated problems*
- *Identify the requirements and indicates the scope of each*

C.5 Reporting Schedule: The contractor will provide a quarterly summary of monthly meetings and conference calls. Progress reports will include detailed descriptions of activities conducted during the previous quarter, planned activities for the upcoming quarter, and a section on challenges or barriers to meeting timelines and completing tasks, and how the contractor has already or plans to overcome these challenges.

C.6 Special Considerations: *Include any information that does not fit neatly or logically into one of the other sections. For example, it may be used to explain any special relationships between the contractor and other contractors working for the government.*

C.7 Period and Place of Performance: *Describe when and where the work shall be performed. If the project includes options or option periods, they should be included.*

C.8 Government Furnished Property (GFP): Issuance of GFP shall be determined by the CDC Contracting Officer Representative (COR). Access to CDC IT systems and facilities is not anticipated. If it is determined that GFP or access is required, it will be controlled through use of CDC-issued HSPD-12 compliant ID badge.

C.9 Travel: *Describe any travel that is projected to take place during the period of performance. Travel may include in-person kick-off meetings or final meetings, attendance at conferences, travel to present deliverables, etc.*

C.10 References: *Describe any reference materials that may be relevant to the work being performed.*

C.11 Deliverables: *Define and describe the deliverables, quantity required, the recipient(s), and the schedule should be attached to the SOW. Deliverables included in Deliverables table must correspond to the tasks outlined under "C.4 Technical Requirements"*

Deliverable	Description	Date	Deliver To

ATTACHMENT 4: SAMPLE COST PROPOSAL

This sample format is designed to provide guidance to offerors in developing a detailed cost proposal.

Cost proposals must be tailored to support the individual Business Proposal(s).

ALL costs must be substantiated in sufficient detail to support the hours, rates and costs described in the individual Business Proposal in order to ensure the Government's understanding of how these costs will support the work required for the proposed research project.

Proposals that do not include cost information presented in sufficient detail will not be evaluated.

DIRECT COSTS

Labor by Category		Hours		Rate		Total	Formula
Project Manager			x	$0.00	=	$0.00	*Equals Hours x Rate*
Principal Investigator			x	$0.00	=	$0.00	*Equals Hours x Rate*
Total Direct Labor					(a)	**$0.00**	*Sum of all Labor*
Overhead Rate	(b)	0.0%			(c)	$0.00	*Equals (a) x (b)*
Total Direct Labor + Overhead					(d)	**$0.00**	*Sum of (a) + (c)*

NOTE: For positions covered under the Service Contract Act, itemize the fringe rate to identify the H&W component.

Fringe Rate	(e)	0.0%	(f)	$0.00	*Equals (a) x (e)*
Total Direct Labor + Overhead + Fringe			(g)	**$0.00**	*Sum of (d) + (f)*

OTHER DIRECT COSTS (ODC)

Travel and Per Diem *(in accordance with FJTR)*				$0.00	
Consultants/Subcontractor				$0.00	
Materials				$0.00	
TOTAL Other Direct Costs			(i)	**$0.00**	*Sum of all ODC*
SubTotal ALL Costs			(j)	**$0.00**	*Sum of (g) + (i)*
G&A	(k)	0.0%	(l)	$0.00	*Equals (j) x (k)*
Subtotal Cost (Before Profit)			(m)	**$0.00**	*Sum of (j) + (i)*
Profit	(n)	0.0%	(o)	$0.00	*Equals (m) x (n)*
TOTAL COST				**$0.00**	*Sum of (m) + (o)*

When applicable, this format can be used to report the base period, option years, and a composite for all periods.

From:	SANDY f
To:	Dobbs, Thomas E; Byers, Paul; Taylor, Kathryn; Edney, MD, Daniel; Raju, Whitney
Subject:	long article-abstract plus discussion
Date:	Friday, November 19, 2021 10:30:34 AM
Attachments:	dbter1.pdf

Use of face masks cuts COVID-19 transmission risk in half, review suggests

Bloomberg (11/18, Fourcade) reports “donning a face mask more than halves the risk of getting COVID,” as well as hand-washing, “according to a review of eight studies published in the British Medical Journal.” Furthermore, physical distancing “cuts the risk by a quarter.”

Sandor Feldman MD
Professor Emeritus of Pediatrics
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Effectiveness of public health measures in reducing the incidence of covid-19, SARS-CoV-2 transmission, and covid-19 mortality: systematic review and meta-analysis

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ABSTRACT

OBJECTIVE

To review the evidence on the effectiveness of public health measures in reducing the incidence of covid-19, SARS-CoV-2 transmission, and covid-19 mortality.

DESIGN

Systematic review and meta-analysis.

DATA SOURCES

Medline, Embase, CINAHL, Biosis, Joanna Briggs, Global Health, and World Health Organization COVID-19 database (preprints).

ELIGIBILITY CRITERIA FOR STUDY SELECTION

Observational and interventional studies that assessed the effectiveness of public health measures in reducing the incidence of covid-19, SARS-CoV-2 transmission, and covid-19 mortality.

MAIN OUTCOME MEASURES

The main outcome measure was incidence of covid-19. Secondary outcomes included SARS-CoV-2 transmission and covid-19 mortality.

DATA SYNTHESIS

DerSimonian Laird random effects meta-analysis was performed to investigate the effect of mask wearing, handwashing, and physical distancing measures on incidence of covid-19. Pooled effect estimates with corresponding 95% confidence intervals were computed, and heterogeneity among studies was assessed using Cochran's Q test and the I^2 metrics, with two tailed P values.

RESULTS

72 studies met the inclusion criteria, of which 35 evaluated individual public health measures and 37 assessed multiple public health measures as a "package of interventions." Eight of 35 studies were included in the meta-analysis, which indicated a reduction in incidence of covid-19 associated with handwashing (relative risk 0.47, 95% confidence interval 0.19 to 1.12, I^2=12%), mask wearing (0.47, 0.29 to 0.75, I^2=84%), and physical distancing (0.75, 0.59 to 0.95, I^2=87%). Owing to heterogeneity of the studies, meta-analysis was not possible for the outcomes of quarantine and isolation, universal lockdowns, and closures of borders, schools, and workplaces. The effects of these interventions were synthesised descriptively.

CONCLUSIONS

This systematic review and meta-analysis suggests that several personal protective and social measures, including handwashing, mask wearing, and physical distancing are associated with reductions in the incidence covid-19. Public health efforts to implement public health measures should consider community health and sociocultural needs, and future research is needed to better understand the effectiveness of public health measures in the context of covid-19 vaccination.

SYSTEMATIC REVIEW REGISTRATION

PROSPERO CRD42020178692.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Public health measures have been identified as a preventive strategy for influenza pandemics

The effectiveness of such interventions in reducing the transmission of SARS-CoV-2 is unknown

WHAT THIS STUDY ADDS

The findings of this review suggest that personal and social measures, including handwashing, mask wearing, and physical distancing are effective at reducing the incidence of covid-19

More stringent measures, such as lockdowns and closures of borders, schools, and workplaces need to be carefully assessed by weighing the potential negative effects of these measures on general populations

Further research is needed to assess the effectiveness of public health measures after adequate vaccination coverage

Introduction

The impact of SARS-CoV-2 on global public health and economies has been profound.[1] As of 14 October 2021, there were 239 007 759 million cases of confirmed covid-19 and 4 871 841 million deaths with covid-19 worldwide.[2]

A variety of containment and mitigation strategies have been adopted to adequately respond to covid-19, with the intention of deferring major surges of patients in hospitals and protecting the most vulnerable people from infection, including elderly people and those with comorbidities.[3] Strategies to achieve these goals are diverse, commonly based on national risk assessments that include estimation of numbers of patients requiring hospital admission and availability of hospital beds and ventilation support.

Globally, vaccination programmes have proved to be safe and effective and save lives.[4 5] Yet most vaccines do not confer 100% protection, and it is not known how vaccines will prevent future transmission of SARS-CoV-2,[6] given emerging variants.[7-9] The proportion of the population that must be vaccinated against covid-19 to reach herd immunity depends

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greatly on current and future variants.[10] This vaccination threshold varies according to the country and population's response, types of vaccines, groups prioritised for vaccination, and viral mutations, among other factors.[6] Until herd immunity to covid-19 is reached, regardless of the already proven high vaccination rates,[11] public health preventive strategies are likely to remain as first choice measures in disease prevention,[12] particularly in places with a low uptake of covid-19 vaccination. Measures such as lockdown (local and national variant), physical distancing, mandatory use of face masks, and hand hygiene have been implemented as primary preventive strategies to curb the covid-19 pandemic.[13]

Public health (or non-pharmaceutical) interventions have been shown to be beneficial in fighting respiratory infections transmitted through contact, droplets, and aerosols.[14 15] Given that SARS-CoV-2 is highly transmissible, it is a challenge to determine which measures might be more effective and sustainable for further prevention.

Substantial benefits in reducing mortality were observed in countries with universal lockdowns in place, such as Australia, New Zealand, Singapore, and China. Universal lockdowns are not, however, sustainable, and more tailored interventions need to be considered; the ones that maintain social lives and keep economies functional while protecting high risk individuals.[16 17] Substantial variation exists in how different countries and governments have applied public health measures,[18] and it has proved a challenge for assessing the effectiveness of individual public health measures, particularly in policy decision making.[19]

Previous systematic reviews on the effectiveness of public health measures to treat covid-19 lacked the inclusion of analytical studies,[20] a comprehensive approach to data synthesis (focusing only on one measure),[21] a rigorous assessment of effectiveness of public health measures,[22] an assessment of the certainty of the evidence,[23] and robust methods for comparative analysis.[24] To tackle these gaps, we performed a systematic review of the evidence on the effectiveness of both individual and multiple public health measures in reducing the incidence of covid-19, SARS-CoV-2 transmission, and covid-19 mortality. When feasible we also did a critical appraisal of the evidence and meta-analysis.

Methods

This systematic review and meta-analysis were conducted in accordance with PRISMA[25] (supplementary material 1, table 1) and with PROSPERO (supplementary material 1, table 2).

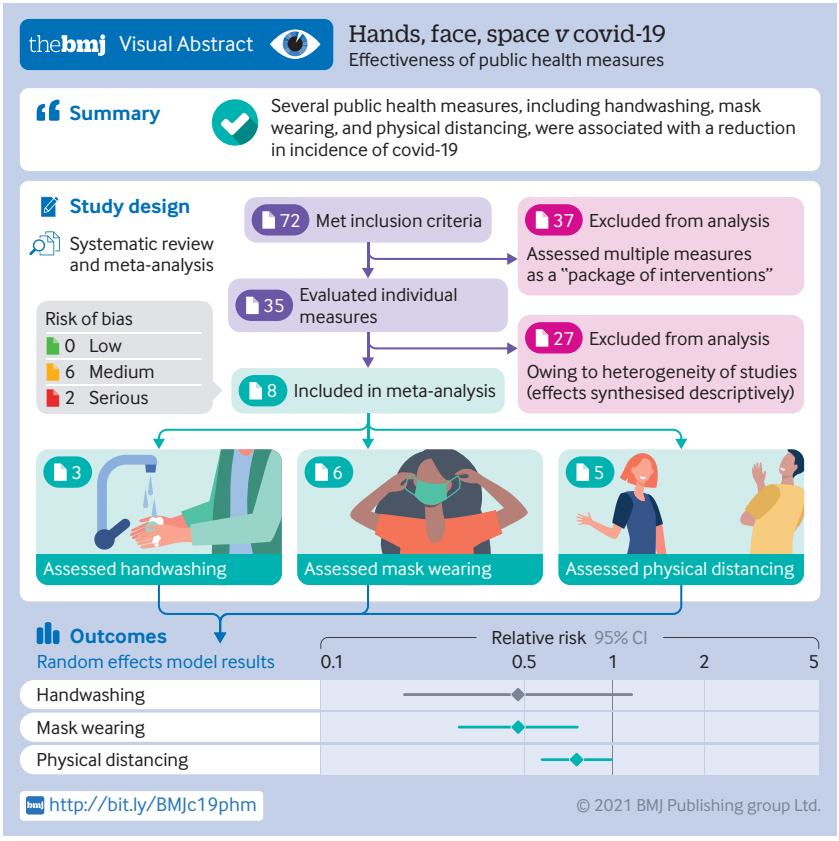
Eligibility criteria

Articles that met the population, intervention, comparison, outcome, and study design criteria were eligible for inclusion in this systematic review (supplementary material 1, table 3). Specifically, preventive public health measures that were tested independently were included in the main analysis. Multiple measures, which generally contain a "package of interventions", were included as supplementary material owing to the inability to report on the individual effectiveness of measures and comparisons on which package led to enhanced outcomes. The public health measures were identified from published World Health Organization sources that reported on the effectiveness of such measures on a range of communicable diseases, mostly respiratory infections, such as influenza.

Given that the scientific community is concerned about the ability of the numerous mathematical models, which are based on assumptions, to predict the course of virus transmission or effectiveness of interventions,[26] this review focused only on empirical studies. We excluded case reports and case studies, modelling and simulation studies, studies that provided a graphical summary of measures without clear statistical assessments or outputs, ecological studies that provided a descriptive summary of the measures without assessing linearity or having comparators, non-empirical studies (eg, commentaries, editorials, government reports), other reviews, articles involving only individuals exposed to other pathogens that can cause respiratory infections, such as severe acute respiratory syndrome or Middle East respiratory syndrome, and articles in a language other than English.

Information sources

We carried out electronic searches of Medline, Embase, CINAHL (Cumulative Index to Nursing and



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Allied Health Literature, Ebsco), Global Health, Biosis, Joanna Briggs, and the WHO COVID-19 database (for preprints). A clinical epidemiologist (ST) developed the initial search strategy, which was validated by two senior medical librarians (LR and MD) (supplementary material 1, table 4). The updated search strategy was last performed on 7 June 2021. All citations identified from the database searches were uploaded to Covidence, an online software designed for managing systematic reviews,[27] for study selection.

Study selection

Authors ST, DG, SS, AM, ET, JR, XL, WX, IME, and XZ independently screened the titles and abstracts and excluded studies that did not match the inclusion criteria. Discrepancies were resolved in discussion with the main author (ST). The same authors retrieved full text articles and determined whether to include or exclude studies on the basis of predetermined selection criteria. Using a pilot tested data extraction form, authors ST, SS, AM, JR, XL, WX, AM, IME, and XZ independently extracted data on study design, intervention, effect measures, outcomes, results, and limitations. ST, SS, AM, and HW verified the extracted data. Table 5 in supplementary material 1 provides the specific criteria used to assess study designs. Given the heterogeneity and diversity in how studies defined public health measures, we took a common approach to summarise evidence of these interventions (supplementary material 1, table 6).

Risk of bias within individual studies

SS, JR, XL, WX, IME, and XZ independently assessed risk of bias for each study, which was cross checked by ST and HW. For non-interventional observational studies, a ROBINS-I (risk of bias in non-randomised studies of interventions) risk of bias tool was used.[28] For interventional studies, a revised tool for assessing risk of bias in randomised trials (RoB 2) tool was used.[29] Reviewers rated each domain for overall risk of bias as low, moderate, high, or serious/critical.

Data synthesis

The DerSimonian and Laird method was used for random effects meta-analysis, in which the standard error of the study specific estimates was adjusted to incorporate a measure of the extent of variation, or heterogeneity, among the effects observed for public health measures across different studies. It was assumed that the differences between studies are a result of different, yet related, intervention effects being estimated. If fewer than five studies were included in meta-analysis, we applied a recommended modified Hartung-Knapp-Sidik-Jonkman method.[30]

Statistical analysis

Because of the differences in the effect metrics reported by the included studies, we could only perform quantitative data synthesis for three interventions: handwashing, face mask wearing, and physical distancing. Odds ratios or relative risks with corresponding 95% confidence intervals were reported for the associations between the public health measures and incidence of covid-19. When necessary, we transformed effect metrics derived from different studies to allow pooled analysis. We used the Dersimonian Laird random effects model to estimate pooled effect estimates along with corresponding 95% confidence intervals for each measure. Heterogeneity among individual studies was assessed using the Cochran Q test and the I^2 test.[31] All statistical analyses were conducted in R (version 4.0.3) and all P values were two tailed, with P=0.05 considered to be significant. For the remaining studies, when meta-analysis was not feasible, we reported the results in a narrative synthesis.

Public and patient involvement

No patients or members of the public were directly involved in this study as no primary data were collected. A member of the public was, however, asked to read the manuscript after submission.

Results

A total of 36 729 studies were initially screened, of which 36 079 were considered irrelevent. After exclusions, 650 studies were eligible for full text review and 72 met the inclusion criteria. Of these studies, 35 assessed individual interventions and were included in the final synthesis of results (fig 1) and 37 assessed multiple interventions as a package and are included in supplementary material 3, tables 2 and 3. The included studies comprised 34 observational studies and one interventional study, eight of which were included in the meta-analysis.

Risk of bias

According to the ROBINS-I tool,[28] the risk of bias was rated as low in three studies,[32-34] moderate in 24 studies,[35-58] and high to serious in seven studies.[59-65] One important source of serious or critical risk of bias in most of the included studies was major confounding, which was difficult to control for because of the novel nature of the pandemic (ie, natural settings in which multiple interventions might have been enforced at once, different levels of enforcement across regions, and uncaptured individual level interventions such as increased personal hygiene). Variations in testing capacity and coverage, changes to diagnostic criteria, and access to accurate and reliable outcome data on covid-19 incidence and covid-19 mortality, was a source of measurement bias for numerous studies (fig 2). These limitations were particularly prominent early in the pandemic, and in low income environments.[47 52 62 63 65] The randomised controlled trial[66] was rated as moderate risk of bias according to the ROB-2 tool. Missing data, losses to follow-up, lack of blinding, and low adherence to intervention all contributed to the reported moderate risk. Tables 1 and 2 in supplementary material 2 summarise the risk of bias assessment for each study assessing individual measures.

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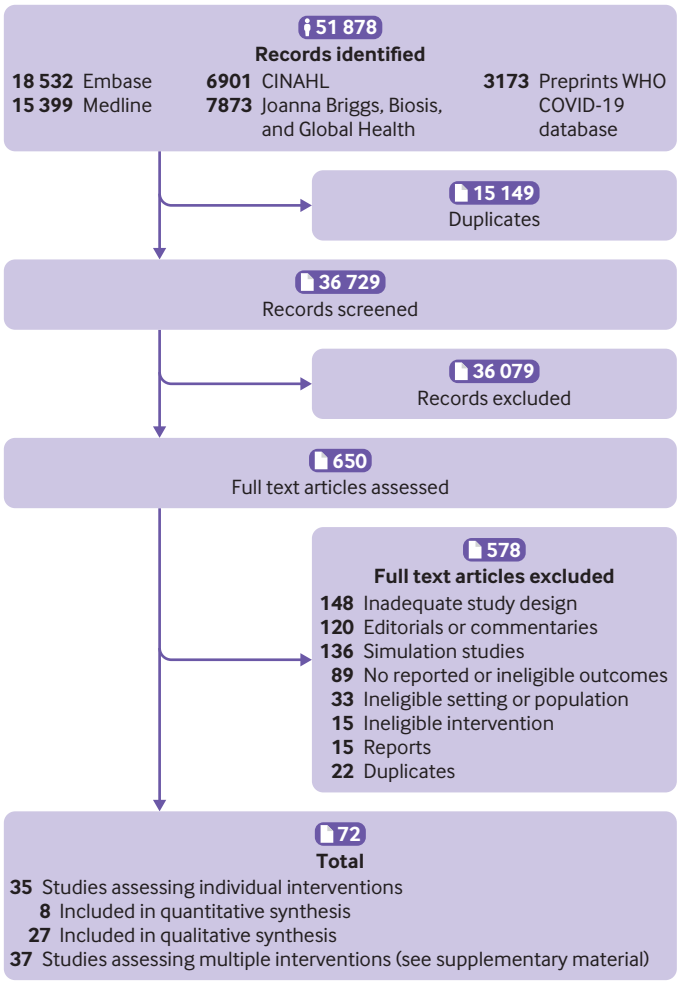

Fig 1 | Flow of articles through the review. WHO=World Health Organization

Study characteristics

Studies assessing individual measures

Thirty five studies provided estimates on the effectiveness of an individual public health measures. The studies were conducted in Asia (n=11), the United States (n=9), Europe (n=7), the Middle East (n=3), Africa (n=3), South America (n=1), and Australia (n=1). Thirty four of the studies were observational and one was a randomised controlled trial. The study designs of the observational studies comprised natural experiments (n=11), quasi-experiments (n=3), a prospective cohort (n=1), retrospective cohorts (n=8), case-control (n=2), and cross sectional (n=9). Twenty six studies assessed social measures,[32 34 35 37-42 44 46-48 52 53 55-59 61 63-65 67 68] 12 studies assessed personal protective measures,[36 43 45 49 50 57 58 63 66 68 69] three studies assessed travel related measures,[54 58 62] and one study assessed environmental measures[57] (some interventions overlapped across studies). The most commonly measured outcome was incidence of covid-19 (n=18), followed by SARS-CoV-2 transmission, measured as reproductive number, growth number, or epidemic doubling time (n=13), and covid-19 mortality (n=8). Table 1 in supplementary material 3 provides detailed information on each study.

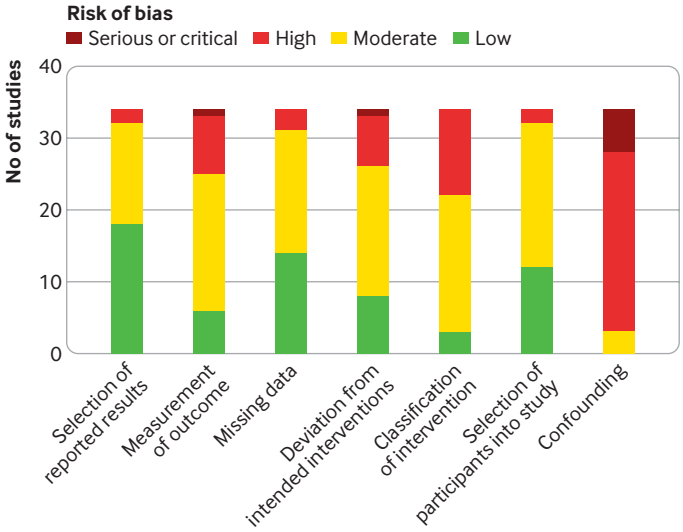

Fig 2 | Summary of risk of bias across studies assessing individual measures using risk of bias in non-randomised studies of interventions (ROBINS-I) tool

Effects of interventions

Personal protective measures

Handwashing and covid-19 incidence—Three studies with a total of 292 people infected with SARS-CoV-2 and 10 345 participants were included in the analysis of the effect of handwashing on incidence of covid-19.[36 63 68] Overall pooled analysis suggested an estimated 53% non-statistically significant reduction in covid-19 incidence (relative risk 0.47, 95% confidence interval 0.19 to 1.12, I^2=12%) (fig 3). A sensitivity analysis without adjustment showed a significant reduction in covid-19 incidence (0.49, 0.33 to 0.72, I^2=12%) (fig 4). Risk of bias across the three studies ranged from moderate[36 60] to serious or critical[63] (fig 2).

Mask wearing and covid-19 incidence—Six studies with a total of 2627 people with covid-19 and 389 228 participants were included in the analysis examining the effect of mask wearing on incidence of covid-19 (table 1).[36 43 57 60 63 66] Overall pooled analysis showed a 53% reduction in covid-19 incidence (0.47, 0.29 to 0.75), although heterogeneity between studies was substantial (I^2=84%) (fig 5). Risk of bias across the six studies ranged from moderate[36 57 60 66] to serious or critical[43 63] (fig 2).

Mask wearing and transmission of SARS-CoV-2, covid-19 incidence, and covid-19 mortality—The results of additional studies that assessed mask wearing (not included in the meta-analysis because of substantial differences in the assessed outcomes) indicate a reduction in covid-19 incidence, SARS-CoV-2 transmission, and covid-19 mortality. Specifically, a natural experiment across 200 countries showed 45.7% fewer covid-19 related mortality in countries where mask wearing was mandatory (table 1).[49] Another natural experiment study in the US reported a 29% reduction in SARS-CoV-2 transmission (measured as the time varying reproductive number Rt) (risk ratio 0.71, 95% confidence interval 0.58 to 0.75) in states where mask wearing was mandatory.[58]

A comparative study in the Hong Kong Special Administrative Region reported a statistically

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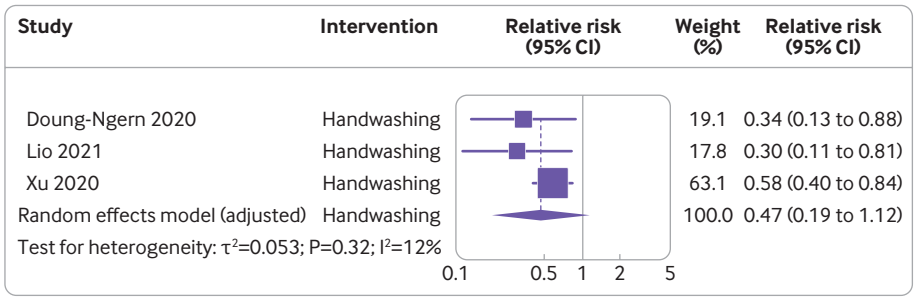

Fig 3 | Meta-analysis of evidence on association between handwashing and incidence of covid-19 using modified Hartung-Knapp-Sidik-Jonkman adjusted random effect model

significant lower cumulative incidence of covid-19 associated with mask wearing than in selected countries where mask wearing was not mandatory (table 1).[69] Similarly, another natural experiment involving 15 US states reported a 2% statistically significant daily decrease in covid-19 transmission (measured as case growth rate) at ≥21 days after mask wearing became mandatory,[50] whereas a cross sectional study reported that a 10% increase in self-reported mask wearing was associated with greater odds for control of SARS-CoV-2 transmission (adjusted odds ratio 3.53, 95% confidence interval 2.03 to 6.43).[45] The five studies were rated at moderate risk of bias (fig 2).

Environmental measures

Disinfection in household and covid-19 incidence

Only one study, from China, reported the association between disinfection of surfaces and risk of secondary transmission of SARS-CoV-2 within households (table 1).[57] The study assessed disinfection retrospectively by asking participants about their "daily use of chlorine or ethanol-based disinfectant in households," and observed that use of disinfectant was 77% effective at reducing SARS-CoV-2 transmission (odds ratio 0.23, 95% confidence interval 0.07 to 0.84). The study did not collect data on the concentration of the disinfectant used by participants and was rated at moderate risk of bias (fig 2).

Social measures

Physical distancing and covid-19 incidence

Five studies with a total of 2727 people with SARS-CoV-2 and 108 933 participants were included in the analysis that examined the effect of physical distancing on the incidence of covid-19.[37 53 57 60 63] Overall pooled analysis indicated a 25% reduction in incidence of covid-19 (relative risk 0.75, 95% confidence interval 0.59 to 0.95, I^2=87%) (fig 6). Heterogeneity among studies was substantial, and risk of bias ranged from moderate[37 53 57 60] to serious or critical[63] (fig 2).

Physical distancing and transmission of SARS-CoV-2 and covid-19 mortality

Studies that assessed physical distancing but were not included in the meta-analysis because of substantial differences in outcomes assessed, generally reported a positive effect of physical distancing (table 2). A natural experiment from the US reported a 12% decrease in SARS-CoV-2 transmission (relative risk 0.88, 95% confidence interval 0.86 to 0.89),[40] and a quasi-experimental study from Iran reported a reduction in covid-19 related mortality (β −0.07, 95% confidence interval −0.05 to −0.10; P<0.001).[47] Another comparative study in Kenya also reported a reduction in transmission of SARS-CoV-2 after physical distancing was implemented, reporting 62% reduction in overall physical contacts (reproductive number pre-intervention was 2.64 and post-intervention was 0.60 (interquartile range 0.50 to 0.68)).[61] These three studies were rated at moderate risk of bias[40 61] to serious or critical risk of bias[47] (fig 2).

Stay at home or isolation and transmission of SARS-CoV-2

All the studies that assessed stay at home or isolation measures reported reductions in transmission of SARS-CoV-2 (table 2). A retrospective cohort study from the US reported a significant reduction in the odds of having

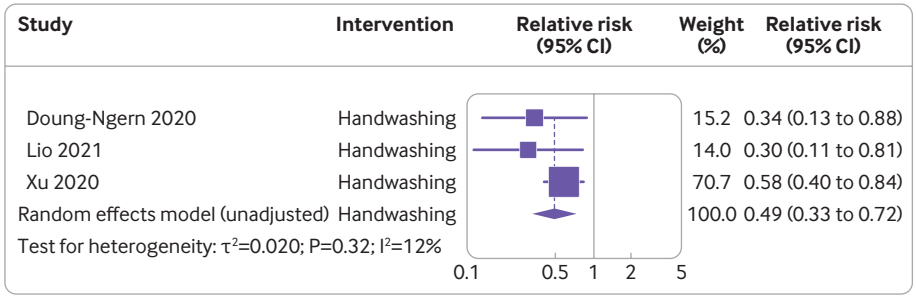

Fig 4 | Meta-analysis of evidence on association between handwashing and incidence of covid-19 using unadjusted random effect model

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Table 1 | Study characteristics and main results from studies that assessed individual personal protective and environmental measures

Reference, country	Study design	Public health measure	Sample size	Outcome measure	Study duration	Effect estimates: conclusions	Risk of bias
Doung-Ngern et al,[63] Thailand	Case-control	Handwashing	211 cases, 839 controls	Incidence	1-31 Mar 2020	Regular handwashing: adjusted odds ratio 0.34 (95% confidence interval 0.13 to 0.87): associated with lower risk of SARS-CoV-2*	Serious or critical
Lio et al,[36] China	Case-control	Handwashing	24 cases, 1113 controls	Incidence	17 Mar-15 Apr 2020	Adjusted odds ratio 0.30 (95% confidence interval 0.11 to 0.80): reduction in odds of becoming infectious*	Moderate
Xu et al,[68] China	Cross sectional comparative	Handwashing	n=8158	Incidence	22 Feb-5 Mar 2020	Relative risk 3.53 (95% confidence interval 1.53 to 8.15): significantly increased risk of infection with no handwashing*	Moderate
Bundgaard et al,[66] Denmark	Randomised controlled	Mask wearing	2392 cases, 2470 controls	Incidence	Apr and May 2020	Odds ratio 0.82 (95% confidence interval 0.54 to 1.23): 46% reduction to 23% increase in infection*	Moderate
Doung-Ngern et al,[63] Thailand	Case-control	Mask wearing	211 cases, 839 controls	Incidence	1-31 Mar 2020	Adjusted odds ratio 0.23 (95% confidence interval 0.09 to 1.60): associated with lower risk of SARS-CoV-2 infection*	Serious or critical
Lio et al,[36] China	Case-control	Mask wearing	24 cases, 1113 controls	Incidence	17 Mar-15 Apr 2020	Odds ratio 0.30 (95% confidence interval 0.10 to 0.86): 70% risk reduction*	Moderate
Xu et al,[68] China	Cross sectional comparative	Mask wearing	8158 people	Incidence	22 Feb-5 Mar 2020	Relative risk 12.38 (95% confidence interval 5.81 to 26.36): significantly increased risk of infection*	Moderate
Krishnamachari et al,[43] US	Natural experiment	Mask wearing	50 states	Incidence (cumulative rate)	Apr 2020	3-6 months, adjusted odds ratio 1.61 (95% confidence interval 1.23 to 2.10): >6 months, 2.16 (1.64 to 2.88): higher incidence rate with later mask mandate than with mask mandate in first month*	Serious or critical
Wang et al,[57] China	Retrospective cohort	Mask wearing	335 people	Incidence (assessed as attack rate†)	28 Feb-27 Mar 2020	Odds ratio 0.21 (95% confidence interval 0.06 to 0.79): 79% reduction in transmission of SARS-CoV-2*	Moderate
Cheng et al,[69] China	Longitudinal comparative	Mask wearing (South Korea *v* HKSAR)	961 cases (HKSAR), average control not available	Incidence	31 Dec 2019-8 Apr 2020	Incidence rate 49.6% (South Korea) *v* 11.8% (HKSAR) P <0.001: 37.8% less SARS-CoV-2 cases*	Moderate
Leffler et al,[49] US	Natural experiment	Mask wearing	200 countries	Mortality (per capita)	Jan-9 May 2020	No masks: mortality rate 61.9% (95% confidence interval 37.0% to 91.0%); masks: 16.2% (−14.4% to 57.4%): 45.7% fewer mortality*	Moderate
Lyu et al,[50] US	Natural experiment	Mask wearing	15 states	Case growth rate	31 Mar-22 May 2020	Mandatory mask wearing: case growth rate 2%: 2% decrease in daily covid-19 growth rate at ≥21 days (P<0.05)*	Moderate
Rader et al,[45] US	Cross sectional	Mask wearing	378 207 people	R0	3 Jun-27 Jul	Adjusted odds ratio 3.53 (95% confidence interval 2.03 to 6.43): 10% increase in self-reported mask wearing was associated with an increased odds of transmission control*	Moderate
Liu et al,[58] US	Natural experiment	Mask wearing	50 states	Rt	21 Jan-31 May 2020	Risk ratio 0.71 (95% confidence interval 0.58 to 0.75): 29% reduction in Rt*	Moderate
Wang et al,[57] China	Retrospective cohort	Chlorine or ethanol based disinfectant	335 people	Incidence (attack rate†)	28 Feb-27 Mar 2020	Odds ratio 0.23 (95% confidence interval 0.07 to 0.84): 77% reduction in transmission of SARS-CoV-2*	Moderate

HKSAR=Hong Kong Special Administrative Region of China; R0=reproductive number; Rt=time varying reproductive number.
*Interpretation of findings as reported in the original manuscript.
†Percentage of individuals who tested positive over a specified period.

a positive reproductive number (R0) result (odds ratio 0.07, 95% confidence interval 0.01 to 0.37),[41] and a natural experiment reported a 51% reduction in time varying reproductive number (Rt) (risk ratio 0.49, 95% confidence interval 0.43 to 0.54).[58]

A study from the UK reported a 74% reduction in the average daily number of contacts observed for each participant and estimated a decrease in reproductive number: the reproductive number pre-intervention was 3.6 and post-intervention was 0.60 (95% confidence interval 0.37 to 0.89).[65] Similarly, an Iranian study projected the reproductive number using serial interval distribution and the number of incidence cases and found a significant decrease: the reproductive number pre-intervention was 2.70 and post-intervention was 1.13 (95% confidence interval 1.03 to 1.25).[55] Three of the studies were rated at moderate to serious or critical risk of bias,[55 58 65] and one study was rated at low risk of bias[41] (fig 2).

Quarantine and incidence and transmission of SARS-CoV-2

Quarantine was assessed in two studies (table 2).[34 59] A prospective cohort study from Saudi Arabia reported

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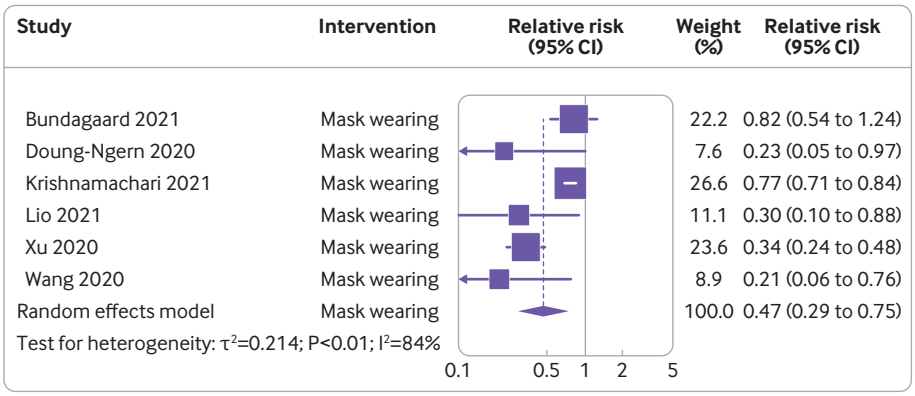

Fig 5 | Meta-analysis of evidence on association between mask wearing and incidence of covid-19 using unadjusted random effect model

a 4.9% decrease in the incidence of covid-19 at eight weeks after the implementation of quarantine.[34] This study was rated at low risk of bias (fig 2). A retrospective cohort study from India reported a 14 times higher risk of SARS-CoV-2 transmission associated with no quarantine compared with strict quarantine (odds ratio 14.44, 95% confidence interval 2.42 to 86.17).[59] This study was rated at moderate risk of bias (fig 2).

School closures and covid-19 incidence and covid-19 mortality

Two studies assessed the effectiveness of school closures on transmission of SARS-CoV-2, incidence of covid-19, or covid-19 mortality (table 2).[44 48] A US population based longitudinal study reported on the effectiveness of state-wide closure of primary and secondary schools and observed a 62% decrease (95% confidence interval −49% to −71%) in incidence of covid-19 and a 58% decrease (−46% to−68%) in covid-19 mortality.[48] Conversely, a natural experiment from Japan reported no effect of school closures on incidence of covid-19 (α coefficient 0.08, 95% confidence interval −0.36 to 0.65).[44] Both studies were rated at moderate risk of bias (fig 2).

School closures and transmission of SARS-CoV-2

Two natural experiments from the US reported a reduction in transmission (ie, reproductive number); with one study reporting a reduction of 13% (relative risk 0.87, 95% confidence interval 0.86 to 0.89)[40] and another reporting a 10% (0.90, 0.86 to 0.93) reduction (table 2).[58] A Swedish study reported an association between school closures and a small increase in confirmed SARS-CoV-2 infections in parents (odds ratio 1.17, 95% confidence interval 1.03 to 1.32), but observed that teachers in lower secondary schools were twice as likely to become infected than teachers in upper secondary schools (2.01, 1.52 to 2.67).[32] All three studies were rated at moderate risk of bias (fig 2).

Business closures and transmission of SARS-CoV-2

Two natural experiment studies assessed business closures across 50 US states and reported reductions in transmission of SARS-CoV-2 (table 2).[40 58] One of the studies observed a significant reduction in transmission of 12% (relative risk 0.88, 95% confidence interval 0.86 to 0.89)[40] and the other reported a significant 16% (risk ratio 0.84, 0.79 to 0.90) reduction.[58] Both studies were rated at moderate risk of bias (fig 2).

Lockdown and incidence of covid-19

A natural experiment involving 202 countries suggested that countries that implemented universal lockdown had fewer new cases of covid-19 than countries that did not (β coefficient −235.8 (standard error −11.04), P<0.01) (table 2).[52] An Indian quasi-experimental study reported a 10.8% reduction in incidence of covid-19 post-lockdown,[56] whereas a South African

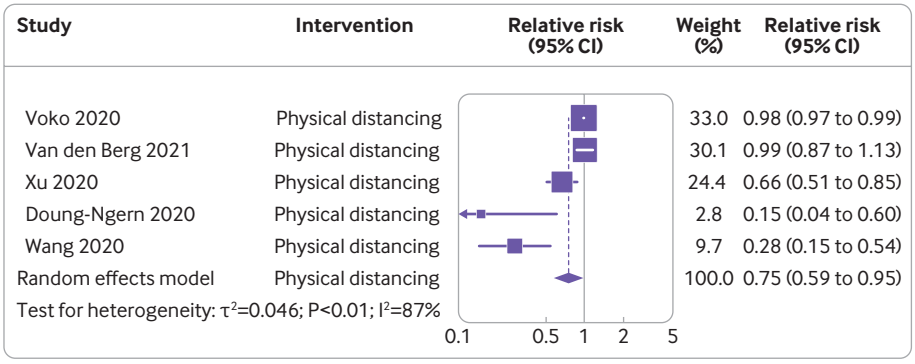

Fig 6 | Meta-analysis of evidence on association between physical distancing and incidence of covid-19 using unadjusted random effect model

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Table 2 | Study characteristics and main results from studies assessing individual social measures

Reference, country	Study design	Public health measure	Sample size	Outcome	Study duration	Effect estimates: conclusions	Risk of bias
Jarvis et al,[65] UK	Cross sectional	Stay at home or isolation	1356 cases	R0	Feb-24 Mar 2020	R0: pre-intervention 3.6, post-intervention 0.60 (95% confidence interval 0.37 to 0.89): 3.0 R0 decrease	Serious or critical
Khosravi et al,[55] Iran	Cross sectional	Stay at home or isolation	993 cases	R0	20 Feb-01 Apr 2020	R0: pre-intervention 2.70 (95% confidence interval 2.10 to 3.40), post-intervention 1.13 (1.03 to 1.25): 1.5 R0 decrease	Moderate
Dreher et al,[41] US	Retrospective cohort	Stay at home or isolation	49 states and territories	R0	NS	Odds ratio 0.07 (95% confidence interval 0.01 to 0.37): decrease in odds of having a positive R0 result*	Low
Liu et al,[58] US	Natural experiment	Stay at home or isolation	50 states	Rt	21 Jan-31 May 2020	Risk ratio 0.49 (95% confidence interval 0.43 to 0.54): contributed about 51% to reduction in Rt*	Moderate
Alfano et al,[52] Italy	Natural experiment	Lockdown	202 countries, 22 018 people	Incidence	22 Jan-10 May 2020	β coefficient −235.8 (standard error −11.04), P<0.01	Serious or critical
Thayer et al,[56] India	Quasi-experimental	Lockdown	NS	Incidence (% median)	2 Mar-1 Sept 2020	Incidence rate: pre-lockdown 15.8% (95% confidence interval 7.0% to 20.2%), post-lockdown 5.0% (4.7% to 5.4%): 10.8% reduction in average incidence rate*	Moderate
Pillai et al,[46] South Africa	Retrospective cohort	Lockdown	162 528	Attack rate†	5 Mar-30 June	Attack rate: pre-lockdown 18.5%, full lockdown 4.1%: 14.1% reduction in risk*	Moderate
Siedner et al,[35] US	Natural experiment	Lockdown	45 states	Case growth rate, mortality growth rate	10-25 Mar 2020	Case growth rate 0.9% decrease (95% confidence interval 1.40% to 0.4%)/day (after 4 days)*; mortality growth rate 2.0% mortality decrease (−3.0% to 0.9%)/day*	Moderate
Silva et al,[42] Brazil	Quasi-experimental	Lockdown	Nationwide	Mortality	5-30 Mar 2020	Post-intervention changes in mortality, São Luís (β coefficient −0.13, P<0.001), Recife (β coefficient −0.06, P<0.001), Belém (β coefficient −0.10, P<0.001), Fortaleza (β coefficient −0.09, P<0.001): 27.4% average difference in mortality	Moderate
Tobias et al,[38] Spain	Natural experiment	Lockdown	Spain and Italy	Mortality	24 Feb-5 Apr 2020	Mortality rates: Italy pre-intervention −32.8 (95% confidence interval 21.0 to 44.6), Italy post-intervention −0.2 (−1.5 to 1.0), Spain pre-intervention 59.3 (23.0 to 95.2), Spain post-intervention −1.8 (−5.0 to 3.1): beneficial effect in both countries*	Moderate
Wang et al,[70] China	Retrospective cohort	Lockdown	Nationwide	R0	10 Jan-16 Feb 2020	R0: pre-intervention 4.95 (95% confidence interval 4.26 to 5.67), post-intervention 0.98 (0.96 to 1.03): 3.97 decrease	Low
Guzzetta et al,[39] Italy	Longitudinal comparative	Lockdown	Nationwide	R0	10-25 Mar 2020	R0: pre-intervention 2.03, 3 weeks 0.76 (95% confidence interval 0.67 to 0.85): 1.27 decrease	Low
Basu et al,[64] India	Retrospective cohort	Lockdown	Nationwide	R0	24 Mar-31 May 2020	R0: pre-intervention 3.36 (95% confidence interval 3.03 to 3.71), post-intervention 1.27 (1.26 to 1.28): 2.09 decrease	Moderate
Guo et al,[40] US	Natural experiment	Lockdown	50 states and one territory (Virgin Islands)	Rt	29 Jan-31 Jul 2020	Relative risk 0.89 (95% confidence interval 0.88 to 0.91): associated with a 11% decrease in risk of Rt*	Moderate
Al-Tawfiq et al,[34] Saudi Arabia	Prospective cohort	Quarantine	1928 cases	Incidence	14 Mar-6 Jun	Incidence rate: 4 weeks 5.9%, 8 weeks 1.0%, 13 weeks 0%: 4.9% decrease at 8 weeks	Low
Vaman et al,[59] India	Retrospective cohort	Quarantine	179 cases	Risk of transmission	24 Mar-30 Apr 2020	Odds ratio 14.44 (95% confidence interval 2.42 to 86.17), relative risk 11.85 (95% confidence interval 2.91 to 48.23): >14 times higher risk without quarantine compared with strict quarantine.* Significant risk of transmission*	Moderate
Auger et al,[48] US	Longitudinal comparative	School closure	Nationwide	Incidence, mortality (adjusted relative change)	9 Mar-7 May 2020	Incidence −62% (95% confidence interval −49% to −71%), mortality rate −58% (95% confidence interval −46% to −68%): decreased covid-19 incidence and mortality*	Moderate
Vlachos et al,[32] Sweden	Cross sectional comparative	School closure	Teachers and parents, number not specified	Incidence	25 Mar-1 Apr 2020	Odds ratio 2.01 (95% confidence interval 1.52 to 2.67): teachers in lower secondary schools twice as likely to become infected with SARS-CoV-2 than teachers in upper secondary school*	Moderate
Iwata et al,[44] Japan	Natural experiment	School closure	Not specified	Incidence	27-Feb 31 Mar 2020	α coefficient 0.08 (95% confidence interval −0.36 to 0.65): no decrease in incidence of SARS-CoV-2‡	Moderate
Liu et al,[58] US	Natural experiment	School closure	50 states	Rt	21 Jan-31 May 2020	Risk ratio 0.90 (95% confidence interval 0.86 to 0.93): contributed about 10% to reduction in Rt*	Moderate
Guo et al,[40] US	Natural experiment	School closure	50 states and one territory (Virgin Islands)	Rt	29 Jan-31 July 2020	Relative risk 0.87 (95% confidence interval 0.86 to 0.89): associated with 13% decrease in risk of Rt*	Moderate
Liu et al,[58] US	Natural experiment	Business closure	50 states	Rt	21 Jan-31 May 2020	Risk ratio 0.84 (95% confidence interval 0.79 to 0.90): contributed about 26% reduction in Rt*	Moderate

(*Continued*)

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Table 2 | Continued

Reference, country	Study design	Public health measure	Sample size	Outcome	Study duration	Effect estimates: conclusions	Risk of bias
Guo et al,[40] US	Natural experiment	Business closure	50 states and one territory (Virgin Islands)	Rt	29 Jan-31 July 2020	Relative risk 0.88 (95% confidence interval 0.86 to 0.89): associated with 12% decrease in risk of Rt*	Moderate
Voko et al,[53] Europe	Natural experiment	Physical distancing	28 countries	Incidence	1 Feb-18 Apr 2020	Incidence rate ratio 1.23 (95% confidence interval 1.19 to 1.28), 0.98 (0.97 to 0.99): 26% decrease in incidence*	Moderate
Van den Berg et al,[37] US	Retrospective cohort	Physical distancing	99 390 staff	Incidence (adjusted)	24 Sep 2020-27 Jan 2021	≥3 *v* ≥6 feet adjusted incidence rate ratio 1.01 (95% confidence interval 0.75 to 1.36), larger physical distancing not associated with lower rates of SARS-CoV-2*‡	Moderate
Xu et al,[68] China	Cross sectional comparative	Physical distancing	8158 people	Incidence	22 Feb-5 Mar 2020	Relative risk 2.63 (95% confidence interval 1.48 to 4.67): significantly increased risk of infection*	Moderate
Doung-Ngern et al,[63] Thailand	Case-control	Physical distancing	211 cases, 839 controls	Incidence	1-31 Mar 2020	>1m physical distance adjusted odds ratio 0.15; 95% confidence interval 0.04 to 0.63)): associated with lower risk of SARS-CoV-2 infection*	Serious or critical
Wang et al,[57] China	Retrospective cohort	Physical distancing	335 people	Incidence (proportions assessed as attack rate†)	28 Feb-27 Mar 2020	Odds ratio 18.26 (95% confidence interval 3.93 to 84.79): risk of household transmission was 18 times higher with frequent daily close contact with the primary case*	Moderate
Alimohamadi et al,[47] Iran	Quasi-experimental	Physical distancing	NS	Incidence, mortality	20 Feb-13 May 2020	Incidence β coefficient −1.70 (95% confidence interval −2.3 to 1.1), mortality β coefficient −0.07 (−0.05 to −0.10): reduced incidence and mortality*	Serious or critical
Quaife et al,[61] Africa	Cross-sectional comparative	Physical distancing	237 cases	R0	1 -31 May 2020	R0: pre-intervention 2.64, post-intervention 0.60 (interquartile range 0.50-0.68): 2.04 decrease in R0	Moderate
Guo et al,[40] US	Natural experiment	Physical distancing	50 states and one territory (Virgin Islands)	Rt	29 Jan-31 Jul 2020	Relative risk 0.88 (95% confidence interval 0.86 to 0.89): associated with a 12% decrease in risk of Rt*	Moderate

R0=reproductive number; Rt=time varying reproductive number.
*Interpretation of findings as reported in the original manuscript.
†Percentage of individuals who tested positive over a specified period.
‡Not an effective intervention.

retrospective cohort study observed a 14.1% reduction in risk after implementation of universal lockdown (table 2).[46] These studies were rated at high risk of bias[52] and moderate risk of bias[46 56] (fig 2).

Lockdown and covid-19 mortality

The three studies that assessed universal lockdown and covid-19 mortality generally reported a decrease in mortality (table 2).[35 38 42] A natural experiment study involving 45 US states reported a decrease in covid-19 related mortality of 2.0% (95% confidence interval −3.0% to 0.9%) daily after lockdown had been made mandatory.[35] A Brazilian quasi-experimental study reported a 27.4% average difference in covid-19 related mortality rates in the first 25 days of lockdown.[42] In addition, a natural experiment study reported about 30% and 60% reductions in covid-19 related mortality post-lockdown in Italy and Spain over four weeks post-intervention, respectively.[38] All three studies were rated at moderate risk of bias (fig 2).

Lockdown and transmission of SARS-CoV-2

Four studies assessed universal lockdown and transmission of SARS-CoV-2 during the first few months of the pandemic (table 2). The decrease in reproductive number (R0) ranged from 1.27 in Italy (pre-intervention 2.03, post-intervention 0.76)[39] to 2.09 in India (pre-intervention 3.36, post-intervention 1.27),[64] and 3.97 in China (pre-intervention 4.95, post-intervention 0.98).[33] A natural experiment from the US reported that lockdown was associated with an 11% reduction in transmission of SARS-CoV-2 (relative risk 0.89, 95% confidence interval 0.88 to 0.91).[40] All the studies were rated at low risk of bias[33 39] to moderate risk[40 64] (fig 2).

Travel related measures

Restricted travel and border closures

Border closure was assessed in one natural experiment study involving nine African countries (table 3).[62] Overall, the countries recorded an increase in the incidence of covid-19 after border closure. These studies concluded that the implementation of border closures within African countries had minimal effect on the incidence of covid-19. The study had important limitations and was rated at serious or critical risk of bias. In the US, a natural experiment study reported that restrictions on travel between states contributed about 11% to a reduction in SARS-CoV-2 transmission (table 3).[36] The study was rated at moderate risk of bias (fig 2).

Entry and exit screening (virus or symptom screening)

One retrospective cohort study assessed screening of symptoms, which involved testing 65 000 people for fever (table 3).[54] The study found that screening for fever lacked sensitivity (ranging from 18% to 24%) in detecting people with SARS-CoV-2 infection. This translated to 86% of the population with SARS-CoV-2 remaining undetected when screening for fever. The study was rated at moderate risk of bias (fig 2).

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Table 3 | Study characteristics and main results from studies that assessed individual travel measures

Reference, country	Study design	Public health measure	Sample size	Outcome measure	Study duration	Effect estimates: conclusions	Risk of bias
Emeto et al,[62] Africa	Natural experiment	Border closure	9 countries	Rt	14 Feb-19 Jul 2020	See supplementary table for data on all countries: minimal effect on reducing transmission (Rt)*†	Serious or critical
Liu et al,[58] USA	Natural experiment	Interstate travel restrictions	50 states	Rt	21 Jan-31 May 2020	Risk ratio 0.89 (95% confidence interval 0.84 to 0.95): contributed about 11% to reduction in Rt*	Moderate
Mitra et al,[54] Australia	Retrospective cohort	Screening for fever	65 000 people	Daily growth rate	9 Mar-13 May 2020	Sensitivity 24%: 86% of cases not detected—poor sensitivity of identifying people with SARS-CoV-2*	Moderate

R0=reproductive number; Rt=time varying reproductive number.
*Interpretation of findings as reported in the original manuscript.
†Not an effective intervention

Multiple public health measures

Study characteristics

Overall, 37 studies provided estimates on the effectiveness of multiple public health measures, assessed as a collective group. Studies were mostly conducted in Asia (n=15), the US (n=11), Europe (n=6), Africa (n=4), and South America (n=1). All the studies were observational. The most commonly measured outcome was transmission of disease (ie, measured as reproductive number, growth number, or epidemic doubling time) (n=23), followed by covid-19 incidence (n=19) and covid-19 mortality (n=8). This review attempted to assess the overall effectiveness of the public health intervention packages by reporting the percentage difference in outcome before and after implementation of measures or between regions or countries studied. Eleven of the 37 included studies noted a difference of between 26% and 50% in transmission of SARS-CoV-2 and incidence of covid-19,[71-81] nine noted a difference of between 51% and 75% in SARS-CoV-2 transmission, covid-19 incidence, and covid-19 mortality,[82-90] and 14 noted a difference of more than 75% in transmission of SARS-CoV-2, covid-19 incidence and covid-19 mortality.[80 81 90-101] For the remaining studies, the overall effectiveness was not assessed owing to a lack of comparators (see supplementary material 3, table 3). Two studies that assessed universal lockdown and physical distancing reported a decrease of between 0% and 25% in SARS-CoV-2 transmission and covid-19 incidence.[80 102] Studies that included school and workplace closures,[92 96 97] isolation or stay at home measures,[81 95] or a combination of both[80 90 94 98-100] reported decreases of more than 75% in SARS-CoV-2 transmission. Supplementary material 3, table 2 provides detailed information on each study.

Discussion

Worldwide, government and public health organisations are mitigating the spread of SARS-CoV-2 by implementing various public health measures. This systematic review identified a statistically significant reduction in the incidence of covid-19 through the implementation of mask wearing and physical distancing. Handwashing interventions also indicated a substantial reduction in covid-19 incidence, albeit not statistically significant in the adjusted model. As the random effects model tends to underestimate confidence intervals when a meta-analysis includes a small number of individual studies (<5), the adjusted model for handwashing showed a statistically non-significant association in reducing the incidence of covid-19 compared with the unadjusted model.

Overall effectiveness of these interventions was affected by clinical heterogeneity and methodological limitations, such as confounding and measurement bias. It was not possible to evaluate the impact of type of face maks (eg, surgical, fabric, N95 respirators) and compliance and frequency of wearing masks owing to a lack of data. Similarly, it was not feasible to assess the differences in effect that different recommendations for physical distancing (ie, 1.5 m, 2m, or 3 m) have as preventive strategies.

The effectiveness of measures such as universal lockdowns and closures of businesses and schools for the containment of covid-19 have largely been effective, but depended on early implementation when incidence rates of covid-19 were still low.[42 52 58] Only Japan reported no decrease in covid-19 incidence after school closures,[44] and other studies found that different public health measures were sometimes implemented simultaneously or soon after one another, thus the results should be interpreted with caution.[32 46 56]

Isolation or stay at home was an effective measure in reducing the transmission of SARS-CoV-2, but the included studies used results for mobility to assess stay at home or isolation and therefore could have been limited by potential flaws in publicly available phone data,[41 58 103] and variations in the enforcement of public health measures in different states or regions were not assessed.[55 58 103] Quarantine was found to be as effective in reducing the incidence of covid-19 and transmission of SARS-CoV-2, yet variation in testing and case detection in low income environments was substantial.[59 97 99] Another study reported that quarantine was effective in reducing the transmission of SARS-CoV-2 in a cohort with a low prevalence of the virus, yet it is unknown if the same effect would be observed with higher prevalence.[34]

It was not possible to draw conclusions about the effectiveness of restricted travel and full border closures because the number of empirical studies was insufficient. Single studies identified that border closure in Africa had a minimal effect in reducing SARS-CoV-2 transmission, but the study was assessed as being at high risk of bias.[62] Screening for fever was also identified to be ineffective, with only 24% of positive cases being captured by screening.[54]

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Comparison with other studies

Previous literature reviews have identified mask wearing as an effective measure for the containment of SARS-CoV-2[104]; the caveat being that more high level evidence is required to provide unequivocal support for the effectiveness of the universal use of face masks.[105 106] Additional empirical evidence from a recent randomised controlled trial (originally published as a preprint) indicates that mask wearing achieved a 9.3% reduction in seroprevalence of symptomatic SARS-CoV-2 infection and an 11.9% reduction in the prevalence of covid-19-like symptoms.[107] Another systematic review showed stronger effectiveness with the use of N95, or similar, respirators than disposable surgical masks,[108] and a study evaluating the protection offered by 18 different types of fabric masks found substantial heterogeneity in protection, with the most effective mask being multilayered and tight fitting.[109] However, transmission of SARS-CoV-2 largely arises in hospital settings in which full personal protective measures are in place, which suggests that when viral load is at its highest, even the best performing face masks might not provide adequate protection.[51] Additionally, most studies that assessed mask wearing were prone to important confounding bias, which might have altered the conclusions drawn from this review (ie, effect estimates might have been underestimated or overestimated or can be related to other measures that were in place at the time the studies were conducted). Thus, the extent of such limitations on the conclusions drawn remain unknown.

A 2020 rapid review concluded that quarantine is largely effective in reducing the incidence of covid-19 and covid-19 mortality. However, uncertainty over the magnitude of such an effect still remains,[110] with enhanced management of quality quarantine facilities for improved effective control of the epidemics urgently needed.[111] In addition, findings on the application of school and workplace closures are still inconclusive. Policy makers should be aware of the ambiguous evidence when considering school closures, as other potentially less disruptive physical distancing interventions might be more appropriate.[21] Numerous findings from studies on the efficacy of school closures showed that the risk of transmission within the educational environment often strongly depends on the incidence of covid-19 in the community, and that school closures are most successfully associated with control of SARS-CoV-2 transmission when other mitigation strategies are in place in the community.[112-118] School closures have been reported to be disruptive to students globally and are likely to impair children's social, psychological, and educational development[119 120] and to result in loss of income and productivity in adults who cannot work because of childcare responsibilities.[121]

Speculation remains as how best to implement physical distancing measures.[122] Studies that assess physical distancing measures might interchangeably study physical distancing with lockdown[35 52 56 64] and other measures and thus direct associations are difficult to assess.

Empirical evidence from restricted travel and full border closures is also limited, as it is almost impossible to study these strategies as single measures. Current evidence from a recent narrative literature review suggested that control of movement, along with mandated quarantine, travel restrictions, and restricting nationals from entering areas of high infection, are effective measures, but only with good compliance.[123] A narrative literature review of travel bans, partial lockdowns, and quarantine also suggested effectiveness of these measures,[124] and another rapid review further supported travel restrictions and cross border restrictions to stop the spread of SARS-CoV-2.[125] It was impossible to make such observations in the current review because of limited evidence. A German review, however, suggested that entry, exit, and symptom screening measures to prevent transmission of SARS-CoV-2 are not effective at detecting a meaningful proportion of cases,[130] and another review using real world data from multiple countries found that border closures had minimal impact on the control of covid-19.[126]

Although universal lockdowns have shown a protective effect in lowering the incidence of covid-19, SARS-CoV-2 transmission, and covid-19 mortality, these measures are also disruptive to the psychosocial and mental health of children and adolescents,[127] global economies,[128] and societies.[129] Partial lockdowns could be an alternative, as the associated effectiveness can be high,[130] especially when implemented early in an outbreak,[86] and such measures would be less disruptive to the general population.

It is important to also consider numerous sociopolitical and socioeconomic factors that have been shown to increase SARS-CoV-2 infection[131 132] and covid-19 mortality.[133] Immigration status,[83] economic status,[82 102] and poverty and rurality[99] can influence individual and community compliance with public health measures. Poverty can impact the ability of communities to physically distance,[134] especially in crowded living environments,[135 136] as well as reduce access to personal protective measures.[135 136] A recent study highlights that "a one size fits all" approach to public health measures might not be effective at reducing the spread of SARS-CoV-2 in vulnerable communities[137] and could exacerbate social and economic inequalities.[136 138] As such, a more nuanced and community specific approach might be required. Even though screening is highly recommended by WHO[139] because a proportion of patients with covid-19 can be asymptomatic,[139] screening for symptoms might miss a larger proportion of the population with covid-19. Hence, temperature screening technologies might need to be reconsidered and evaluated for cost effectiveness, given such measures are largely depended on symptomatic fever cases.

Strengths and limitations of this review

The main strength of this systematic review was the use of a comprehensive search strategy to identify and select studies for review and thereby minimise selection bias. A clinical epidemiologist developed the search

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strategy, which was validated by two senior medical librarians. This review followed a comprehensive appraisal process that is recommended by the Cochrane Collaboration[31] to assess the effectiveness of public health measures, with specifically validated tools used to independently and individually assess the risk of bias in each study by study design.

This review has some limitations. Firstly, high quality evidence on SARS CoV-2 and the effectiveness of public health measures is still limited, with most studies having different underlying target variables. Secondly, information provided in this review is based on current evidence, so will be modified as additional data become available, especially from more prospective and randomised studies. Also, we excluded studies that did not provide certainty over the effect measure, which might have introduced selection bias and limited the interpretation of effectiveness. Thirdly, numerous studies measured interventions only once and others multiple times over short time frames (days *v* month, or no timeframe). Additionally, the meta-analytical portion of this study was limited by significant heterogeneity observed across studies, which could neither be explored nor explained by subgroup analyses or meta-regression. Finally, we quantitatively assessed only publications that reported individual measures; studies that assessed multiple measures simultaneously were narratively analysed with a broader level of effectiveness (see supplementary material 3, table 3). Also, we excluded studies in languages other than English.

Methodological limitations of studies included in the review

Several studies failed to define and assess for potential confounders, which made it difficult for our review to draw a one directional or causal conclusion. This problem was mainly because we were unable to study only one intervention, given that many countries implemented several public health measures simultaneously; thus it is a challenge to disentangle the impact of individual interventions (ie, physical distancing when other interventions could be contributing to the effect). Additionally, studies measured different primary outcomes and in varied ways, which limited the ability to statistically analyse other measures and compare effectiveness.

Further pragmatic randomised controlled trials and natural experiment studies are needed to better inform the evidence and guide the future implementation of public health measures. Given that most measures depend on a population's adherence and compliance, it is important to understand and consider how these might be affected by factors. A lack of data in the assessed studies meant it was not possible to understand or determine the level of compliance and adherence to any of the measures.

Conclusions and policy implications

Current evidence from quantitative analyses indicates a benefit associated with handwashing, mask wearing, and physical distancing in reducing the incidence of covid-19. The narrative results of this review indicate an effectiveness of both individual or packages of public health measures on the transmission of SARS-CoV-2 and incidence of covid-19. Some of the public health measures seem to be more stringent than others and have a greater impact on economies and the health of populations. When implementing public health measures, it is important to consider specific health and sociocultural needs of the communities and to weigh the potential negative effects of the public health measures against the positive effects for general populations. Further research is needed to assess the effectiveness of public health measures after adequate vaccination coverage has been achieved. It is likely that further control of the covid-19 pandemic depends not only on high vaccination coverage and its effectiveness but also on ongoing adherence to effective and sustainable public health measures.

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Supplementary information: additional material

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Cc:	Carolyn McCoy; Andy Baker-White; Marcus Plescia; Meredith Allen; Grace Lee; Ericka McGowan; Patricia Vinson; Griffin, Jenny
Subject:	Materials for Tuesday"s ASTHO IDPC call
Date:	Sunday, November 14, 2021 7:29:07 AM
Attachments:	image001.png IDPC Agenda November 2021.docx DRAFT - Public Health Authority Policy Statement.001.docx Preparing for the Next Pandemic white paper draft_11.11.21.docx

Hello IDPC members,

Attached please see the agenda and 2 documents for discussion at the IDPC meeting scheduled for **Tuesday, November 16 at 12:00 PM ET.**

We look forward to speaking with you then.

Kate

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PUBLIC HEALTH AUTHORITY TO PREVENT AND CONTROL THE SPREAD OF COMMUNICABLE AND INFECTIOUS DISEASE

POSITION

The Association of State and Territorial Health Officials (ASTHO) supports the establishment of robust public health legal authorities to facilitate the timely and adequate response to communicable and infectious disease outbreaks. These legal authorities are often exercised without the need of an emergency declaration and may allow, among other things, the abatement of nuisances, investigation of the causes of disease, institution of quarantine measures, ordering individuals or groups to isolate, conducting contact tracing and case investigations, collecting data, temporarily limiting or canceling public events, temporarily restricting or closing venues, and requiring vaccination verification for certain conduct and activities (e.g., school attendance). Beyond their use in the response to the historic pandemic caused by the novel coronavirus, in the past, these powers have been routinely exercised for more commonly experienced disease outbreaks, such as mumps and measles. Additionally, other societal sectors, such as business, education, cultural, and religion often depend on public health to stop the spread of infectious disease, prevent widespread disruptions, and quell public anxiety and fear. Maintaining these state and territorial legal authorities are key to being prepared for communicable and infectious disease outbreaks both now and in the future.

Summary of Recommendations:

- Public health legal authority that facilitates a skillful response to disease outbreaks without undue delay.
- Public health authorities that are guided by data and science.
- Ensure that public health authority balances individual rights with the responsibility to protect the public's well-being.
- Support public health authority that is reasonable and aligned with disease prevention and control activities.
- Public health legal authority that is able and sufficient to respond to future disease

BACKGROUND

Establishing and using legal authority to control the spread of infectious disease dates to before the founding of the country. For example, colonial governments implemented isolation and quarantine precautions for incoming ships to prevent the introduction and spread of smallpox and other contagions.[1] These powers and activities were seen not only as a way of protecting the health of the local communities but also protective of trade and commerce.[2] As the scientific understanding of communicable and infectious disease grew, new tools such as contact tracing, disease investigation, data collection, and vaccines were added to public health's legal authority and practice. During the current pandemic public health authority has been used, with evidenced benefit, to slow the spread of the coronavirus by limiting the size of gatherings, encouraging social distancing, temporarily closing high-risk venues, and requiring the use of face coverings in certain places.[3,4,5,6,7,8,9]

Despite the successes in exercising public health authority, grave questions and negative perceptions about the role and use of public health powers in response to the pandemic and, by implication, future infectious disease outbreaks have arisen. Over the last year, the critical attitude toward the pandemic response has led to the rolling back of public health authority in several jurisdictions.[10] The reductions in public health legal authority will conceivably make it more difficult to respond to future disease outbreaks. As state and territorial policy makers

continue to address the many issues related to the current pandemic, they are encouraged to consider these potential impacts and costs.

RECOMMENDATIONS

With regards to state and territorial public health authority to prevent and control the spread of communicable and infectious disease, ASTHO recommends:

- Maintaining public health's ability to implement non-medical and medical interventions (e.g., social distancing and distribution of vaccines) swiftly and adeptly by resisting the establishment of administrative burdens that delay public health action, endangers the public and leaves our community vulnerable to infectious disease outbreaks.
- Support evidence-based laws and policies related to the identification, prevention, and control of communicable and infectious diseases.
- Ensure that public health legal authority properly and adequately balances the rights of individuals with the responsibility and obligation to protect the public's health and well-being. Law and policy that undermines and encumbers public health decision making or arbitrarily limits the scope of public health authority, can impede the ability to prevent and control the spread of disease.
- Maintain public health legal authority that is reasonable and aligned with the preventing and controlling the spread of infectious disease. For example, individuals subject to isolation or quarantine should be guaranteed the right to due process, allowed to petition a court to review the government's action, and ensured of reducing any economic, social, or emotional harm. Additionally, public health authority should be able to align with disease it is confronted and allowed to be exercised in a way to address the identifiable characteristics of the disease.
- Ensure public health legal authorities that are appropriate and necessary for the prevention and control of future communicable and infectious disease outbreaks. Other airborne, highly contagious illnesses, like measles, can be effectively contained by implementing public health measures similar to those that have been questioned during the pandemic. Furthermore, the next major public health threat may spread in other ways meaning public health authority must be able to respond to novel, unknown diseases.

APPROVAL DATES

Prevention Policy Committee Approval:
Board of Directors Approval:
Policy Expires:

ASTHO membership supported the development of this policy, which was subsequently approved by the ASTHO Board of Directors. Be advised that the statements are approved as a general framework on the issue at a point in time. Any given state or territorial health official must interpret the issue within the current context of his/her jurisdiction and therefore may not adhere to all aspects of this Policy Statement.

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Infectious Disease Policy Committee

Agenda

November 16, 2021

12:00 p.m. ET

Join Zoom Meeting
https://astho.zoom.us/j/97444170576?pwd=bWRZVDdNTVdqWXZQSlFjbHIvQ2gwZz09

Meeting ID: 974 4417 0576
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Thomas Dobbs (MS), Scott Harris (AL), Jose Romero (AR), Nirav Shah (ME), Terry Dwelle (Alumni-ND), Kristen Ehresmann (AIM rep - MN), David Lakey (Alumni-TX), Randy Mayer (NASTAD Rep – IA), Joe McLaughlin (CSTE Rep - AK), Jeff Stover (NCSD Rep -VA)

Call Agenda:

12:00 p.m.	**Roll Call**	Dr. Thomas Dobbs (MS), Chair
12:05 p.m.	**Welcome**	Dr. Thomas Dobbs (MS), Chair
12:10 p.m.	**Flexible Funding for Public Health discussion update**	Carolyn McCoy, Senior Director, Government Affairs (ASTHO)
12:20 p.m.	***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease*** draft policy statement	Andy Baker-White, Senior Director, State Health Policy (ASTHO)
12:35 p.m.	***Preparing for the Next Pandemic/Public Health Crisis*** white paper overview and discussion	Dr. Thomas Dobbs (MS), Chair
12:50 p.m.	**Open Discussion/Topics for Future IDPC Calls**	IDPC members
1:00 p.m.	**Adjourn**	

astho™

Preparing for the Next Pandemic/Public Health Crisis: Lessons from the Last Decade and Beyond

- Audience: those developing/enacting policy and those implementing those policies

Core concepts/Needs:

- Strong and ever-ready public health core infrastructure
- Ready and available funding sources
- Public health must demonstrate credibility, depoliticize response(s), and champion health literacy.

Background

ASTHO will describe how programs, policy, and partnerships adapted and evolved during the COVID-19 pandemic response and propose approaches to sustain gains and/or respond in areas where gaps were identified. ASTHO will draw from peer networks, policy committees, and other stakeholders to collect lessons learned. The white paper will provide recommendations for policymakers for future responses. The background will include a summary of the:

- Historical context of public health crises during the last decade+
    - H1N1
    - Ebola
    - Zika
    - COVID

- Impact of public health crises on highlighting health disparities and inequities
- The need to support ongoing health literacy improvements nationally

<u>Barriers/Challenges, Solutions, and Lessons Learned</u>

Depoliticization of public health

- Public health principles and recommendations were challenged by many of our elected officials during the COVID-19 response. Public health must secure protection and support from leaders for future responses.
- Roles for state and federal public health and elected officials must be further clarified to allow for clearer crisis response.
    - There is a need for federal officials to initiate a review process to define more clearly the respective roles and responsibilities of public health officials at the federal, state, and local levels during a global pandemic.[1]
- Public health must practice good communication before, during, and after a crisis. Misinformation about the COVID-19 pandemic caused confusion, substandard uptake of COVID-19 vaccines, some in the public rejecting public health measures, and has led to harassment and violence against public health, health, and other frontline workers.[2]

- Improve communication will help to build support for public health for the future.[3]
- Governments can:
    - Convene partner organizations
    - Increase investment in research on misinformation
    - Continue to modernize public health communications
    - Increase resources and technical assistance to state and local public health agencies
    - Expand efforts to build long-term resilience to misinformation.[2]

Advancing Health Equity

- **Communities play a critical role in supporting the clinical response to the pandemic.**
    - Inadequate community engagement can lead to fear, mistrust, and a lack of compliance to public health measures by communities. Communities played a critical role in surveillance, testing, and contact tracing efforts.[4]
    - Communities must be central in the pandemic preparedness and response. Community engagement is not a one-time effort. Risk communication is necessary but not sufficient for successful community engagement and embracing a community resilience approach is needed for future pandemic response.[4]
- **The COVID-19 pandemic disproportionately impacted under-resourced and historically marginalized communities, who have faced both poorer health and economic outcomes.**
    - Social determinants of health have historically prevented populations from having fair opportunities for economic, physical, and emotional health, and the pandemic has exacerbated these factors.[7]

Sustainable, Consistent, Flexible and Available Funding

- **Funding should not be overly restricted or prescriptive.**
    - Federal funding is often overly prescriptive, and there is a growing need for more flexible funding to maintain capabilities before and between crises. Funding priorities should be made based on input from state/locals who understand their communities.
    - Funding should always support long-term resiliency and preparedness.
    - The federal funding strategy for public health primarily has favored a crisis-response approach over robust, sustained investment; and fiscal challenges at the state and local levels have further compounded the pressures on health departments nationwide.[5]
    - Strong pre-existing infrastructure is critical and requires steady and flexible federal funding
        - Infrastructure should include collaborations with healthcare, education, etc. and be flexible enough to respond with whatever information is available at the time and change as needed throughout the response.
- **Sometimes state public health must act before guidance is available.**
    - State/Local public health needs to be in a perpetual state of readiness with clear and available sources or emergency funding. This is essential.

- Key among the issues are workforce-related. Diminished funding has resulted in health departments being unable to attract, recruit, and retain the number of professionals with skills needed to respond to health threats.[7]

Conclusion

- Significant funding has provided opportunities for public health to respond to the current crisis, but more is still needed to continue to demonstrate the credibility of public health, depoliticize future responses, protect vulnerable members of society, and plan for the future.

Citations

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From: Mississippi Health Advocacy Program
To: Byers, Paul
Subject: Medicaid News & Updates: October 13, 2020
Date: Tuesday, October 13, 2020 11:24:25 AM

October 13, 2020

Medicaid News & Updates

Mississippi lawmakers hear from doctors on what they'd

like to see in next Medicaid tech bill

October 12, WLBT, Courtney Ann Jackson - While Medicaid expansion wasn't brought up by lawmakers, the president of the state medical association ended his remarks with this request. "Inexcusably, we have forgone billions in federal assistance that would've helped our most vulnerable citizens," said Dr. Mark Horne. "We ask the legislature to act on expanding coverage in the upcoming session." The Mississippi Health Advocacy Program points to Medicaid expansion gaining new ground in other states that previously rejected it. "COVID 19 has caused us to re-evaluate our healthcare policies and choices," said Roy Mitchell, MHAP Executive Director. "So, it's time we re-evaluate our position on Medicaid expansion as well. Medicaid expansion has proven to save lives. We've got so far to go in correcting all the health inequities of this state. Let's start with Medicaid expansion."

Health care law on line at court, but is it likely to fall?

October 13, 2020, Associated Press, Jessica Gresko and Mark Sherman - The case before the court this year stems from Congress' decision in 2017 to eliminate the law's unpopular fines for not having health insurance. Despite repealing the fines, lawmakers left in place the law's requirement that virtually all Americans have coverage. Texas and other conservative-led states argue that the change makes the requirement unconstitutional and also dooms the rest of the law because the mandate was so central to it. But the court could simply "sever" the mandate from the law and leave the rest of the law alone. Many observers see that as a likely outcome and note the upheaval that would result across the American healthcare system if the law were to be struck down in its entirety. Before the Supreme Court's term began in October, Paul Clement, who argued in the 2012 Affordable Care Act case, said he wasn't sure that the addition of a new justice would change the outcome of the case. He suggested that it is unlikely that the whole statute will fall.

Mississippi Health Department makes free COVID-19 rapid testing available

October 12, 2020, The Clarion Ledger, Alissa Zhu - The Mississippi State Department of Health is making free rapid testing available at its drive-through community test sites, State Health Officer Dr. Thomas Dobbs announced Monday. Rapid test results will be returned within 15 minutes, but it's unclear how accurate they will be, Dobbs said. Rapid tests are done in the "front of the nose," as opposed to the deeper PCR tests MSDH has been using, he said. If people choose to take the rapid test, they will also receive a PCR test, the results of which will be returned within a few days, he said. They can also choose to take the PCR test only.

Almost two weeks without mask mandate, COVID-19 indicators trend in "wrong direction"

October 13, 2020, Mississippi Today, Alex Rozier - The seven-day average for new COVID-19 cases in Mississippi is now at 646, a 24% rise in the last week alone, and a 25% increase since Gov. Tate Reeves lifted the statewide mask mandate on Sept. 30.

Even as the Economy Grew, More Children Lost Health Insurance

October 9, The New York Times, Margot Sanger-Katz and Abby Goodnough - The share of children with health coverage in the United States fell for the third consecutive year in 2019, according to census data, after decades of increases. The decline occurred during a period of economic growth — before the coronavirus pandemic caused broad job losses that might have cost many more Americans their health insurance. A report Friday by the Georgetown Center for Children and Families found that the ranks of uninsured children grew the most in Texas and Florida, and that Latino children were disproportionately affected. Nationally, the number of children without health insurance rose by 320,000 last year alone, to a total of nearly 4.4 million children, the report found.

Cities and counties continue mask mandates as statewide order expires

October 8, 2020, MPB News, Kobee Vance - New coronavirus cases and hospitalizations have increased this week in Mississippi, and health officials have concerns about residents not wearing masks in public. The Governor chose not to extend his mask mandate last week, but some local officials have extended orders in their jurisdiction. Tupelo Mayor Jason Shelton has mandated face coverings be worn in public until November 11th. He says he's following recommendations of local health experts and says he's concerned that leaders like the President are discouraging mask usage. "The President kinda came across as anti-mask. That was [at] the debate on Tuesday. The next day you see his acolyte, Governor Reeves, do away with the mask requirement in the state of Mississippi," says Mayor Shelton. "That leads to people in the city of Tupelo refusing to wear a mask, and they're going to end up in the hospital or even worse."

Mississippi will not mandate masks at the polls ahead of Nov. 3 election

October 7, 2020, Daily Journal, Mississippi Center for Investigative Reporting, Jerry Mitchell - In Mississippi, those entering a school, a Wendy's or a Walmart must wear masks to prevent the spread of COVID-19. But those entering packed polling places don't have to don one."This is absolute insanity," said Dr. Claude Earl Fox III, a Mississippi native and former head of public health in Alabama. "What's to be gained by a no-mask requirement on Election Day?" Mississippi Secretary of State Michael Watson says masks can't be mandated at the polls this November because it's a federal election.
Assistant Secretary of State Kendra James explained that while their office recommends wearing masks, "the governor, nor anyone else, may impose requirements on voting. No entity other than Congress, the Mississippi Legislature or a validly enacted constitutional amendment may place requirements, such as wearing a mask, on voters."

Dr. Dobbs Warns Of COVID Surge, as State Fair Opens Without Mask Mandate

October 7, 2020, Jackson Free Press, Nick Judin - Only a week after Gov. Tate Reeves lifted the state's mask mandate, Mississippi's coronavirus numbers have reversed course, showing the first consistent signs of a new surge in what would be the third spike in the pandemic in the Magnolia State. The Mississippi State Department of Health announced 975 new cases of COVID-19 late last night, the highest single-day total since Aug. 19.

For-profit nursing homes in Mississippi had 3 times more COVID-19 deaths, analysis shows

October 7, 2020, The Clarion Ledger, Jerry Mitchell, Jayme Fraser and Kristine De Leon, Mississippi Center For Investigative Reporting - Twice as many residents caught COVID-19 at Mississippi's for-profit nursing homes, and nearly three times more died there, an analysis of health data by the Mississippi Center for Investigative Reporting shows. The average number of confirmed COVID-19 cases in these for-profit homes? Four in 10 residents. One possible factor: 80% of Mississippi's nursing homes had already been cited for infection-control problems before the pandemic hit. Charlene Harrington, a professor emeritus at the University of California at San Francisco who discovered similar results in a just-released study of nursing homes in California, said the current pandemic is exposing problems that have persisted for decades. "We've just looked the other way for 30 years," she said.

Mask Use Dropping Rapidly After Mississippi Mandate Ends, Dr. Dobbs Warns

October 6, 2020, Jackson Free Press, Julian Mills and Nick Judin - State Health Officer Dr. Thomas Dobbs is sounding the alarm, warning that mask usage is declining in Mississippi immediately after the governor lifted the statewide mask requirement. "Listen to the secret of Sweden's COVID response," Dobbs tweeted on Sunday, Oct. 4. "Near universal, voluntary compliance with public health guidance. Please mask up. Discouraging to see mask use dropping off so rapidly after mandate lifted."

Coalition calls for Medicaid expansion

October 2, 2020, MPB, Kobee Vance - Members of Southerners for Medicaid Expansion are holding a vigil honoring the more than 200,000 people who have died from the Coronavirus in the US. The coalition believes by not expanding the healthcare program, it has hurt the south's response to the coronavirus pandemic, especially for essential workers who's jobs are low pay. Dr. Charlene Collier with the state Department of Health says the coronavirus only made health disparities worse. "One of those being not having health insurance and access to adequate healthcare so even when you're thinking you're sick you don't have a doctor to start your care with, and then once you do finally get coverage, it's often for something that's more catastrophic, so not getting that early preventive care," says Dr. Collier.

Resource of the Week

Children's Uninsured Rate Rises by Largest Annual Jump in More Than a Decade

October 8, 2020, Georgetown University, Joan Alker and Alexandra Corcoran - For many years, the United States was on a positive trajectory in reducing the number and rate of uninsured children; in 2016, the nation attained a historic low of 3.6 million uninsured children. This progress occurred as a result of expansions of public coverage—primarily Medicaid and the Children's Health Insurance Program (CHIP)—and was accelerated by the implementation of the Affordable Care Act's (ACA) major coverage expansions in 2014. As employer-sponsored insurance became increasingly unaffordable for dependents, public coverage ameliorated the impacts of private coverage losses for children. However, the number of uninsured children began to increase in 2017 as Medicaid enrollment began to decline, and as Figure 1 shows, reached 4.4 million in 2019. This represents an increase of 726,000 children during this three-year period. The rate of uninsured children rose a full percentage point from 4.7 percent to 5.7 percent. Much of the gain in coverage that children made as a consequence of the ACA's major coverage expansions has now been eliminated. Moreover, the most recent year of data (2018 to 2019) shows the biggest one-year loss in children's coverage during this time period, with 320,000 more children becoming uninsured. These coverage losses occurred in a healthy economy with the lowest unemployment rate in decades prior to the economic shocks and job loss associated with the COVID-19 pandemic.

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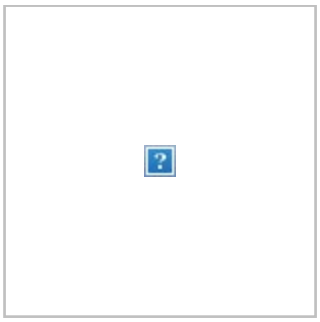

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From: Kaye Bender
To: Dobbs, Thomas E
Cc: Griffin, Jenny
Subject: Modernizing Public Health Report
Date: Thursday, December 2, 2021 1:48:46 PM
Attachments: PublicHealthForwardReportfromBipartisanPolicyCenter.pdf

---

I am sure that you got this from ASTHO, but in case not, I am sending it along. Was released today.

Kaye

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Bipartisan Policy Center

Public Health Forward: Modernizing the U.S. Public Health System

December 2021

MS-DOH-21-1816-A-001055

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ACKNOWLEDGMENTS

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MS-DOH-21-1816-A-001058

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MS-DOH-21-1816-A-001059

Call to Action for State, Territorial, and Local Policymakers to Move Public Health Forward

THE OPPORTUNITY

COVID-19 exposed numerous, long-standing, and deep fractures in our public health system and highlighted pervasive disparities among communities regarding factors that affect an individual's physical and mental health – access to affordable and nutritious food options, safe and affordable housing, financial security, and quality, affordable medical care. The infusion of federal relief funds presents policymakers with a historic opportunity to correct these problems and set a new course for health in the United States that advances health equity and enables each person to achieve their best health.

Public health serves a critical yet often invisible role in health. Although a disproportionate amount of attention is placed on medical care and the treatment of diseases, illnesses, and injuries, public health takes a community-wide approach to improving health and the social factors that contribute to good health. Healthy behaviors, social and economic factors, the physical environment, and other issues account for 80% of health outcomes, while clinical care is responsible for only 20%.[1] Through such activities as promoting healthy eating and active living, controlling infectious disease outbreaks, and preventing injuries, public health efforts allow Americans to live longer, healthier lives and is essential to the viability and prosperity of communities across the country. However, many Americans do not recognize the value that public health systems bring to their communities until these systems are most needed.

Public Health Forward: Modernizing the U.S. Public Health System defines a vision for health in the 21st century and provides a practical, prioritized, bipartisan set of actions for policymakers and public health officials to guide strategic investments and decision-making to achieve this vision. These actions are informed by evidence, build on previous consensus frameworks and objectives, and represent work by national thought leaders that has the support of public health practitioners across the country. **The nation's safety, security, and economic prosperity depends on a strong public health system.** ***We respectfully urge state and local policymakers to act now to fully realize the potential of this unique moment and secure the future of the public's health.***

THE VISION

In 2026, the United States is becoming a healthier nation because elected and public health officials seized the historic opportunity to invest in new and transformative ways to modernize the governmental public health system. The system is prepared to respond to a range of public health challenges, including a pandemic, obesity, mental illness, substance abuse, and climate change. In a healthier America:

- **Advances in health equity continue to be made** because public health departments partner with various sectors (e.g., housing, food, transportation), stakeholders (e.g., businesses, faith-based organizations, community-based organizations (CBOs), health care), and community members, and also engage in Tribal consultation, toward the shared goal of providing a fair and just opportunity for all to achieve good health and well-being.
- **Sufficient, predictable, and flexible public health funding supports the public health system** to sustain healthy communities. States, territories, and localities act quickly to protect the public from expected and unexpected health issues. This means that all public health departments have the necessary resources to support nationally agreed-upon core programs and cross-cutting skills and to meet national public health practice standards.
- **A robust, modern, interoperable, and secure public health information system delivers real-time, accurate, and actionable data** to help public health officials detect new or growing threats, identify groups that may be at risk, and respond quickly with tailored policy, practice, and program interventions. Public health departments also translate and share data with policymakers and other stakeholders in a timely manner.
- **Modernized laws, policies, and statutes** protect and promote the public's health in a manner that reflects ongoing threats and challenges, enables public health officials to make decisions without political influence, and ensures public health responsibilities remain intact and protected.
- **A highly skilled, trained, and diverse public health workforce** provides evidence-informed programs and services that address community health needs, encourage healthy behaviors, and act swiftly to respond to emerging threats. Staff feel valued and incentives exist to pursue long careers in governmental public health.

RECOMMENDED ACTIONS FOR STATE, TERRITORIAL, AND LOCAL POLICYMAKERS

Financing

1. **Provide flexible funding and maximize existing assets to support public health services and capabilities, including those needed to address health inequities.**

    A. Request assessments on the state of public health systems, specifically nationally agreed-upon core programs and cross-cutting skills needed to support public health everywhere.

        i. Devote funds for conducting these assessments, developing and implementing strategies to fill the gaps, engaging in continual quality improvement, and otherwise working toward meeting national public health practice standards.

    B. Direct appropriate agencies to work together and support this alignment by co-funding programs and strategies to improve health, based on routine needs assessments and improvement plans.

    C. Develop, advocate, and support budgetary mechanisms to facilitate blending and braiding funds from multiple sources, as well as accompanying measures to ensure transparency and accountability.

    D. Allocate funding for health departments to hire and retain a health equity leader who will have direct accountability to state, territorial, and local health directors, and develop measures that demonstrate health equity practices and their achievements.

2. **Evaluate the social and economic impact of public health programs and strategies.**

    A. Invest in public health system evaluation to illustrate the effects of allocations and investments at the state, territorial, and local levels.

Data and Information Technology

1. **Strengthen the collection of timely and actionable public health data to guide programs, respond to emergencies, and address health inequities.**

    A. Invest in modern, efficient, and interoperable information technology that equips state, territorial, and local health departments to:

        i. Collect, analyze, and share timely, accurate, subcounty data on health and health-related issues disaggregated by race, ethnicity, and other key sociodemographic characteristics.

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ii. Work with partners to ensure that data submitted are complete and of high quality.

B. Require that public health data are reported to agencies at all levels of government using interoperable electronic mechanisms.

2. **Invest in data sharing between public health departments and health care entities.**

A. Remove or support the removal of technical and legal barriers to data system interoperability with health care systems and Tribal health entities while ensuring that sufficient security safeguards are in place to achieve compliance with the Health Insurance Portability and Accountability Act (HIPAA).

B. Ensure that data sharing regulations are secure without being onerous.

i. Proactively support and incentivize partnerships that utilize official Memorandum of Agreement (MOU) documents to guide their collaboration.

C. Through legislation, require adherence to standards of the Office of the National Coordinator for Health Information Technology and the Centers for Disease Control and Prevention (CDC) for the collection and sharing of common data points.

Workforce

1. **Invest in the recruitment and retention of a diverse and inclusive governmental public health workforce.**

A. In partnership with local health departments, perform a statewide public health workforce needs assessment and fund public health department assessments of organizational culture.

B. Establish or promote robust and equitable employment programs on the state, territorial, and local levels to recruit, hire, and retain the next generation of public health practitioners, with a particular focus on individuals from communities experiencing health inequities.

2. **Improve hiring and promotion policies and processes to ensure high-quality public health services.**

A. Modernize existing civil service requirements and institute competitive pay structures to accommodate roles and responsibilities specific or unique to public health.

B. Approve budgets that ensure:

i. The training and professional development of the public health workforce involved with implementing core programs and applying

all necessary cross-cutting skills.

ii. Salary structures that are commensurate with roles and responsibilities and that are competitive with salaries for similar positions in nongovernmental agencies.

Public Health Laws and Governance

1. **Review, evaluate, and modernize public health governance structures and statutory responsibilities.**

   A. Conduct or promote a bipartisan, comprehensive review of existing policies and revise as needed to reflect the current roles and responsibilities of government in protecting and promoting health, including the ability of public health departments to make decisions without undue political influence.

      i. Work across various levels of government to determine the proper federal, state, territorial, and local framework for preemption, establishing minimum and maximum requirements, particularly in light of recent state action to roll back public health powers and place limits on local elected officials.

      ii. Consider how structures, processes, roles, and responsibilities should remain the same or change during a public health emergency; this task should include ensuring flexibility in personnel and procurement processes.

      iii. Examine whether existing funding streams are sufficient to support the revised public health governance structures and statutory authorities; elevate funding needs to relevant appropriators to fill gaps.

      iv. Ensure the law as written promotes trust through the removal of stigmatizing language, particularly as it relates to populations experiencing health inequities.

   B. For policymakers in jurisdictions adjacent to or containing sovereign Tribal Nations and health systems, review lines of communication and opportunities for formalized partnerships.

   C. Ensure that public health department leaders are empowered to make decisions without inappropriate political influence and have access to counsel with expertise in public health law.

2. **Support and clearly communicate the roles of public health departments to the public.**

   A. Invest in evidence-informed messaging and effective communication by health departments, using multiple platforms.

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i. Use all media outlets, including online and social media vehicles.

ii. Use media outlets serving subpopulations, including those in different languages.

B. Coordinate messaging with and across public health departments, both during emergency and non-emergency situations.

i. Ensure messaging is culturally competent.

ii. Use language that elicits a sense of trust in government.

C. Engage with constituents during public health emergencies to correct misinformation and explain the role of public health departments.

D. Provide forums for stakeholders in public health, the business community, and health care to identify shared goals and strategies that reflect public health authorities, public health protection, and a strong and stable economy.

Partnerships

1. **Incentivize partnerships between public health departments and other sectors (e.g., housing, food, transportation) and stakeholders (e.g., business, faith-based organizations, health care).**

   A. Allocate funding to support the development and maintenance of partnerships that aim to provide a fair and just opportunity for all to achieve good health and well-being.

2. **Establish a dedicated body charged with routinely monitoring, assessing, and influencing the implications for health in all government sector policy discussions.**

   A. Establish and participate in an advisory board that integrates and articulates health considerations into policymaking across all government sectors to improve the health of people and communities.

   B. Conduct health impact assessments on legislation to identify potential connections between health and factors that affect health (e.g., housing, affordable and nutritious food options, employment, and environment).

Community Engagement

1. **Invest in long-term relationship-building and partnership development with residents and community-based organizations (particularly those serving communities experiencing health inequities) and in Tribal consultation.**

A. Allocate funds to public health departments for community collaboration and develop output measures that account for progress toward building trust and working in partnership.

B. Engage in routine Tribal consultation to support intergovernmental public health planning that recognizes Tribal authority, autonomy, and self-governance.

C. Act as liaisons between public health departments and citizen representatives, especially from communities historically experiencing health inequities, who can elevate on-the-ground concerns and offer their input on public health issues.

2. **Invest in increasing the capacity of community-based organizations (CBOs) and provide resources to support collaboration with public health departments.**

   A. Allocate funds to support the capacity-building of CBOs.

   B. Lead regular town halls and forums with CBOs and public health officials to present evidence-based information that deepens understanding of health inequities, their causes, and their consequences.

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Call to Action for State, Territorial, and Local Public Health Departments to Move Public Health Forward

THE OPPORTUNITY

COVID-19 exposed numerous, long-standing, and deep fractures in our public health system and highlighted pervasive disparities among communities regarding factors that affect an individual's physical and mental health – access to affordable and nutritious food options, safe and affordable housing, financial security, and quality, affordable medical care. The infusion of federal relief funds presents policymakers with a historic opportunity to correct these problems and set a new course for health in the United States that advances health equity and enables each person to achieve their best health.

Public health serves a critical yet often invisible role in health. Although a disproportionate amount of attention is placed on medical care and the treatment of diseases, illnesses, and injuries, public health takes a community-wide approach to improving health and the social factors that contribute to good health. Healthy behaviors, social and economic factors, the physical environment, and other issues account for 80% of health outcomes, while clinical care is responsible for only 20%.[2] Through such activities as promoting healthy eating and active living, controlling infectious disease outbreaks, and preventing injuries, public health efforts allow Americans to live longer, healthier lives and is essential to the viability and prosperity of communities across the country. However, many Americans do not recognize the value that public health systems bring to their communities until these systems are most needed.

Public Health Forward: Modernizing the U.S. Public Health System defines a vision for health in the 21st century and provides a practical, prioritized, bipartisan set of actions for policymakers and public health officials to guide strategic investments and decision-making to achieve this vision. These actions are informed by evidence, build on previous consensus frameworks and objectives, and represent work by national thought leaders that has the support of public health practitioners across the country. **The nation's safety, security, and economic prosperity depends on a strong public health system.** ***We respectfully urge state and local public health officials to act now to fully realize the potential of this unique moment and secure the future of the public's health.***

THE VISION

In 2026, the United States is becoming a healthier nation because elected and public health officials seized the historic opportunity to invest in new and transformative ways to modernize the governmental public health system. The system is prepared to respond to a range of public health challenges, including a pandemic, obesity, mental illness, substance abuse, and climate change. In a healthier America:

- **Advances in health equity continue to be made** because public health departments partner with various sectors (e.g., housing, food, transportation), stakeholders (e.g., businesses, faith-based organizations, community-based organizations (CBOs), health care), and community members, and also engage in Tribal consultation, toward the shared goal of providing a fair and just opportunity for all to achieve good health and well-being.
- **Sufficient, predictable, and flexible public health funding supports the public health system** to sustain healthy communities. States, territories, and localities act quickly to protect the public from expected and unexpected health issues. This means that all public health departments have the necessary resources to support nationally agreed-upon core programs and cross-cutting skills and to meet national public health practice standards.
- **A robust, modern, interoperable, and secure public health information system delivers real-time, accurate, and actionable data** to help public health officials detect new or growing threats, identify groups that may be at risk, and respond quickly with tailored policy, practice, and program interventions. Public health departments also translate and share data with policymakers and other stakeholders in a timely manner.
- **Modernized laws, policies, and statutes** protect and promote the public's health in a manner that reflects ongoing threats and challenges, enables public health officials to make decisions without political influence, and ensures public health responsibilities remain intact and protected.
- **A highly skilled, trained, and diverse public health workforce** provides evidence-informed programs and services that address community health needs, encourage healthy behaviors, and act swiftly to respond to emerging threats. Staff feel valued and incentives exist to pursue long careers in governmental public health.

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RECOMMENDED ACTIONS FOR PUBLIC HEALTH DEPARTMENTS

Financing

1. **Provide flexible funding and maximize existing assets to support public health services and capabilities, including those needed to address health inequities.**

   A. Develop accountability measures for all funding streams.

   B. Assess public health systems, including evaluating current investments and capacity, identifying gaps in core programs and cross-cutting skills, and analyzing whether they meet national public health standards.

   C. Embed principles of health equity in core programs and cross-cutting skills and dedicate resources as needed to ensure they are operational.

   D. Collaborate with the state Medicaid agency to identify opportunities to co-fund health initiatives targeting communities experiencing health inequities.

   E. As appropriate, explore resource sharing arrangements with neighboring departments to fill in gaps or increase effectiveness and efficiency of foundational public health services.

2. **Evaluate the social and economic impact of public health programs and strategies.**

   A. Develop a dashboard to track high-level expenditures and progress toward meeting shared goals and targets.

Data and Information Technology

1. **Strengthen the collection of timely and actionable public health data to guide programs, respond to emergencies, and address health inequities.**

   A. Consistently collect data needed to identify, document, and address health inequities in local communities.

   B. Work with partners to submit data to public health departments that is timely, accurate, and complete.

   C. Share and display this data in real time, with user-friendly data dashboards available to other governmental agencies and the public.

2. **Invest in data sharing between public health departments and health care entities.**

A. Develop and implement policies and procedures that adhere to the standards of the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Disease Control and Prevention (ONC/CDC).

B. Ensure that those reporting data are adhering to ONC/CDC standards.

C. Enter into data-sharing agreements with Medicaid agencies.

Workforce

1. **Invest in the recruitment and retention of a diverse and inclusive governmental public health workforce.**

   A. Determine the number and type of staff needed to provide public health services.

   B. Formalize partnerships and programs with academic institutions including Historically Black Colleges and Universities, Hispanic-Serving Agricultural Colleges and Universities, and Tribal Colleges and Universities—local boards of health, and technical training programs to build a cross-disciplinary workforce and provide students with experiential opportunities in public health.

   C. Work with partners to expand internships, fellowships, workforce pipeline, loan-repayment, and other career on-ramp programs.

      i. Provide tailored opportunities to individuals in under-represented populations.

   D. Hire outreach workers who live in communities experiencing health inequities to assist with building trusting relationships and engaging community members.

   E. Assess organizational culture and make changes as needed to ensure the workplace is culturally competent and supportive of all staff.

2. **Improve hiring and promotion policies and processes to ensure high-quality public health services.**

   A. Partner with leaders in government reform to update merit systems, civil service requirements, position descriptions, and human resources systems.

   B. Provide professional development opportunities, giving public health workers the skills and knowledge needed to meet modern public health challenges (e.g., change management, data science skills, and cultural and linguistic competencies).

   C. Work to secure a full complement of health supports to prevent burnout and turnover, including mental health services and comprehensive paid leave.

Public Health Laws and Governance

1. **Review, evaluate, and modernize public health governance structures and statutory responsibilities.**

    A. Direct counsel with public health law expertise to review existing regulations and ensure they are relevant, provide the ability to protect the health of the public, and are legally sound.

    B. Ensure that opportunities for public input in rule-making processes are widely publicized, transparent, and easily accessible.

        i. Specifically solicit feedback from those who will be most affected by new rules.

2. **Support and clearly communicate the roles of public health departments to the public.**

    A. Develop and maintain ongoing relationships with local and statewide media.

    B. Develop, routinely update, and implement a communications plan that articulates public health responsibilities.

    C. Maintain the expertise to develop and implement a risk communications strategy.

Partnerships

1. **Incentivize partnerships between public health departments and other sectors (e.g., housing, food, transportation) and stakeholders (e.g., business, faith-based organizations, health care).**

    A. Clearly delineate shared goals, respective responsibilities, and collaboration guidelines for decision-making, conflict resolution, and data sharing; use this as a foundation for sustainable collaborations.

2. **Establish a dedicated body charged with routinely monitoring, assessing, and influencing the implications for health in all government sector policy discussions**

    A. Provide examples and evidence-informed practices to support health impact assessments and policy discussions.

Community Engagement

1. **Invest in long-term relationship-building and partnership development with residents and community-based organizations, particularly those serving communities experiencing health inequities, and engage in Tribal consultation.**

A. Dedicate staff time to long-term community engagement efforts.

B. Compensate community members and organizations for their time and expertise on planning and implementing health improvement strategies and actions.

C. Invest in and formalize consultation practices between state and local health departments and Tribal health departments to address community-wide health planning and decision-making.

2. **Invest in the capacity of community-based organizations (CBOs) and provide resources to support collaboration with public health departments.**

   A. Formalize public health planning and processes that rely on input from, and share decision-making with, CBOs and the people they serve.

   B. Work with CBOs to identify opportunities to strengthen their organizational capacity and dedicate staff time and funds to mentor and train on topics such as grant writing, grant reporting, data collection and analysis, project evaluation, and publishing academic papers.

Introduction

COVID-19 has made clear that the nation's safety, health, and economic prosperity depend on its ability to minimize the effects of devastating public health threats. Even in the absence of an emergency, a robust governmental public health system is needed to ensure conditions in which all people can achieve their fullest potential for health and well-being. Although clinical health care plays an important role in treating disease, public health plays an equally important but largely invisible role in keeping people healthy.

Public health seeks to protect the health of entire populations through the promotion of healthy lifestyles; the research and applied practice of disease and injury prevention; and the detection and prevention of, as well as response to, infectious diseases.[3] In the 20th century, the average lifespan in the United States increased by 30 years, with 25 of those years attributable to public health advances.[4] These advances included safer food and water, improvements in motor vehicle safety due to the addition of features such as seat belts and changes in highway design, and widespread vaccinations, which have drastically reduced the rate of many diseases, especially for children. And yet, decades of decreased funding for public health has hampered its ability to make meaningful advances in tackling challenges such as the obesity and opioid epidemics. Chronic underfunding also means that most public health departments do not have the bandwidth to support a growing crisis in mental health or sufficiently prepare for anticipated health crises related to climate change.

Pervasive health inequities, driven by socioeconomic differences in urban, rural, and Tribal communities that have existed for much of the country's history, were also illuminated during the pandemic. These inequities prevent the United States from meeting its full potential, not only as it relates to the health of affected individuals but also to the estimated $93 billion in excess medical care costs and $42 billion in lost productivity per year attributed to health disparities.[5] Because 80% of a person's health can be attributed to socioeconomic factors such as access to nutritious food, quality education, and a safe physical environment,[6] public health should partner with other sectors and government agencies to address these sources of health and reduce inequities.

In addition, the pandemic has worsened behavioral health, with individuals reporting higher levels of stress and more disorders, including depression and anxiety. Traditionally, the health care system has taken a clinical approach to help such individuals. A public health approach to behavioral health as pioneered by cities such as New York and Philadelphia offers promise by strengthening community-based services to meet behavioral needs along a

continuum, not just those requiring clinical intervention, and emphasizing prevention and early intervention.[7]

Compounding all of these challenges, it is an unfortunate reality that public health also has a deep trust problem. Polls conducted in the spring of 2020 showed great support for public health, with 85% of Republicans and 74% of Democrats rating public health officials such as those at the CDC as "doing an excellent/good job responding to the coronavirus outbreak."[8] And yet, an RWJF/Harvard poll conducted from mid-February to mid-March 2021 found something markedly different: Only 44% of respondents trusted the recommendations of their local health department a great deal or quite a lot, and 41% trusted those from their state health department a great deal or quite a lot, leaving the remainder only somewhat trusting them or not trusting them at all.[9] Politicization, misinformation, and mixed communication initiatives are some of the factors responsible for these findings. The lack of trust undermines public safety and the purpose of public health now and in the future.

Public Health Forward: Modernizing the U.S. Public Health System defines a vision for a modernized public health system in the 21st century and provides a framework of practical, prioritized, and bipartisan actions for policymakers and public health officials to guide strategic investments and decision-making to help translate the vision into a reality with a focus on equity. The federal government continues to provide critical leadership and funding to navigate the current pandemic and has a responsibility to make significant investments and changes in public health for the post-pandemic future. Long-term, increased, sustainable funding and policy leadership from the federal government will be crucial to support this five-year vision, framework, and set of actions, as most public health departments are concerned over their funding levels, notwithstanding the recent infusion of money.[10]

Researchers have estimated that it would cost $10.94 billion in additional resources annually, or $34.20 per capita, to fund what experts consider a minimum package of public health services for each state and local public health department.[11] Separate from this project, the Bipartisan Policy Center recently published a report that called for Congress to pass $4.5 billion in permanent annual funding to be distributed to states, localities, tribes, and territories to support foundational public health capabilities, and to reform the existing Prevention and Public Health Fund and increase its annual funding to $4 billion to support public health programs and meet local needs. Departments and agencies with jurisdiction over public health such as the CDC, U.S. Department of Agriculture, and U.S. Department of Health and Human Services (HHS) all make meaningful contributions through the development of regulations, standards, and effective public health messaging and guidance. However, this report's focus is on governmental public health systems at the state, territorial, and local levels, where most public health policy is enacted and

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critical decisions are made regarding the stewardship and allocation of federal funds. While Tribal health systems and public health departments are critical to community health, this report is not intended to provide recommendations to support the modernization of these systems. The report does include recommendations to improve consultation and collaboration between U.S. and Tribal governments to support shared public health priorities. Policymakers and public health leaders must embrace this unique moment and strategically plan and implement a well-resourced, modern public health system that builds capacity at all levels of government and in every state, territory, and locality.

THE OPPORTUNITY

The infusion of federal COVID-19 relief funds is an opportunity to strategically invest in and modernize the public health system. Legislation to improve the sustainability of public health departments includes $7.4 billion for the recruitment and hiring of public health workers and $2.45 billion for emergency preparedness and response purposes. In addition, some of the COVID-19 relief funding packages can be invested in public health departments to provide long-term benefits by supporting public health science, policy, systems, and infrastructure. (See Appendix 1: Federal Investments in Public Health in COVID-19 Relief Legislation for additional details.) Policymakers should use the growing awareness of the importance of the public health field to set a new course for health in the United States, while also fostering greater trust in government and science.

Public Health Forward provides recommended actions to policymakers and public health leaders to steward the use of this one-time infusion to provide long-term strategic benefits to state, territorial, and local public health systems. As noted above, greater, sustained, and less siloed funding will be necessary in the near future to ensure these benefits continue.

The report's recommendations build on several national public health frameworks and reports which articulate the foundational requirements for optimal public health systems. These reports include the following:

- *Public Health 3.0* describes the role of public health departments in the 21st century and calls on public health leaders to serve as Chief Health Strategists for their communities and departments to engage in cross-sector partnerships; upgrade and monitor data systems with an emphasis on hyper-local data; hire a diverse and inclusive workforce; and provide foundational public health capabilities.[12]
- *Foundational Public Health Services* defines the cross-cutting skills and capabilities, as well as the core programs, needed in all health departments to fulfill their responsibilities.[13]

- *Public Health COVID-19 Impact Assessment* examines how public health departments fared during the pandemic, including their key contributions and challenges faced, and identifies "priority areas and policy considerations" for policymakers to develop a 21st century public health system.[14]
- Recommendations by the Robert Wood Johnson Foundation's National Commission to Transform Public Health Data Systems are targeted at government at all levels, businesses, CBOs, philanthropy, and other parties to "reimagine how data are collected, shared, and used, and identify the investments needed to improve health equity."[15]
- CDC's Data Modernization Initiative presents a vision of what the modernization strategy was created to do, guides decisions for allocating resources, and provides a structure to track progress and success along the way.[16]
- The National Consortium for Public Health Workforce Development's report, *Building Skills for a More Strategic Public Health Workforce: A Call to Action*, provides a common framework for modernizing the state, local, territorial, and Tribal public health workforce through recruitment, hiring, and retention priorities.[17]

Additionally, a number of states, including Indiana,[18] Kentucky,[19] Ohio,[20] Oregon,[21] Washington,[22] and others[23] have modernized their public health systems or are in the process of modernizing. These states' efforts are a natural learning laboratory and provide examples of this report's recommendations in action.

In short, we already know what needs to be done, and we urge policymakers and public health officials to seize this unique moment and take action.

METHODOLOGY

The *Public Health Forward* project team was led by a Steering Committee representing national philanthropic foundations, public health membership associations, the Bipartisan Policy Center, and two public health practice consultants. An Advisory Board of national high-level public health leaders and experts also provided valuable input. A research team from the Johns Hopkins Bloomberg School of Public Health reviewed literature on public health frameworks in several focus areas (see Appendix 2) and supported several qualitative research activities to ensure that the project reflected the needs and recommendations from the perspective of public health leaders, practitioners, and community members who have experienced health inequities.

The project team conducted an inclusive mixed methods outreach process that included project oversight, guidance, and key input from critical stakeholders in alignment with the *Public Health Forward* project goals. This mixed-methods

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process was designed to capture real-time perspectives from high-level decision-makers, experts, and front-line practitioners on needs, challenges, and best practices to support public health responsiveness, improved health outcomes for all populations, and performance improvement and innovation. The project's Steering Committee, a Public Health Advisory Board of national public health leaders, and a bipartisan task force representing former elected officials, health care, businesses, and faith-based leaders provided general oversight and guidance to the project team to inform the project goals and recommendations. The team received additional input and feedback throughout the project via:

- Roundtable discussions with experts in each of the six priority areas.
- Listening sessions and town halls with state and local public health officials and staff members (including those in rural areas and big cities); Tribal public health stakeholders; and community-based organizations.
- Follow-up one-on-one interviews to gather additional information on health equity, data transformation, and public health funding challenges.
- An online survey using the Qualtrics XM platform to gather feedback from more than 650 public health stakeholders to understand public health priorities, public health practice opportunities and challenges, and COVID-19 considerations affecting public health system modernization.
- An online survey to gather feedback from roundtable participants on the final actions and recommendations.

All meetings, roundtables, listening sessions, and town halls were conducted and recorded via Zoom. The survey results and session transcripts were analyzed to thematically categorize the responses.

The Vision

In 2026, the United States is becoming a healthier nation because elected and public health officials seized the historic opportunity to invest in new and transformative ways to modernize the governmental public health system. The system is prepared to respond to a range of public health challenges, including a pandemic, obesity, mental illness, substance abuse, and climate change. In a healthier America:

- **Advances in health equity continue to be made** because public health departments partner with various sectors (e.g., housing, food, transportation), stakeholders (e.g., businesses, faith-based organizations, community-based organizations (CBOs), health care), and community members, and also engage in Tribal consultation, toward the shared goal of providing a fair and just opportunity for all to achieve good health and well-being.
- **Sufficient, predictable, and flexible public health funding supports the public health system** to sustain healthy communities. States, territories, and localities act quickly to protect the public from expected and unexpected health issues. This means that all public health departments have the necessary resources to support nationally agreed-upon core programs and cross-cutting skills and to meet national public health practice standards.
- **A robust, modern, interoperable, and secure public health information system delivers real-time, accurate, and actionable data** to help public health officials detect new or growing threats, identify groups that may be at risk, and respond quickly with tailored policy, practice, and program interventions. Public health departments also translate and share data with policymakers and other stakeholders in a timely manner.
- **Modernized laws, policies, and statutes** protect and promote the public's health in a manner that reflects ongoing threats and challenges, enables public health officials to make decisions without political influence, and ensures public health responsibilities remain intact and protected.
- **A highly skilled, trained, and diverse public health workforce** provides evidence-informed programs and services that address community health needs, encourage healthy behaviors, and act swiftly to respond to emerging threats. Staff feel valued and incentives exist to pursue long careers in governmental public health.

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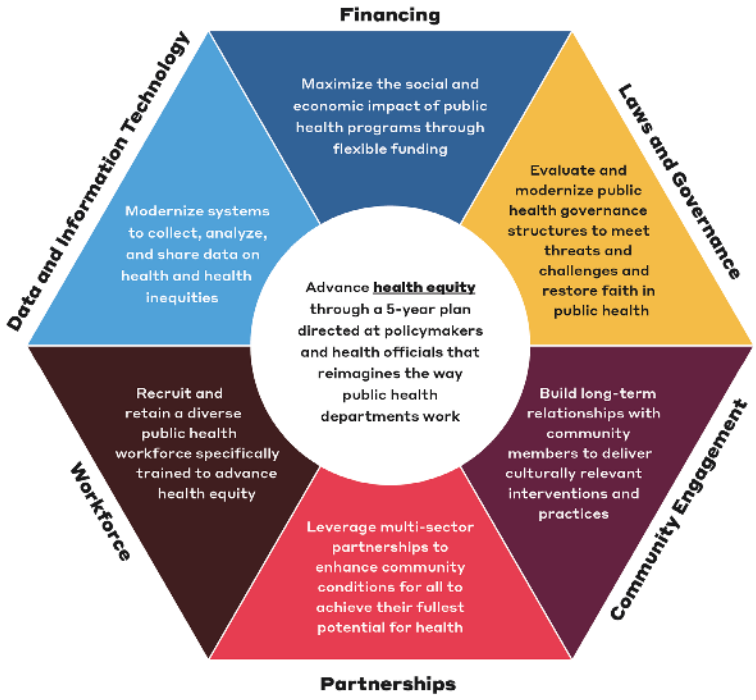
Framework for a 21st Century Public Health System

The country faces tremendous public health challenges beyond the pandemic, including the growing prevalence of obesity and chronic health conditions such as diabetes, mental illness and substance abuse, and the emerging effects of climate change. The mission is daunting but identifying key actions for state and local policymakers and public health officials will enable the United States to prioritize and take the necessary steps in the next five years to plan and implement a system to address these and future, unknown challenges. To manifest its vision of a 21st century public health system, the task force proposes the following framework that consists of action in six core areas.



This framework is designed for elected and public health officials to implement together, and the actions are intended to be tailored to meet the unique needs and realities of each community. This framework, and the actions it supports, is intentionally centered on health equity, which requires addressing the conditions necessary for all people to achieve their fullest potential for health and well-being. These actions, as part of a public health transformation, will drive tangible improvements in health outcomes such as infant mortality, the prevalence of chronic diseases that are the leading cause of death and disability, and mental wellness, and will enable the country to better prevent and address pandemics, natural disasters, lead contamination of water, and other major incidents.

Recommended Actions

Because of federalism, funding resources are directed in most cases to states and territories, where public health policy typically resides. Therefore, this report's focus is the state/territory and its subdivisions. That said, big cities in particular retain many authorities through statute or federal or local funding mechanisms that can lead to implementation of different policies and practices than their state counterparts. The public health system in each state or territory consists of policymakers and public health departments at all levels of government (including, in some places, Tribal Nations), the health care sector, community-based organizations, and others who contribute to the public's health and well-being. In this document, we call on elected policymakers to enact policies that will transform the public health system in their state, and we urge public health department leaders to take specific actions critical to fully implementing policies.

FINANCING

Vision: Sufficient, predictable, and flexible funding supports the public health system *and enables it to sustain healthy communities across the country and act quickly to protect the public from expected and unexpected health issues. All public health departments need the resources, support, and skills to provide core programs, address challenges unique to their jurisdictions, and meet national public health practice standards.*

For many years, public health departments have been forced to rely on limited and inconsistent funding—often in the form of state and federal grants that are restricted to addressing specific diseases and health conditions—to do their work.[24] This siloed approach makes it nearly impossible for public health departments to build the cross-cutting competencies and skills needed to address challenges and health inequities experienced by low-income, rural, Tribal Nations, and communities of color. Accordingly, restrictive funding sources inhibit public health departments by reducing their nimbleness to respond to emerging problems and limiting their ability to address priority issues specific to their jurisdiction and advance health equity. Finally, budget cuts over the past two decades have further hampered the ability of many public health departments to offer basic public health services, not only for COVID-19 and other infectious diseases but for all public health threats and conditions.

Basic public health services, comprising core programs and the skills needed to implement them, are detailed in Foundational Public Health Services, a

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framework developed by national thought leaders and embraced by public health practitioners. Public health departments need sufficient, predictable, and flexible funding to support these core programs and skills – not only in the pandemic's immediate aftermath but also in the long term. Flexible funding refers to multisource funding that gives recipients latitude in usage, particularly to meet local needs that may vary by community, and it stands in contrast to restricted funding. Sound accountability mechanisms are also necessary. Achieving public health accreditation, or being on a pathway to accreditation, is one way for public health departments to demonstrate their adherence to national standards (which include sound fiscal practices). Funding should also incorporate the supports needed for public health departments to participate in the accreditation process.

Resource sharing offers another potential strategy for enhancing the financing of public health departments. By pooling resources and sharing staff, expertise, funds, and programs, local public health departments often accomplish more together than they could alone. Cross-agency resource-sharing agreements take many different forms (in terms of precisely what is shared and how activities are governed) and are driven by what the partners want to achieve. When established by willing partners and developed in a thoughtful and comprehensive manner, sharing arrangements can improve the efficiency and effectiveness of programs and strategies, and thus may merit consideration in some circumstances.[25]

Finally, a solid understanding of the social and economic value of the public health system would well serve the public and policymakers. Many public health functions are invisible and taken for granted; for example, the public typically sees tap water and food as safe for consumption. Sadly, public health programs and services become visible only when a problem arises, for example when inspections identify contamination, or departments issue public warnings and address hazards. More evidence about the effect of public health interventions would provide further accountability and additional justification about the importance of investing in public health.

Action #1: Provide flexible funding and maximize existing assets to support public health services and capabilities, including those needed to address health inequities.

A clear need exists to redesign how funds are allocated and appropriated. We encourage policymakers to blend and braid funds from multiple sources to provide a single pool of funding that supports core programs and cross-cutting skills for all state and local jurisdictions. Accountability mechanisms should be built in to track how funding from each source is spent and what was achieved, with greater focus on outcomes and less focus on reporting. Also, where

appropriate, policymakers can support cross-agency service sharing (following best practices and adapting models developed by the Center for Sharing Public Health Services[26]) as another way of ensuring that jurisdictions are served by core programs and cross-cutting skills in an effective and efficient manner.

Although this report's focus is on short-term activities, long-term funding strategies are needed to sustain a robust public health system. Implementing the recommendations will establish the foundation needed to build a modern public health system that is equipped to meet health challenges while providing a structure to be supported in the long-term by sustainable funding mechanisms.

1. Request assessments on the state of public health systems, specifically nationally agreed-upon core programs and cross-cutting skills needed to support public health everywhere.
    A. Devote funds for conducting these assessments, developing and implementing strategies to fill the gaps, engaging in continual quality improvement, and otherwise working toward meeting national public health practice standards.
2. Direct appropriate agencies to work together and support this alignment by co-funding programs and strategies to improve health, based on routine needs assessments and improvement plans.
3. Develop, advocate, and support budgetary mechanisms to facilitate blending and braiding funds from multiple sources, as well as accompanying measures to ensure transparency and accountability.
4. Allocate funding for health departments to hire and retain a health equity leader who will have direct accountability to state, territorial, and local health directors, and develop measures that demonstrate health equity practices and their achievements.

1. Develop accountability measures for all funding streams.
2. Assess public health systems, including evaluating current investments and capacity, identifying gaps in core programs and cross-cutting skills, and analyzing whether they meet national public health standards.
3. Embed principles of health equity in core programs and cross-cutting skills and dedicate resources as needed to ensure they are operational.
4. Collaborate with the state Medicaid agency to identify opportunities to co-fund health initiatives targeting communities experiencing health inequities.

5. As appropriate, explore resource sharing arrangements with neighboring departments to fill in gaps or increase effectiveness and efficiency of foundational public health services.

Action #2: Evaluate the social and economic impact of public health programs and strategies.

The social and economic value of public health is often underestimated and misunderstood, despite the numerous studies that find huge cost savings and gains in the 20th century and the first decade of the 21st century from public health improvements. A systematic review of public health interventions in high-income countries, including the United States, Australia, and the United Kingdom, found that the median return on investment for all public health interventions was 14 to 1.[27]

More recent public health accomplishments include healthier newborns, greater prevention of cardiovascular diseases, and greater occupational safety.[28] Because it may not always be possible to quantitively assess certain public health programs and strategies, evaluations should be holistic in determining the impact on population health, reflecting changes to health outcomes, community feedback, and qualitative analysis.

1. Invest in public health system evaluation to illustrate the effects of allocations and investments at the state, territorial, and local levels.

1. Develop a dashboard to track high-level expenditures and progress toward meeting shared goals and targets.

DATA AND INFORMATION TECHNOLOGY

Vision: A robust, modern, interoperable, and secure public health information system delivers real-time, accurate, and actionable data *to policymakers, public health departments, and other stakeholders to help public health officials detect new or growing threats, identify groups that may be at risk, and respond quickly with well-targeted policies and programs.*

Data-driven decision-making, critical to public health practice, requires accurate and real-time information about disease prevalence and diagnoses, potential threats, and disparities in health outcomes, particularly for communities experiencing health inequities. Because data provide the basis for improving community health outcomes and evaluating public health programs, high-quality data are central to ensuring transparency and accountability. However, many public health departments rely on non-existent or obsolete and siloed information technology systems.[31] Additionally, much of the data sent to public health agencies is transmitted in outdated ways, such as by fax or the U.S. Postal Service. Moreover, the quality of data sent is often poor due to incomplete information.

These deficiencies were very apparent during the pandemic, reinforcing the decades-old need to significantly upgrade and modernize data and information technology systems in public health departments and to make them interoperable with health care providers.

Action #1: Strengthen the collection of timely and actionable public health data to guide programs, respond to emergencies, and address health inequities.

As a first step, it is critical to establish data and information technology systems that facilitate the collection of high-quality data in a timely fashion. Data need to consistently include age, race, ethnicity, disability status, and other indicators that characterize populations experiencing health inequities. As these systems are established and improved, the workforce needs to be trained to fully realize their potential.

1. Invest in modern, efficient, and interoperable information technology that equips state, territorial, and local health departments to:

    A. Collect, analyze, and share timely, accurate, subcounty data on health and health-related issues disaggregated by race, ethnicity, and other key sociodemographic characteristics.

B. Work with partners to ensure that data submitted are complete and of high quality.

2. Require that public health data are reported to agencies at all levels of government using interoperable electronic mechanisms.

1. Consistently collect data needed to identify, document, and address health inequities in local communities.
2. Work with partners to submit data to public health departments that is timely, accurate, and complete.
3. Share and display this data in real time, with user-friendly data dashboards available to other governmental agencies and the public.

Action #2: Invest in data sharing between public health departments and health care entities.

State and local public health departments currently operate a mismatched network of siloed public health information systems – most of which do not talk to each other, other government agencies, or the health care delivery sector.[32] This patchwork is particularly challenging in areas with restricted internet access, such as some rural communities and Tribal nations. Common data points collected by public health and health care systems, as well as shared using electronic case reporting, are needed for the automated exchange of clinical information. In addition, separate data systems need to be shared, linked, and synthesized in real time, while protecting data security and individual privacy. This interoperability between systems is crucial if health departments are going to be able to address urgent health threats to address urgent health threats. Success with interoperability will also aid subsequent efforts to develop interoperable systems with other partners, such as community-based organizations.

1. Remove or support the removal of technical and legal barriers to data system interoperability with health care systems and Tribal health entities while ensuring that sufficient security safeguards are in place to achieve compliance with the Health Insurance Portability and Accountability Act (HIPAA).
2. Ensure that data sharing regulations are secure without being onerous.

   A. Proactively support and incentivize partnerships that utilize official Memorandum of Agreement (MOU) documents to guide their collaboration.

3. Through legislation, require adherence to standards of the Office of the National Coordinator for Health Information Technology and the Centers for Disease Control and Prevention (CDC) for the collection and sharing of common data points.

1. Develop and implement policies and procedures that adhere to the standards of the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Disease Control and Prevention (ONC/CDC).
2. Ensure that those reporting data are adhering to ONC/CDC standards.
3. Enter into data-sharing agreements with Medicaid agencies.

WORKFORCE

Vision: A highly skilled, trained, and diverse public health workforce *provides evidence-informed programs and services that address community health needs, encourage healthy behaviors, and act swiftly to respond to emerging threats. Staff feel supported and are incentivized to pursue long careers in governmental public health.*

The governmental public health workforce has been declining for more than a decade, a direct reflection of funding cuts to health departments, an aging workforce, burnout, and high rates of turnover. According to a new analysis, the nation needs an additional 80,000 full-time equivalent positions in state and local health departments—an 80% increase in the current workforce—just to provide the core programs that every community needs.[35] Clearly, state and local public departments entered the pandemic with a staffing deficit, impeding their ability to deliver their core capabilities, much less to quickly and comprehensively address the most significant public health crisis of the century.

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As the pandemic has ground on, the ongoing firings, resignations, and personal safety threats to public health officials due to criticism of pandemic lockdowns and mask mandates have deepened the staffing challenges. A lack of competitive salaries and cumbersome, bureaucratic hiring processes further hamper efforts to recruit, hire, and retain staff. Public officials have used much of the supplemental funding allocated to states, territories, and localities to hire temporary staff and meet pressing needs.[36]

The public health workforce is essential to advancing health equity. A workforce representative of various life experiences, whether Black, Indigenous, or other people of color; residents of rural or urban communities; LGBTQ+ people; immigrants; people with disabilities; people with low incomes; and others who face unique public health challenges have unique insights into ways of achieving health and the opportunity to thrive. A diverse workforce also signals to the public that the department is a welcoming place and facilitates trust among populations that may otherwise be distrustful or feel like outsiders.

Rural communities, which are navigating significant health challenges, are especially underfunded and understaffed. Residents often have to travel long distances to access health care, as they struggle with recruitment and retention of providers.[37] The same is true for Tribal health departments, which face significant challenges in their efforts to meet the needs of Native American communities in both rural and urban areas, while struggling to recruit and retain staff, especially in remote locations.[38]

As the nation continues to navigate the pandemic and build the long-term infrastructure needed to sustain public health, public health departments must:

- Employ a sufficient number of staff to deliver the full range of public health services in their jurisdiction;
- Hire a workforce that reflects the diversity of the community served;
- Build robust and equitable pathways to employment and advancement; and
- Cultivate working environments that foster inclusive and supportive cultures to support retention.

Action #1: Invest in the recruitment and retention of a diverse and inclusive governmental public health workforce.

To build up to optimal staffing levels, public health departments need to be able to recruit from a diverse pool of people who are aware of governmental public health, interested in joining the workforce, and equipped with the knowledge, capabilities, experience, and commitment to health equity to partner effectively with communities. There is a particular need to expand opportunities and reduce barriers for Black and Indigenous communities, people of color,

and people with differing abilities, all of whom are under-represented in governmental public health, particularly in leadership positions.[39]

Many who enter the public health field do so through direct experience working in a health department (e.g., through an internship or fellowship). People who might otherwise be interested in joining the field do not have enough exposure to governmental public health to spark their interest, or they may have poor perceptions of governmental public health jobs and a lack of understanding about the work. Moreover, public health education and training is expensive and not all internships are paid, making these opportunities inaccessible to people from lower-income backgrounds. A number of institutions play important roles in building awareness and training potential health department staff: Historically Black Colleges and Universities; Hispanic-Serving Agricultural Colleges and Universities; Tribal colleges and universities; other minority serving institutions; community colleges; and rural-serving institutions.[40]

Finally, managers/supervisors should devote time to creating inclusive, engaging work environments that incentivize staff to stay and thrive. Policymakers could contribute to staff morale by touring public health departments in their jurisdiction – and in the process, they would gain valuable insights on the day-to-day operations of public health.

1. In partnership with local health departments, perform a statewide public health workforce needs assessment and fund public health department assessments of organizational culture.
2. Establish or promote robust and equitable employment programs on the state, territorial, and local levels to recruit, hire, and retain the next generation of public health practitioners, with a particular focus on individuals from communities experiencing health inequities.

1. Determine the number and type of staff needed to provide public health services.
2. Formalize partnerships and programs with academic institutions—including Historically Black Colleges and Universities, Hispanic-Serving Agricultural Colleges and Universities, and Tribal colleges and universities—local boards of health, and technical training programs to build a cross-disciplinary workforce and provide students with experiential opportunities in public health.
3. Work with partners to expand internships, fellowships, and workforce pipeline, loan-repayment, and other career on-ramp programs.
    A. Provide tailored opportunities to individuals in under-represented populations.

4. Hire outreach workers who live in communities experiencing health inequities to assist with building trusting relationships and engaging community members.
5. Assess organizational culture and make changes as needed to ensure the workplace is culturally competent and supportive of all staff.

Action #2: Improve hiring and promotion policies and processes to ensure high-quality public health services.

Numerous issues pose barriers to the hiring and advancement of the public health workforce, including lengthy and cumbersome hiring processes, outdated job descriptions and job requirements, low salaries (making it exceptionally difficult to attract candidates with student loan debt), limited student loan forgiveness programs, and professional growth opportunities that do not keep pace with the expectations of today's workers. In addition, the elimination of entry-level jobs due to budget cuts has made it difficult for early-career professionals to enter the field.[41] Recruiters also need to recognize that academic degrees and prior work experience in specific programmatic areas are not the only qualifications to consider; rather, a variety of skills and experiences, even in the absence of post-high school degrees, equip candidates to support communities with advancing health equity. All these barriers and issues must be addressed when officials seek to recruit the public health workforce of the future.

1. Modernize existing civil service requirements and institute competitive pay structures to accommodate roles and responsibilities specific or unique to public health.
2. Approve budgets that ensure:
    A. The training and professional development of the public health workforce involved with implementing core programs and applying all necessary cross-cutting skills.
    B. Salary structures that are commensurate with roles and responsibilities and that are competitive with salaries for similar positions in nongovernmental agencies.

1. Partner with leaders in government reform to update merit systems, civil service requirements, position descriptions, and human resources systems.
2. Provide professional development opportunities, giving public health

workers the skills and knowledge needed to meet modern public health challenges (e.g., change management, data science skills, and cultural and linguistic competencies).

3. Work to secure a full complement of health supports to prevent burnout and turnover, including mental health services and comprehensive paid leave.

PUBLIC HEALTH LAWS AND GOVERNANCE

Vision: Modernized laws, policies, and statutes *to protect and promote the public's health in a manner that reflects ongoing threats and challenges and ensures public health authority remains intact and protected.*

Public health laws vary by state, and governance of public health ranges from centralized to decentralized systems. As a result, public health roles vary, as do the related interactions between the state and local levels. Perhaps not surprisingly, there also is wide variation among communities in support and willingness to finance public health functions and services, and the willingness of potential public health partners to collaborate on mutually beneficial goals related to improved health outcomes.

Public health departments need a consistent set of legal responsibilities, given by policymakers, to be able to provide core programs and implement all actions in this report. The public health system has a legal responsibility that it cannot abandon, as most of what it does is through policy, rules, and laws.

Action #1: Review, evaluate, and modernize public health governance structures and statutory responsibilities.

Variation in decision-making structures and resources available to health departments across the nation has led to stark differences in outcomes between jurisdictions, both before and during the pandemic.[43] Moreover, many public health governance structures are outdated and were designed and developed

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generations ago. This makes it difficult for them to address the challenges and opportunities of the 21st century, including health equity, social determinants of health (SDOH), technological advances, and emergency response challenges.[44,45] Similarly, antiquated public health laws require modernization.

In 2021, more than half of all states considered bills to limit state and local public health powers, and 10 states have enacted laws doing so. Most of these laws shift power from local public health experts to state politicians (who typically do not have public health expertise), which not only limits localities' ability to implement tailored, effective actions to stop the spread of COVID-19 but also has long-term negative consequences, including the deepening of mistrust of public health officials.[46] These laws and other factors, such as the sharp increase in personal threats and the pressures of the pandemic, have led to more than 300 state and local public health officials to resign, retire, or be fired since April of 2020.[47] The long-term consequences associated with further limiting the authority of the public health system to deliver services is an ongoing threat to the safety, economic prosperity, and security of the United States.

1. Conduct or promote a bipartisan, comprehensive review of existing policies and revise as needed to reflect the current roles and responsibilities of government in protecting and promoting health, including the ability of public health departments to make decisions without undue political influence.

    A. Work across various levels of government to determine the proper federal, state, territorial, and local framework for preemption, establishing minimum and maximum requirements, particularly in light of recent state action to roll back public health powers and place limits on local elected officials.

    B. Consider how structures, processes, roles, and responsibilities should remain the same or change during a public health emergency; this task should include ensuring flexibility in personnel and procurement processes.

    C. Examine whether existing funding streams are sufficient to support the revised public health governance structures and statutory authorities; elevate funding needs to relevant appropriators to fill gaps.

    D. Ensure the law as written promotes trust through the removal of stigmatizing language, particularly as it relates to populations experiencing health inequities.

2. For policymakers in jurisdictions adjacent to or containing sovereign Tribal Nations and health systems, review lines of communication and opportunities for formalized partnerships.

3. Ensure that public health department leaders are empowered to make decisions without inappropriate political influence and have access to counsel with expertise in public health law.

1. Direct counsel with public health law expertise to review existing regulations and ensure they are relevant, provide the ability to protect the health of the public, and are legally sound.
2. Ensure that opportunities for public input in rule-making processes are widely publicized, transparent, and easily accessible.
    A. Specifically solicit feedback from those who will be most affected by new rules.

Action #2: Support and clearly communicate the roles of public health departments to the public.

Although recognition of and support for public health is high in many states and localities, in some places the reverse is true. Public health measures instituted to protect against further spread of COVID-19 have generated harassment of public health officials, legal challenges to emergency powers and measures, and refusal to follow mask mandates and vaccination recommendations.[48] These displays of opposition not only have caused local disruptions but also have contributed to the nationwide difficulties to end the pandemic.

1. Invest in evidence-informed messaging and effective communication by health departments, using multiple platforms.
    A. Use all media outlets, including online and social media vehicles.
    B. Use media outlets serving subpopulations, including those in different languages.
2. Coordinate messaging with and across public health departments, both during emergency and non-emergency situations.
    A. Ensure messaging is culturally competent.
    B. Use language that elicits a sense of trust in government.
3. Engage with constituents during public health emergencies to correct misinformation and explain the role of public health departments.
4. Provide forums for stakeholders in public health, the business community, and health care to identify shared goals and strategies that reflect public health authorities, public health protection, and a strong and stable economy.

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1. Develop and maintain ongoing relationships with local and statewide media.
2. Develop, routinely update, and implement a communications plan that articulates public health responsibilities.
3. Maintain the expertise to develop and implement a risk communications strategy.

PARTNERSHIPS

Vision: Public health departments partner with various sectors (e.g., housing, food, transportation) and stakeholders *(e.g., business, faith-based organizations, health care) toward the shared goal of providing a fair and just opportunity for all to achieve good health and well-being.*

A community's health is like a building—it depends on a strong and stable foundation. Quality education, accessible and nutritious food options, safe and affordable housing, access to health care, and employment opportunities enable positive health outcomes for everyone in important ways.[50] Building thriving communities requires that many sectors—not only health—work closely to construct a solid foundation that supports long-lasting good health for everyone. This foundation comprises both programs and policies, and thus requires partnerships with different sectors in the community and different government sectors.

Providing fair and just opportunities requires the work of those in business, education, health care, community development, faith communities, community-based organizations, social services, and many other sectors—neither public health nor any other sector can do this alone. Therefore, cross-sector partnerships that identify collaborative solutions to community health challenges and advance health equity are essential. Partnerships can be especially critical in areas with workforce shortages, e.g., by leveraging staff time and expertise to achieve shared goals and by collaborating on recruitment efforts. Building partnerships, coalitions, and other collaborative relationships requires continuous effort, but all too often public health departments lack the

means—the funding, necessary time, resources, and capacity—to sustain these partnerships.[51]

Government sectors also need to work together to ensure policies enhance health and the conditions that support health, and at the very least do not inadvertently cause harm. Public health departments can provide data, evidence-informed strategies and practices, and other insights to discussions regarding the impact of policies on the community's health and well-being.

Action #1: Incentivize partnerships between public health departments and other sectors (e.g., housing, food, transportation) and stakeholders (e.g., business, faith-based organizations, health care).

Through partnerships with a multitude of sectors, health departments are best equipped to access real-time data collected by others to track and monitor health impacts, gain a complete picture of the jurisdiction's needs and assets, inform and guide resource allocation, identify shared priorities, and forge collaborative and collective solutions to advance them.[52] Through partnerships, public health departments can support and further efforts to address health issues that may not fall directly within their responsibilities, e.g., addressing mental and behavioral health issues and preventing or lessening the effects of climate change. Flexible funding for cross-sector partnership development (as opposed to categorial disease-specific funding) enables partners and coalitions to work on a range of issues specific to their jurisdictions' health and well-being, a departure from the typical current funding practices that are often short term and disease-specific.

1. Allocate funding to support the development and maintenance of partnerships that aim to provide a fair and just opportunity for all to achieve good health and well-being.

1. Clearly delineate shared goals, respective responsibilities, and collaboration guidelines for decision-making, conflict resolution, and data sharing; use this body of work as a foundation for sustainable collaborations.

Action #2: Establish a dedicated body charged with routinely monitoring, assessing, and influencing the implications for health in all government sector policy discussions

Integrating health considerations into policy and decision-making across all government sectors can help secure a government-wide commitment to public health.[53] This approach recognizes that health is created by numerous factors

beyond public health departments and the health care sector, leverages all government sectors' interests and resources to achieve mutually beneficial goals, and helps to avoid adverse health effects inadvertently resulting from a policy generated by any sector. This partnership can take the form of a special council or board; alternatively, an existing body can add the impact of health in all policies to its agenda on a regular basis.

1. Establish and participate in an advisory board that integrates and articulates health considerations into policymaking across all government sectors to improve the health of people and communities.
2. Conduct health impact assessments on legislation to identify potential connections between health and factors that affect health (e.g., housing, affordable and nutritious food options, employment, and environment).

1. Provide examples and evidence-informed practices to support health impact assessments and policy discussions.

COMMUNITY ENGAGEMENT

Vision: Public health departments partner with community members *toward the shared goal of providing a fair and just opportunity for all to achieve good health and well-being.*

Community engagement is vital to public health's mission. Effective community engagement drives public health to prioritize the *right* interventions, policies, practices, and approaches to community-driven health priorities with community-driven approaches, which can and should be informed by people who have experienced health inequities and by communities that may not have been consulted in the planning of public health activities. Working alongside community members and sharing decision-making with them to collect data, design and implement programs, and evaluate public health's effectiveness enhances public health practice and outcomes.

Action #1: Invest in long-term relationship-building and partnership development with residents and community-based organizations (particularly those serving communities experiencing health inequities) and in Tribal consultation.

Establishing trust is a prerequisite to successful partnerships and collaborations. Therefore, public health departments must consistently expend time and effort to build the trusted relationships needed for authentic community engagement. Performative, halfhearted, and time-limited community outreach efforts not only damage trust but also can do more harm than good. Routine contacts and meetings are required to facilitate deep and sustained community participation in public health programming. Meetings need to be held in communities to make it easier for residents to participate; in the process, health departments will also demonstrate their commitment to eliciting input and centering the community's voice in identifying priorities and shaping program strategies. Moreover, CBOs and the people they serve should be appropriately compensated for the time, effort, and unique expertise they devote to improving public health efforts.

While sovereign and autonomous, Tribal Nation leaders and public health departments are critical partners in the U.S. governmental public health system. Through their authority and self-governed resources, Tribal public health systems often consult and collaborate with U.S. public health departments to provide needed services, such as response and recovery from natural disasters and supporting low-capacity U.S. health departments during the COVID-19 pandemic. However, consultation practices are not uniform, and U.S. policymakers and public health leaders must ensure practices that respectfully honor the public health authorities of Tribal Nations.

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1. Allocate funds to public health departments for community collaboration and develop output measures that account for progress toward building trust and working in partnership.
2. Engage in routine Tribal consultation to support intergovernmental public health planning that recognize Tribal authority, autonomy, and self-governance.
3. Act as liaisons between public health departments and citizen representatives, especially from communities historically experiencing health inequities, who can elevate on-the-ground concerns and offer their input on public health issues.

1. Dedicate staff time to long-term community engagement efforts.
2. Compensate community members and organizations for their time and expertise on planning and implementing health improvement strategies and actions.
3. Invest in and formalize consultation practices between state and local health departments and Tribal health departments to address community-wide health planning and decision-making.

Action #2: Invest in the capacity of CBOs and provide resources to support collaboration with public health departments.

All too often community-based organizations that serve communities experiencing health inequities are under-resourced; as a result, they do not achieve their full potential and thus their influence and potential impact are often underappreciated. As an example, CBOs may not have the capacity to participate in meetings due to other demands. Moreover, the input of CBOs often is ignored or minimized in favor of opinions by people from well-resourced organizations that brought an executive team member to the table. And sometimes greater weight is put on input from people with advanced academic credentials as opposed to those with the most experience with the population being served or the health issue being addressed.

Given that improved population health outcomes largely depend on reducing health disparities,[55] the value of strengthening the ability of CBOs that serve communities experiencing health inequities to meet their missions and simultaneously engage as equal players in health improvement collaborations cannot be understated. As such, CBOs should share in decision-making and receive help to expand their capacity.

1. Allocate funds to support the capacity-building of CBOs.
2. Lead regular town halls and forums with CBOs and public health officials to present evidence-based information that deepens understanding of health inequities, their causes, and their consequences.

1. Formalize public health planning and processes that rely on input from, and share decision-making with, CBOs and the people they serve.
2. Work with CBOs to identify opportunities to strengthen their organizational capacity and dedicate staff time and funds to mentor and train on topics such as grant writing, grant reporting, data collection and analysis, project evaluation, and publishing academic papers.

Conclusion

The pandemic has had a devastating and lasting impact. More than 740,000 Americans have died and unknown thousands continue to suffer from long-term symptoms after recovery from the virus.[57] About 66 million eligible Americans are unvaccinated, at the time of publication,[58] and misinformation on the virus and vaccines is rampant in some areas of the country.

The federal government made substantial investments to bolster public health deficiencies and respond to the pandemic. Despite the funding influx, some states and localities have legally and politically undermined public health departments trying to carry out their mission to combat COVID-19 and meet other public health challenges.[59]

The vision, framework, and actions laid out in this report are a guide so that elected and health officials can prepare their communities for the next pandemic or public health challenge and improve the quality of life of their neighbors.

We cannot learn the wrong lessons from the pandemic. This moment is an opportunity for elected and health officials to reimagine public health in a bipartisan fashion, with the goal of an equitable, effective, and sustainable public health system.

Appendix 1: Federal Investments in Public Health in COVID-19 Relief Legislation

Congress provided $305.6 billion through five COVID-19 relief bills to the Public Health Services Agencies and the Public Health and Social Service Emergencies Fund (PHSSEF)[60].

Allocations include:

- $280 billion to PHSSEF, an account controlled by the Health and Human Services secretary that receives annual appropriations to operate some HHS offices, including the Office of the HHS Assistant Secretary for Preparedness and Response, but often for one time or short-term funding.

  Within this amount, $53.4 billion is allocated to medical countermeasures and boosting surge capacity:

  - At least $24.2 billion for the Biomedical Advanced Research and Development Authority.
  - Up to $19.25 billion for the Strategic National Stockpile, which stores medicines and medical supplies for distribution to jurisdictions during public health emergencies.

- $15.3 billion for the CDC.

  - Broadly available funding:

    - At least $2.45 billion for grants to state, local, territorial, and tribal governments "to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities."
    - $800 million for global disease detection and emergency response.
    - $600 million for the Infectious Disease Rapid Response Reserve Fund (IDRRRF).
    - $500 million for "public health data surveillance and analytics infrastructure modernization."

  - $1 billion to expand and improve COVID-19 testing.

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    - $8.75 billion for vaccine-related funding, $4.5 billion of which must go toward state, local, territorial and tribal grants.

- $4.7 billion for the Substance Abuse and Mental Health Services Administration.
- $3 billion for the National Institutes of Health (NIH).
- $1.3 billion for the Health Resources and Services Administration.
- $1.1 billion for the Indian Health Service.
- $196 million for the Food and Drug Administration.
- $12.5 million for the Agency for Toxic Substances and Disease Registry (headed by the CDC director).
    - $7.5 million for the Geospatial Research, Analysis and Services Program "to support spatial analysis and Geographic Information System mapping of infectious disease hot spots, including cruise ships."
    - $5 million to Pediatric Environmental Health Specialty Units and state health departments "to provide guidance and outreach on safe practices for disinfection for home, school, and daycare facilities."

Note: The American Rescue Plan provided substantial mandatory funding for a long list of public health activities. This departure from regular order is expected to be temporary. The appropriations committees will resume their role overseeing public health funding in the appropriations bills that will be worked on in summer of 2022.

The American Rescue Plan[61] provided additional public health funding of nearly $90 billion.

Allocations include:

- Vaccines/therapeutics: ($15.05 billion).
    - $7.5 billion to the CDC for COVID-19 vaccine activities.
    - $1 billion to the CDC for vaccine confidence activities.
    - $6.05 billion for research and development, manufacturing, and purchase of vaccines, therapeutics and other medical supplies for COVID and other pandemics.
    - $500 million to FDA to evaluate continued effectiveness of COVID-19 products.
- Testing and data: ($50.8 billion).
    - $47.8 billion to HHS for testing, contact tracing, surveillance, and mitigation activities.
    - $1.75 billion to HHS/CDC for genomic sequencing.

- $750 million to HHS/CDC to combat COVID-19 globally.
- $500 million to HHS/CDC for data infrastructure modernization.

- Workforce: ($7.76 billion).
  - $7.66 billion to HHS for public health workforce.
  - $100 million for Medical Reserve Corps.

- Other public health investments: ($8.98 billion).
  - $7.6 billion to HHS for community health centers for COVID-19 mitigation.
  - $800 million to HHS for National Health Service Corps (loan repayment).
  - $200 million to HHS for Nurse Corps (loan repayment).
  - $330 million to HHS for medical education and training--expanding primary care programs, maintaining existing staff, boosting federal response to public health emergencies.
  - $50 million to HHS for family planning grants.

- Mental health/substance use disorders: ($3.88 billion).
  - $1.5 billion to HHS for community mental health grants.
  - $1.5 billion to HHS for substance use prevention and treatment.
  - $80 million to HHS and HRSA for MH and SUD training in rural/ underserved areas.
  - $20 million to HHS/CDC for wellness campaign for health care professionals.
  - $40 million to HHS/HRSA for grants to promote mental health among health workforce.
  - $30 million to HHS for local SUD services.
  - $50 million to HHS for local behavioral health services.
  - $10 million to HHS for national child traumatic stress network.
  - $30 million to HHS for advancing wellness in education.
  - $20 million to HHS for youth suicide prevention.
  - $100 million to HHS for behavioral health workforce training.
  - $80 million to HHS for pediatric mental health care telehealth access programs.
  - $420 million to HHS for community behavioral health clinics.

Appendix 2: Public Health Focus Area Background

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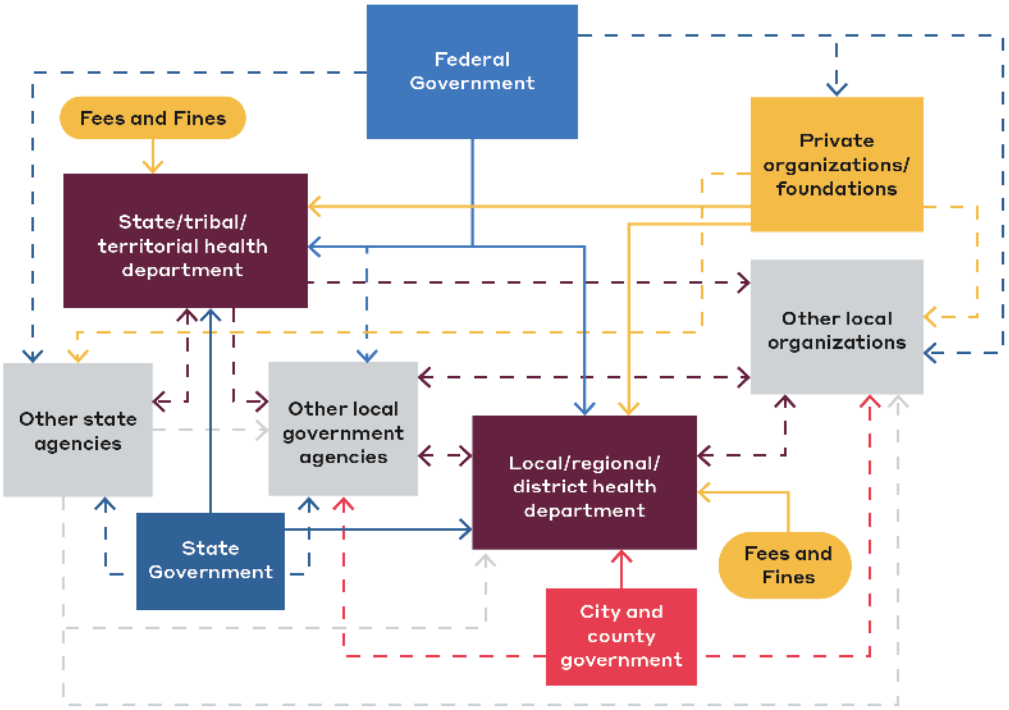
PUBLIC HEALTH FINANCE

The Importance of Public Health Finance

Public health finance includes the acquisition, utilization, and management of public health resources,[62] including those required to deliver public health services to populations. It also includes the impact of resources on the health and health equity of those populations.[63] As depicted below, resources for public health come from a range of sources with the bulk of funding provided by federal and state governments. Funds typically flow from federal to state, territorial and tribal health departments, and then to local governments.

Figure 1. Public Health Funding Flows
Adapted from Institute of Medicine. 2012. *For the Public's Health: Investing in a Healthier Future*. Washington, DC: The National Academies Press. https://doi.org/10.17226/13268.



Core Issues:

- A long-standing neglect of and reduction in public health funding at all levels of government, despite increases in the scope of public health services and needs,[64,65,66] has resulted in reduced state, regional, and local capacity. Communities nationwide are not able to deliver needed public health services and to respond to the COVID-19 pandemic and other public health emergencies.
- The structure, organization, and delivery of public health services varies widely. When coupled with differences in state and local investments and funding disbursements, these variances have resulted in a patchwork system with a wide range of public health spending per capita, from a low of $7 to a high of $140 in 2019.[67]
- Many public health funding streams are **"categorical,"** restricted to specific priority areas (e.g., chronic disease prevention), limiting funds to basic public health system needs (e.g., data systems, staffing) or to ramp up surge capacity in response to emergencies.
- Flexible funding streams allow for the shifting of money as needed, but such flexible streams (e.g., block grants[68] or the Prevention and Public Health Fund[69]) have been vulnerable to funding cuts or reallocation to cover non-health priorities (e.g., tax cuts[70]).
- Leaders in the field have proposed uniform standards and accounting measures to monitor resources and evaluate capacity for delivery of a basic set of public health services; however, without dedicated, long-term funding for such measures, adoption has been limited.[71]

Gaps:

There has been inadequate recognition of:

- Structural variations (e.g., budgeting cycles and practices) across state and local governments which hampers accurate costs estimates; lack of transparency in state and local resource allocations; and little accountability for where and how public health funds are spent;
- Needed additional resources and financial flexibility to address systemic inequities and upstream SDOH through cross-sector partnerships and community engagement in local communities;
- Governance and policy considerations that affect funding; resource allocation laws; and policies and practices dictating the use and distribution of funds to state and local government agencies, communities, and other organizations.

Public Health Finance: Challenges and Opportunities for Action Going Forward

Insufficient and inconsistent ("boom-bust") funding leaves the public health system unprepared to:

- Adequately protect communities from public health emergencies and ongoing public health challenges, such as violence, substance use, and climate change;
- Address health inequities and disparities through equitable provision of services, resources, and supports to communities;
- Adopt a broad vision of public health to foster cross-sector partnerships and community engagement to address upstream determinants of health such as housing, transportation, and employment.

- Assure a basic level of public health service delivery in each community;
- Enable nimbleness so agencies can respond to public health emergencies and crises as needed;
- Sustain the ability of public health agencies to collaborate across sectors to address upstream drivers of health and promote health equity and improved health;
- Standardize tracking and monitoring over time to assess and ensure funding is being used to its full capacity and impact in local communities;
- Foster a scale-up of effective resource allocation and distribution practices to local communities;
- Improve data systems and health information to track and address communicable disease outbreaks and public health emergencies, such as extreme weather events and substance use crises in a more timely and targeted manner.

The Importance of Data and Information Technology

Data and information technology encompasses not only the collection, usage, and storage of data but also the platforms, software, and hardware to support individual and population-level public health surveillance. This technology enables the public health system to undertake interventions and monitor and communicate public health outcomes. As demonstrated during the COVID-19 pandemic, all aspects of the nation's data and information technology systems are critical to a well-functioning public health system.

Core Issues:

The following are essential to an effective public health system:

- **Modern technology** and **cybersecurity** measures.
- **Staff capacity** to collect, disaggregate, analyze, interpret, report, and communicate data.
- **Data sharing** across health and public health systems and geographic jurisdictions.
- **Access to timely, quality, and meaningful data** (e.g., accurate case counts, disaggregated data), to respond to public health emergencies, evaluate health outcomes, implement accountability measures, and identify health disparities and inequities.
- **Standardized data measures, capacity, and reporting practices** for consistent and comparable reporting, monitoring, and communication across states and local communities.

Gaps:

Key gaps in prior discussions on public health data and information technology modernization include:

Primary focus on a specific component(s) of the system (e.g., interoperability or privacy concerns) rather than the entire system.

- **Exclusion of nontraditional data sources** (e.g., community input, lived experiences, etc.).
- Need for expanded **focus beyond data** to translation of data to benefit impacted communities.
- Need for **partnerships and community engagement** to establish data measures, information systems, and communications that measure, communicate, and advance cross-sector efforts to address the social determinants of health.

Data and Information Technology: Challenges and Opportunities for Action

- Lack of interoperable data platforms across sectors and jurisdictions results in fragmented and inefficient data exchange and hinders effective public health responses and improved health outcomes;[72,73]
- Use of obsolete technology platforms creates data integrity and quality challenges and leads to delays in real time reporting and response;[72,73]
- Insufficient and ineffective collection and disaggregation of data (e.g., by race, ethnicity, geographic locations) stymies efforts to track, monitor, and reduce health disparities and address the social determinants of health;[72,74]
- Lack of funding and support for data modernization initiatives at the federal, state, and local levels hinders capacity, interoperability, and data access and communications.[72,74,75]

- Broaden information access and coordination across sectors, public and private entities, and communities to address the social determinants of health;[72,73,76] and
- Improve public health surveillance to better monitor, investigate, prevent, and control disease outbreaks and emerging public health threats.[75,77]

PUBLIC HEALTH WORKFORCE

The Importance of the Public Health Workforce

A strong governmental public health workforce (state, local, and territories) is representative of the communities it serves; has effective leaders; is sufficiently staffed to meet the public's needs; and has the competencies, tools, and skills necessary to respond quickly to emerging public health challenges.[76,78,79,80]
A well-trained public health workforce is the country's first line of defense to prevent disease, advance the health and well-being of all populations, and keep people safe.

The Public Health Workforce: Core Issues and Gaps

A skilled and diverse public health workforce requires:[76,78,79,80,81]

- A competent **workforce with effective leadership that reflects the population served;**
- Training and education that **incorporate a broad base of skills and competencies,** including technical, strategic, and leadership skills;
- More equitable pathways to successful public health careers, including **recruitment, retention, and career advancement opportunities;**
- Creating a workforce **culture of accountability, inclusiveness, quality improvement, and lifelong learning;** and
- **Cultivating partnerships with schools and programs of public health** to build a pipeline for the future workforce.

There has been inadequate recognition of:

- Public health professionals and institutions do not serve communities equitably and are insufficiently **equipped to address structural inequalities.**
- Inadequate attention to individual employee **career paths and goals poses** challenges for recruitment, retention, and morale.
- **Workforce learning, training, and professional development** lacks sustained financial support, access is limited, and content is often siloed and driven by funding availability;
- **Relationships between health departments and partner organizations** (e.g., academia, health, education, business) are often not optimized due to funding and other organizational constraints. This limits the effectiveness of training, and departments are losing out on recruitment and partnership opportunities.
- Burdensome human resource policies and practices in health departments (e.g., noncompetitive salaries; inadequate facilities and equipment; limited recruitment pools, especially in more rural/remote locations; and bureaucratic and lengthy hiring practices) are barriers to **recruiting and retaining top talent.**
- Discussion is needed as to how best to leverage available mechanisms to bolster the public health workforce such as nongovernmental fast track hires and employee unions.
- Inadequate attention has been given to supporting the **well-being, mental health, and safety** of the **public health workforce** as fundamental to the mission of public health.

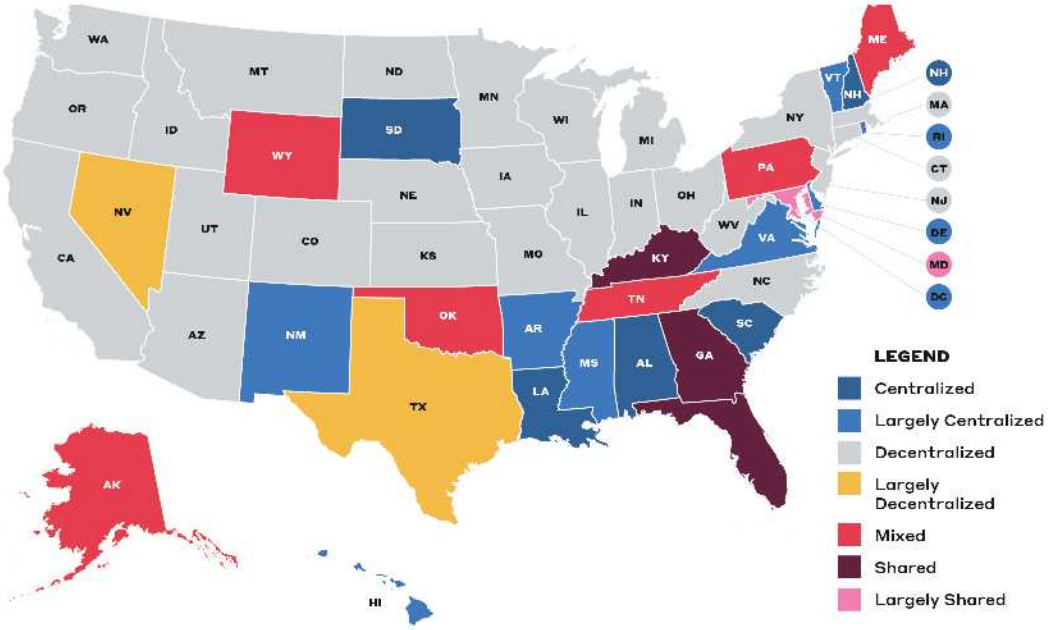
Public Health Workforce: Challenges and Opportunities for Action Going Forward

- Throughout the previous decade, 66,000 state and local public health jobs were lost. Retirements, burnout, firings, harassment, and threats accelerated the exodus during the pandemic. This loss challenges health departments' abilities to maintain the current workforce.[76,80]
- Nearly half of those working in public health are considering leaving the field within five years, either through retirement or plans to leave public health entirely.[76,80]
- Most employees join public health agencies without formal training or education in public health, requiring time and resources to train new staff.[80]
- In response to the pandemic, the public health workforce expanded dramatically, but often through temporary positions, thus focusing on the short term rather than addressing long-term workforce needs.[76]

- Adopt interdisciplinary leadership models to build new partnerships and cross-cutting collaborative opportunities.[76,78,79]
- Continue to invest in the development, improvement, and coordination of training in "strategic skills" that equip health departments to meet the complex needs of contemporary public health and an operational focus on improving health outcomes and health equity.[82]
- Broaden recruitment opportunities by fostering new partnerships with hiring organizations and academic institutions, including Historically Black Colleges and Universities, as well as with Hispanic-serving, Tribal, and other minority-serving institutions. Develop training programs focused on public health competencies and real-world experience through service learning, work practicum, and internship opportunities.[76,79,80]
- Target recruitment efforts in local communities, with a focus on building a public health workforce pipeline for people with lived experience from all cultural and economic backgrounds.[76,79]
- Focus resources and systems changes to advance recruitment, retention, and succession planning within the current workforce, including efforts to create advancement and leadership opportunities, improve job satisfaction, and increase low pay.[76,79,80]

The Importance of Public Health Governance and Law

U.S. public health governance is the legal authority and responsibility to protect and promote the health of populations. Governance and laws set the structure and boundaries in which public health interventions and policies are developed, implemented, and evaluated. As depicted below, structures vary among states and across localities within a state. In a centralized governance structure, the state maintains authority over most local level public health operations. In a decentralized structure, local governments maintain authority over most local public health operations. During the response to COVID-19, governance variations resulted in differing policies, interventions, and messaging across states and local jurisdictions.



Source: ASTHO Profile of State and Territorial Public Health

Public Health Governance and Law: Core Issues and Gaps

Core Issues:

Core public health governance and law issues include:

- Public health is governed by a **complex and fragmented system** of federal, state, territorial, tribal, and local health agencies, all with missions to advance and protect the public's health;

- Public health operations, interventions, and outcomes are **anchored at the local level,** allowing the local context to inform delivery of public health services to communities;
- **Authority granted by public health laws** are used by public health and elected officials at all governmental levels to declare public health emergencies and institute disease prevention measures; and
- It is imperative to **affirm the mandate** for public health through accountability and coordination across state and local health departments.[76,79,80,81]

Gaps in public health law and governance include:

- Inadequate acknowledgment of public health laws and governance as an important underlying factor in:
- **Health outcomes and health disparities;**
- **Public health system structure and function,** such as resource allocation, workforce capacity, laws and responsibilities, data collection, and reporting;
- **Politicization of public health actions,** often resulting from conflicts across levels of government (e.g., federal preemption over state laws), and conflicts between the executive branch, of which public health agencies are a part, and the legislative branch, which grants authority to public health agencies (e.g., legislative efforts to take away authority from public health officials and prohibit use of public health protections in response to COVID-19);
- Inequitable **application and enforcement of public health laws and interventions.**

Public Health Governance and Law: Challenges and Opportunities for Action Going Forward

- Delegation of authority from federal to state to local during the pandemic fueled tension and distrust of public health officials, ambiguity about decision-making authority, and inconsistency in decisions and communications; [76,80]
- Inconsistent governance and laws contributed to narratives that public health officials were operating outside their scope of authority; this sowed a polarized public health climate, eroded trust in public health expertise, and spurred legislative efforts to roll back public health authority;[76,80]

- Current governance structures were designed and developed generations ago and often are outdated. As made clear in the COVID-19 response, the current structures often do not lend themselves to addressing public health challenges in the 21st century.

- Improved **clarity in governance and law can:**
- Create consistent opportunities for accountability (e.g., national health department accreditation); [76,78,80]
- Harmonize statutory authority across jurisdictions;[76]
- Encourage collaboration, consistency, and coordination between and across jurisdictions;[76,80]
- Reduce redundancy and optimize local health department performance;[76]
- Clarify scope of health department authority to foster shared accountability with key governmental and nongovernmental partners.[76]

CROSS-SECTOR PARTNERSHIPS AND COMMUNITY ENGAGEMENT

The Importance of Cross-Sector Partnerships and Community Engagement

Cross-sector partnerships and community engagement are foundational components for improved community health and are critical to advancing health, health equity, effective communication, and nimble responses to public health emergencies and challenges. Although they often overlap, partnerships and community engagement are distinct:

- Cross-sector partnerships focus on coordinating multisector changes to address the social determinants of health.
- Community engagement focuses on building relationships and trust with communities served and affected by the public health system.

Cross-Sector Partnerships and Community Engagement: Core Issues and Gaps

Effective cross-sector partnerships include:

- Developing and maintaining **multisector coalitions**, which include, but are not limited to, community groups or organizations; private businesses; health-related organizations; policymakers; tribal entities; health and non-health government agencies;[76,78,79,80,81]
- Engaging authentically with community partners to identify and develop **structured processes and strategies** (e.g., community health improvement plan) for identifying and aligning priorities, activities, and resources.[76,78,79,80,81]

Effective community engagement includes:

Establishing mechanisms for multidirectional communication to increase learning and sharing among all stakeholders;[76,79,80,81]

Cultivating and maintaining trust with community members and organizers. [76,78,79,80,81]

Gaps in partnerships and community engagement include:

- **No clear distinction** between partnership and engagement opportunities and challenges;
- Inconsistent **focus on equity;**
- Insufficient emphasis in partnerships and community engagement around **consensus-building, action, and impact;**
- No discussion of **"in-name-only" partnerships and engagement** that tokenizes, rather than authentically engages, stakeholders;
- **The focus on health departments** as anchors for partnerships and engagement opportunities as opposed to empowering communities;
- Insufficient consideration of **additional staff time and other resources required** for partnership development and engagement in trust- and community- building.

Partnerships and Engagement Challenges and Opportunities for Going Forward

Cross-sector partnership barriers include:

- Insufficient and inconsistent financing and turnover contribute to inadequate staff capacity in building cross-sector partnerships;[76,80]
- Consensus-building with stakeholders with differing agendas;[81]
- Lengthy governmental bureaucratic processes and approvals that hinder timely sharing of information;[78]
- Funding and programming restrictions that limit the scope of work to specific issues and outcomes;[78,80]
- Silo culture for programs and partnerships (e.g., housing viewed within the

lens of housing only and not considered a public health issue).[80]

Community engagement barriers include:

- Insufficient and inconsistent funding for nonspecific work such as "coalition-building" or "community engagement and outreach";[76,78,79,80]
- Disparate access to higher education in public health for racial and ethnic minorities, reducing diversity in the public health workforce;[79,80]
- Finding an appropriate balance between community engagement and internal agency limitations (e.g., community priorities may not align with agency funding availability);[76]
- Localizing community engagement to align with different levels of government (e.g., local health department engagement differs from state or tribal agency engagement).[76]

Partnerships offer opportunity to:

- Address the social determinants of health and underlying causes of conditions such as racism and poverty;[78]
- Promote racial equity in public health programs while recognizing cultural differences;[76]
- Coordinate activities, leverage funding, and promote collective action to maximize resources;[76,78,80]
- Establish shared visions for strategic and non-program specific actions;[78]
- Establish pathways for workforce recruitment and development.

Community engagement offers opportunities to:

- Center affected communities in decision-making;[76,78,79]
- Enhance community resiliency and ameliorate historical harms;[78]
- Increase nimbleness in public health responses to emergencies;[76]
- Broaden networks for timely communication of health information to affected populations.[76,80]

HEALTH EQUITY

The Importance of Health Equity

Health equity is the cornerstone of an effective public health system and

promotes a "state in which everyone has the opportunity to achieve their full health potential."[80] Aligning public health efforts with systemic social justice issues, such as racism, oppression, and poverty, is central to improving health and generating more effective health care spending, a more productive workforce, and more stable, economically viable and resilient communities.

Equity: Core Issues and Gaps

Health equity is a key domain[80] of public health and includes:[76,78,79,80,81]

- Identifying and measuring **system-level health and social disparities** (e.g., racial, cultural, geographical, economic) within communities;
- **Collaborating with community stakeholders** to identify and support culturally appropriate interventions; and
- Ensuring mechanisms for a **diverse public health workforce** that reflects the communities being served.

Gaps in discussions of equity in public health include:

- Inconsistent approaches to **equity** across national public health initiatives (e.g., some stakeholders position equity as a core operational principle while others include it as a general concept to consider);
- Minimal discussion of equity issues **beyond racial and socioeconomic status;**
- Lack of consideration of **additional staff time and resources required** for equity-specific community building work;
- **Focusing on health departments** for community-based health equity work as opposed to empowering communities; and
- Lack of consideration of the **need for consensus-building** with stakeholders on equity priorities and approaches.

Health Equity: Challenges and Opportunities for Action

Barriers are persistent and common at all levels of government and include:

- Insufficient and inconsistent financing for efforts to improve health equity and address the social determinants of health;[76,78,79,80]
- Inadequate staff capacity due to turnover and insufficient and unstable resources;[76,80]
- Challenges with timely and consistent data collection and reporting of disparities (e.g., data broken out by race, ethnicity, and other socioeconomic

demographics);[76,79]

- Disparate access to higher education in public health for racial and ethnic minorities, leading to challenges in workforce diversity;[79,80]
- Mistrust of public health communication and interventions due to historical and current systemic injustices;[76,79"]
- Inconsistent enforcement of public health laws and regulations across communities and populations;[76]
- Funding restrictions that do not allow funds to be used for community-building activities to advance health equity;[78,80]

Health equity work focuses on addressing:

- Disparate outcomes in population health (e.g., violence, infections, hospitalizations, mortality;)[76,79]
- Racial, socioeconomic, geographic, and other inequities that lead to poor health outcomes through policy interventions;[76,79]
- Barriers to health care access (e.g., transportation, financial costs, cultural barriers, medical mistrust);[79,80]
- Multidirectional communication with communities to develop meaningful, culturally resonant messaging and educational products;[79]
- Training and mentoring programs to increase diversity in the public health workforce;[79,80]
- Viable and sustainable cross-sector partnerships for "creating health, equity, and resilience in communities;[76,79,80,81]
- Timely, reliable, and granular data to monitor health disparities and improve social determinants of health;[78,79,81]
- Holistic approaches that advance beyond disease-specific programs to address upstream SDOH;[78]
- Strategic planning and implementation for health equity across all programs within a health department;[81]
- Historical divisions between public health and social services for broader system-level change.[76]

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Policy Areas

Campus Free Expression

Economy

Education

Energy

Governance

Health

Immigration

Infrastructure

IDEAS. ACTION. RESULTS.

MS-DOH-21-1816-A-001125

From:	Brooks, Richard
To:	Aldridge, Amanda; Allen, Tabitha; Bang, Elizabeth; Boxx, Robert; Byers, Paul; Campbell, Thomas; Chambers, Rita Kay; Collins, Heather; Cooper, Margaret; Craft, Christy; Craig, Jim; Darnell, Tim; Dawson, Lauren; Dobbs, Thomas E; Dreiling, Donna; Drumm, Kelly; eamundson@dps.ms.gov; Etheridge, Donna; Feldman, Alex; Flowers, Roderick; Hall, David; Head, Matthew; Holsapple, Wes; Hoover, Christy; Horn, Marshall; Hubanks, Jonathan; Jennings, Twyla; Jernigan, Curtis; Johnson, Rodney; Jones, Steven; Lewers, Debra; Manasco, Kimberly; McCain, Lalita M; McCain, Sharon; McLeod, Terry; McMinn, Sharon D.; Morrow, Yolanda; Musa, Lori A; Dowdy, Sharon; Parker, Melissa; Pearson, Meg; Sartin, Steven; Schmitz, Burton; Sharlot, Liz; Simkins, Festus; Smith, Bobby; Taylor, Lisa A; Tedford, Lisa; Trader, Sherika; Vail Fuller, Melanie; Vaughn1, Wayne; Ware, Daphne; Whitfield, Jim; Williams, Alisa; Winston, Melody; Woods, Alex; Worley, Richelle
Subject:	MSDH Daily Situation Report 7/30/20
Date:	Thursday, July 30, 2020 9:04:32 AM
Attachments:	OEPR SITREP 7.30.pdf image001.png

Good morning.

The daily situation reports are also posted on MSDH's HSIN webpages.

Please contact me if any changes or additions are needed to the daily report.

Thank you.

Richard A. Brooks
State Watch Officer
Office of Emergency Planning and Response
Mississippi State Department of Health
131 Freightways Drive
Jackson, Mississippi 39208
Office: 601-939-2660
Cell: 601-862-0666
Email: Richard.Brooks@msdh.ms.gov

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MISSISSIPPI STATE DEPARTMENT OF HEALTH

OFFICE OF EMERGENCY PLANNING AND RESPONSE
DAILY SITUATION REPORT

Mississippi State Department of Health

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OFFICE OF EMERGENCY PLANNING AND RESPONSE
DAILY SITUATION REPORT
30 July 2020

Today's Local Noteworthy Topics:

- Airlines still struggling to fill seats as pandemic continues
- Report: 71 of 82 Mississippi counties deemed coronavirus "red zones"
- Rankin County schools announce mask mandates, dress codes
- Travel Warning: Americans from 34 states should stay home, per Harvard's COVID-19 tracking site
- First 2020 cases of West Nile Virus reported in state
- Unknown seeds from China end up in Mississippi couple's mailbox
- Mental health experts in Flowood see uptick of depression patients
- Poverty and the pandemic in Mississippi
- Medical marijuana headed to Mississippi ballots in November
- Pearl school leaders prepare for students to return with COVID-19 precautions in place
- Governor Reeves weighs "life or death" school reopening options
- Mississippi Department of Human Services offers childcare support for front-line workers
- Statewide COVID-19 new cases: 1,505; total cases: 55,804; deaths: 20; statewide total deaths: 1,563.

Key Leadership Locations:

OHP: Jim Craig - NSTR
OEPR: Christy Craft-Berry – Capitol City Testing Site: Farmer's Market - Jackson, MS
FINANCE: Twyla Jennings – NSTR
OPS/LOGS: Marshall Horn - NSTR
PLANNING: Tommy Box – MEMA
RAD HEALTH: BJ Smith - NSTR
ACS: David Hall - NSTR
EMS: Alisa Williams – MEMA

Daily Battle Rhythm:

PHCC: Epidemiology - COVID-19 Response Efforts
MEMA: COVID-19 Response Efforts
FEMA: COVID-19 Response Efforts

Response Status Summary:

Level 1: Any disaster or emergency that requires full state response where the state and local governments clearly are overwhelmed.
Level 2: Involves an emergency or disaster that requires full state response and possible federal response and recovery assistance.
Level 3: Involves any emergency or pending disaster that is likely to require the involvement of several ESFs.
Level 4: Virtual activation of the PHCC and/or SEOC/MEMA
Level 5: Normal day-to-day operational activities.

- PHCC: Level 3
- SEOC/MEMA: Level 2 (Partial Activation)

- OPS/LGS: Level 2

Emergency Support Function (ESF) Readiness:

- **ESF – 8 Resources**
  - SMAT **(Deployable)**
  - METTS **(Staged @ UMMC)**
  - Field Hospitals
    - MRTS 42 **(Deployable @ OEPR Warehouse)**
    - MRTS 43 **(Deployed @ UMMC - Jackson)**
    - MRTS 47 **(Staged @ UMMC Grenada)**
  - State & Regional Medical Needs Shelters
    - **11 Pre-Designated Sites (Ready)**
    - **2 FMS Sites (Ready)**

Emergency Support Function Activation:

- Federal: **Activated / COVID-19 Response**
- SEOC: **Partially Activated / Level 2 / COVID-19 Response**
- ESF – 6 Department of Health and Human ServicesMass Care: **Activated / Level 3** - **COVID-19**
- ESF – 8 Health and Medical Response: **Activated / Level 3 / COVID-19**

Recovery Support Function (RSF – 6):

- Louisville, North MS Tornado DR #4175
  - Counties affected: Itawamba, Jones, Leake, Lee, Lowndes, Newton, Rankin, Wayne, Winston
- Holly Springs, North MS Tornado DR #4248:
  - Counties affected: Benton, Chickasaw, Clay, Coahoma, Itawamba, Marshall, Monroe, Panola, Prentiss, Quitman, Tallahatchie, and Tippah
- Statewide Flooding DR #4268:
  - Counties affected: Bolivar, Claiborne, Clarke, Coahoma, Covington, Forrest, Greene, Holmes, Issaquena, Jefferson Davis, Jones, Lamar, Lawrence, Leake, Leflore, Lincoln, Marion, Panola, Pearl River, Perry, Quitman, Sunflower, Tallahatchie, Tate, Tunica, Walthall, Washington, Wayne.
- Hattiesburg Tornado 2017 DR #4295
  - Counties affected: Forrest, Lamar, Perry
- Durant Tornado DR #4314
  - Counties affected: Adams, Calhoun, Carroll, Claiborne, Holmes, Jefferson, Montgomery, Webster, Yazoo
- Hurricane Nate DR #4350
  - Counties affected: George, Greene, Hancock, Harrison, Jackson
- South East MS Flood DR #4415
  - Counties affected: Clarke, Covington, Forrest, Greene, Jasper, Jones, Marion, Newton, Noxubee, Perry, Wayne
- Columbus Tornado DR #4429
  - Counties affected: Alcorn, Calhoun, Carroll, Chickasaw, Clay, Coahoma, Grenada, Humphreys, Issaquena, Itawamba, Lafayette, Lee, Leflore, Lowndes, Montgomery, Panola, Pontotoc, Prentiss, Quitman, Sharkey, Sunflower, Tallahatchie, Tishomingo, Union, Warren, Washington, Webster, Yalobusha, Yazoo
- Hamilton Tornado DR #4450

    - Counties affected: Clarke, Clay, Itawamba, Kemper, Monroe, Oktibbeha, Warren, Yazoo
- Tropical Storm Olga DR#4470
    - Counties affected: Alcorn, Chickasaw, Choctaw, Covington, Itawamba, Jasper, Jefferson Davis, Leake, Lee, Marion, Neshoba, Newton, Oktibbeha, Pontotoc, Prentiss, Scott, Simpson, Smith, Tippah
- Hernando Tornado DR#4478
    - Counties affected: Bolivar, Chickasaw, Choctaw, Clay, Desoto, Oktibbeha, Panola, Prentiss, Quitman, Sunflower, Tallahatchie, Tishomingo, Washington
- COVID 19 DR #4528
    - Counties affected: Statewide
- Easter Tornado DR #4536
    - Counties affected: Bolivar, Calhoun, Carroll, Chickasaw, Choctaw, Clay, Coahoma, Covington, Grenada, Holmes, Jasper, Jefferson Davis, Jones, Lafayette, Lawrence, Leake, Montgomery, Noxubee, Panola, Quitman
- Pearl River Flooding DR #4538
    - Counties affected: Attala, Carroll, Claiborne, Clay, Copiah, Grenada, Hinds, Holmes, Issaquena, Leflore, Marion, Sharkey, Warren, Wilkinson, Yazoo
- April 2020 Tornadoes - Federal Declaration requested
    - Counties affected: Amite, Claiborne, Covington, George, Jefferson Davis, Jones, Lawrence, Pike, Simpson, Smith, Wayne
- Tropical Storm Cristobal – Federal Declaration requested
    - Counties affected: Hancock, Harrison, Jackson.

Mitigation

Hazard Mitigation is any action taken to reduce or eliminate long term risk to people and property from natural disasters. Mitigation grant funds are available after a federally declared disaster under the Hazard Mitigation Grant Program. Eligible applicants include state agencies, local governments, private non-profits, and federally-recognized tribes.

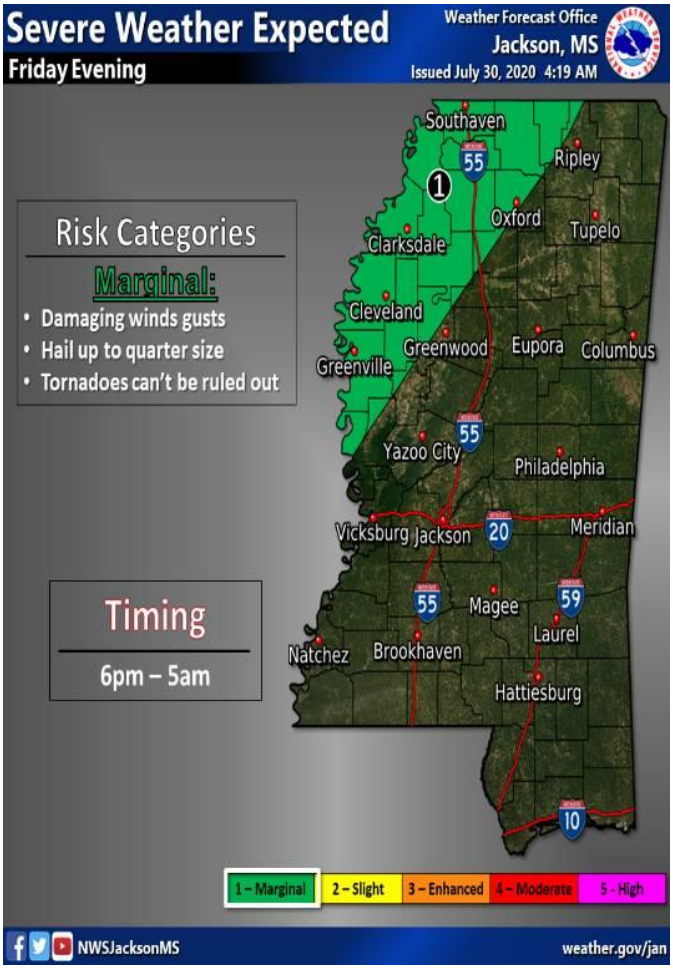
Wiggins Medical Needs
Shelter Project GS#522-046

WEATHER:

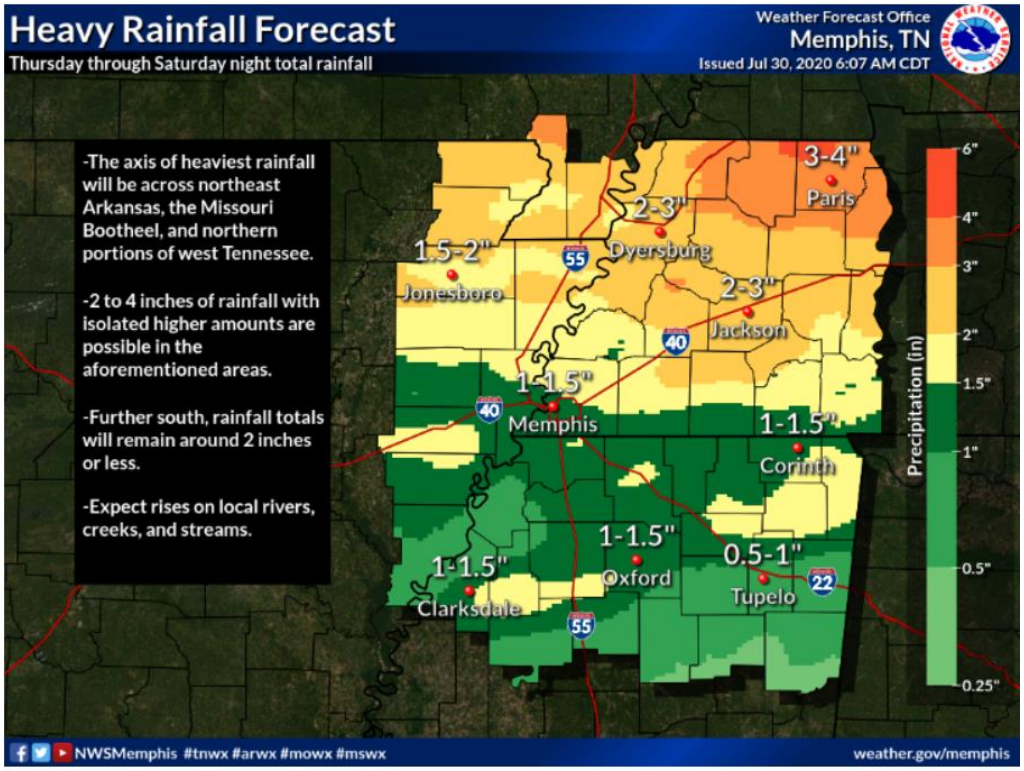
July 30, 2020

Severe Weather Outlook:

North & Central:

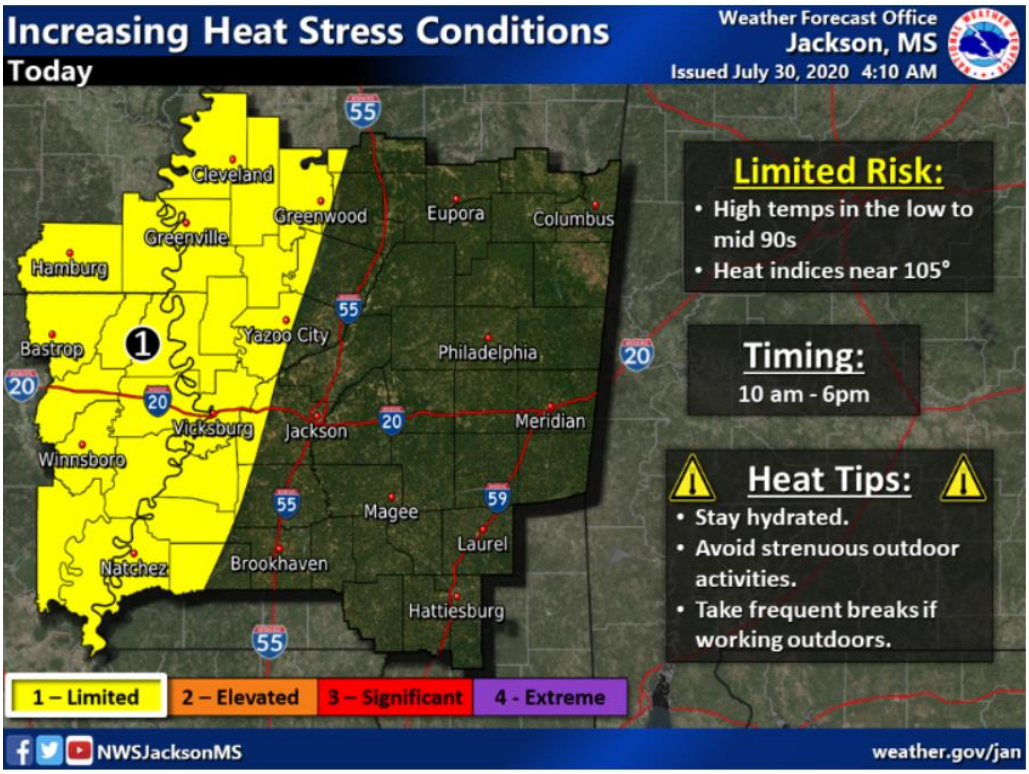


Isolated severe storms capable of damaging wind gusts and hail to the size of quarters is possible Friday night into Saturday morning. A tornado cannot be ruled out.



North

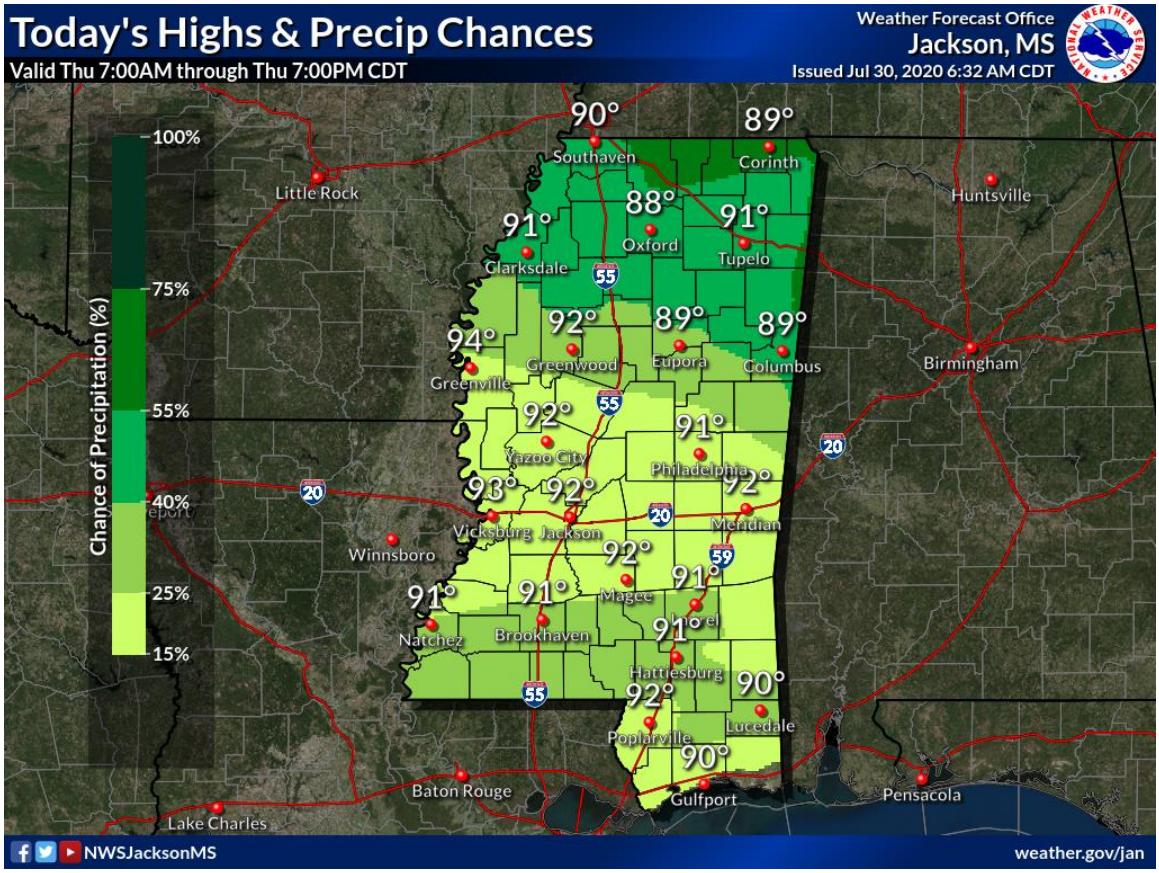
Multiple rounds of heavy rainfall are expected to begin early Thursday morning and continue through late Saturday night. Expect 1 to 2 inches of rainfall over these areas with isolated 3+ inches possible. A more robust system will arrive Friday into Saturday with an additional 1 to 3 inches of widespread rainfall possible. In addition, a few strong storms will be possible Thursday, Friday, and Saturday. The main threat will be damaging winds.



Central

High temperatures in the low to mid 90s will combine with high humidity to produce heat indices near 105 degrees.

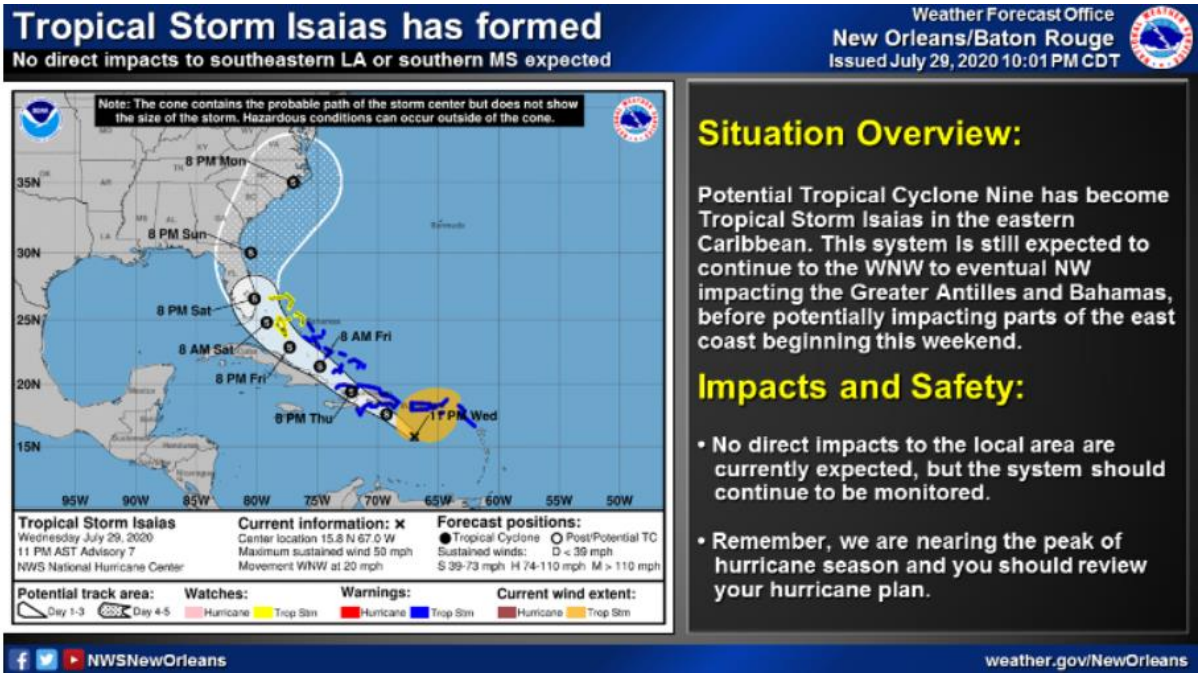
Forecast / Tropics:

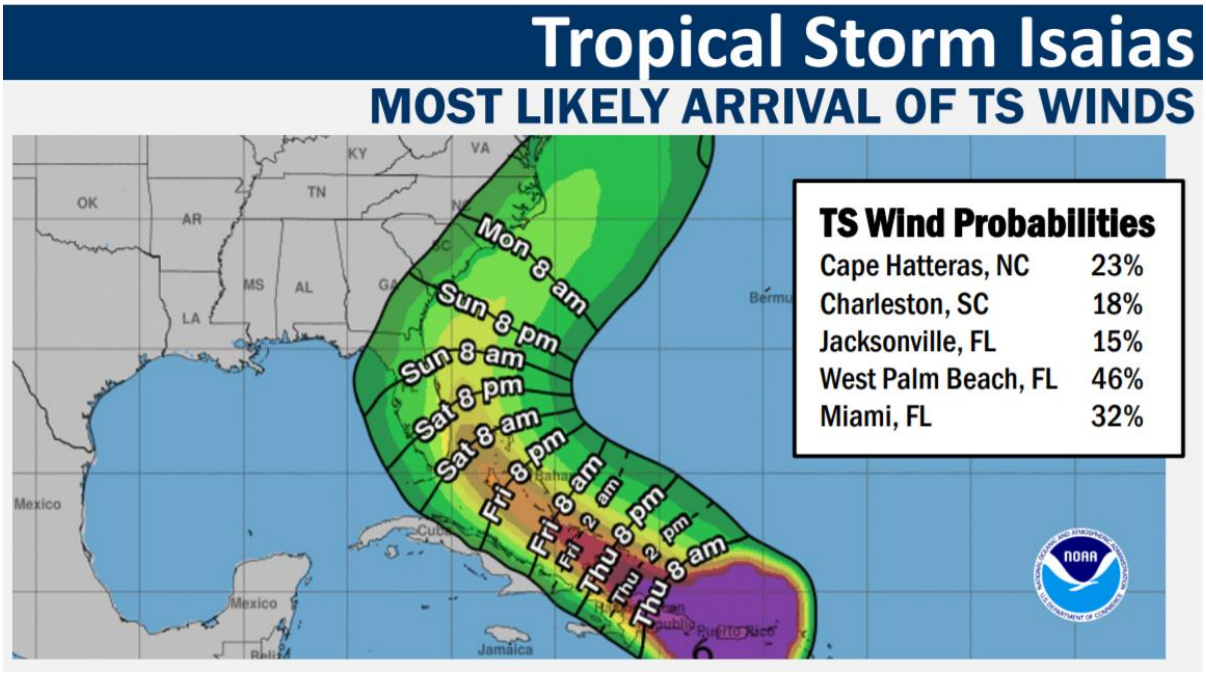


NORTH: TODAY... MOSTLY CLOUDY, CHANCE OF THUNDERSTORMS. TONIGHT...CHANCE OF SHOWERS AND THUNDERSTORMS. FRIDAY...PARTLY SUNNY, CHANCE OF SHOWERS AND T-STORMS. FRIDAY NIGHT... CLOUDY, CHANCE OF SHOWERS AND T-STORMS.

CENTRAL: TODAY...PARTLY SUNNY, CHANCE OF SHOWERS AND T-STORMS.TONIGHT...MOSTLY CLEAR, CHANCE OF SHOWERS AND T-STORMS. FRIDAY...MOSTLY SUNNY, CHANCE OF SHOWERS AND T-STORMS. FRIDAY NIGHT...CHANCE OF SHOWERS AND THUNDERSTORMS.

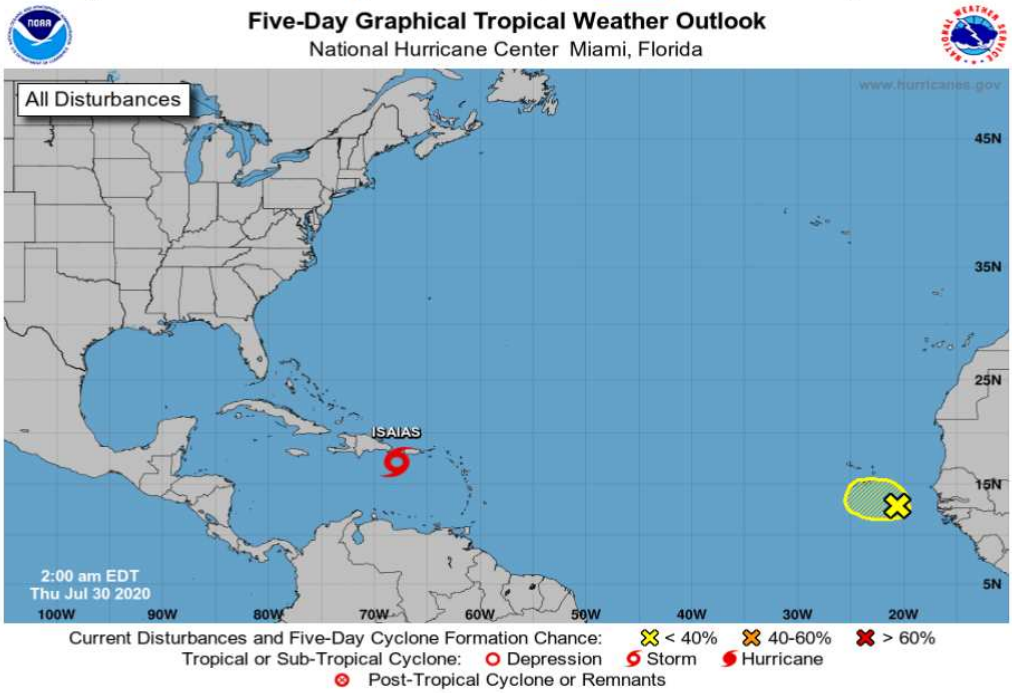
SOUTH: TODAY... SLIGHT CHANCE OF SHOWERS AND THUNDERSTORMS. TONIGHT...MOSTLY CLEAR, LOWS IN THE LOWER TO MD 70S. FRIDAY...MOSTLY SUNNY. CHANCE OF SHOWERS AND T-STORMS. FRIDAY NIGHT...CLEAR, SLIGHT CHANCE OF RAIN AND T-STORMS.





10PM July 29th update on Tropical Storm Isaias: This system continues to show some slow organization in the eastern Caribbean, with steady west-northwest motion and slow strengthening expected through late week and into the weekend. No direct impacts expected across southeastern Louisiana and southern Mississippi, however we will continue to closely monitor this system.

Tropical – Five-Day Outlook (See NHC for the latest information)



NOTABLE RECENT TRAFFIC ALERTS:
NSTR

For additional road closures and alerts visit MDOT's alert page.

HEALTH

Boil Water Notices: 6

- **Pattison Water Association**

  Located in Claiborne County, 7/28/2020

- **City Of Jackson (Hamilton Blvd, Northwood Cr, Beasley Rd, Watkins Dr, Echelon Parkway, Livingston Rd, West County Line Rd And Lakeover Subdivision)**

  Located in Hinds County, 7/27/2020

- **Eastabuchie Water Association**

  Located in Jones County, 7/26/2020

- **City of Jackson - East Northside Drive**

  Located in Hinds County, 7/24/2020

- **West Madison Utility District**

  Located in Madison County, 6/1/2020 & 6/23/2020

- **Curtis Sudduth Mobile Home Park**

  Located in Pontotoc County, 03/26/2012

National / World Media Report Summary:

- Harvested antibodies now being tested as a prevention tool against COVID-19
- What happens when a hurricane hits a coronavirus hot spot? South Texas cities found out the hard way
- Mysterious coronavirus outbreak catches Vietnam by surprise
- What do we know about children and coronavirus transmission?
- Coronavirus: Researchers identify six different "types" of COVID-19
- These countries are banning alcohol or closing bars in response to coronavirus surges
- Unemployment caused by coronavirus pandemic may be accelerating drug overdose
- Rural COVID-19 "Red Zones" are on the rise
- EDM Wednesday briefing: NHC issuing advisories for potential tropical cyclone nine
- States scramble to deal with the compounding covid and opioid epidemic
- Yes, the coronavirus IS in the air
- Florida will pause coronavirus testing due to impending storm
- How COVID-19 spread, and was contained, at two nursing homes
- US announces plans to remove 12,000 troops from Germany, with half coming home
- Eat simple plant based diets for a longer, healthy life
- COVID-19 U.S. Situation: Total Cases – 4,398,898 • Total Deaths – 150,090 • All 50 states, District of Columbia, Puerto Rico, Guam, and US Virgin Islands are reporting cases

Restaurant Inspections:

The facilities below received a grade of C for a critical violation not corrected at the time of inspection, or a critical violation repeated from a previous inspection:

	Name	District	City	Street	Inspection Date	Result	Type
Details	BUMPERS DRIVE INN	District II	BALDWYN	618 FOURTH ST.	07/27/2020	C	Fast Food or Delicatessen
Details	RICK'S EXPRESS #4	District III	GREENVILLE	3085 HWY 1 SOUTH	07/24/2020	C	Fast Food or Delicatessen
Details	Kentucky Fried Chicken	District II	Fulton	413 Interchange Drive	07/29/2020	C	Fast Food or Delicatessen
Details	Pike County Speedway LLC	District VII	Magnolia	4151 Hwy 568 W	07/24/2020	C	Fast Food or Delicatessen

LINKS
MS Homeland Security Training

Calendars:
MSDH Airport Warehouse Training Room
MSDH Events Calendar

State Emergency Management Resources:
Mississippi Emergency Management Agency

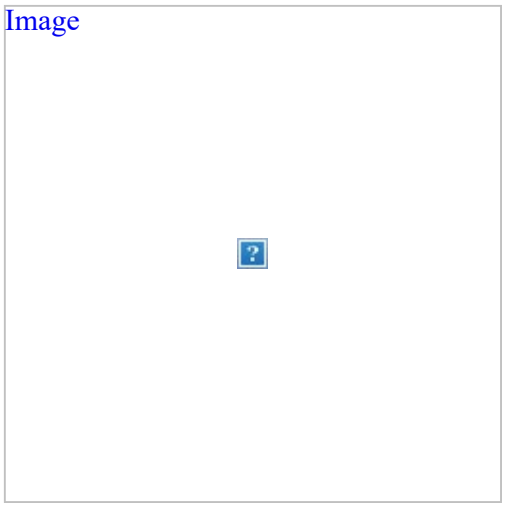
Other State Resources:
Mississippi Department of Public Safety
Mississippi Department of Health
Mississippi Department of Health Contact information
Mississippi State Legislature
Mississippi Hospital Association
Mississippi Homeland Security
MCDEMA

Federal Emergency Management Resources:
The Federal Emergency Management Agency
National Hurricane Center
Central United States Earthquake Consortium

Other Federal Resources:
American Red Cross
The Salvation Army
U.S. Food and Drug Administration

News:
The Clarion Ledger
WLBT-WDBD
WAPT Jackson
Mississippi Business Journal

From: The Network for Public Health Law
To: Williams, Christin
Subject: Network Report 9/9: Town Hall - Assault on Public Health Authority to Act for the Collective Good
Date: Thursday, September 9, 2021 10:40:41 AM



Network Report

Thursday, September 9, 2021

Assault on Public Health Authority to Act for the Collective Good: Confronting the Danger — A Special Town Hall

This Town Hall at the close of the 2021 Virtual Public Health Law Conference will discuss the current climate of threats to public health officials, and to the legal infrastructure and public health's authority to act to protect the health of communities. After a brief introduction to current aspects of this challenge, Town Hall attendees will participate to share experiences: concerns and successes; strategies to address these threats; legal resources and research needs; and coordination of effort. Learn more and register.

Law & Policy Insights

The Network's Harm Reduction Legal Project Recognizes International Overdose Awareness Day

Like many others, the Network recently recognized the 20th International Overdose Awareness Day, an especially somber occasion

Image

given that more people have died from preventable overdose this past year than at any other time. Despite the seemingly endless stream of drug overdose deaths, restrictive laws and policies all too often increase, rather than decrease, the risk of overdose and other drug-related harm.

Image

Improving Childhood Health: The Unrealized Potential of Medicaid's EPSDT Program

In the United States, millions of children live in poverty and are at a much greater risk of experiencing adverse health outcomes compared to their contemporaries in higher income households. Medicaid's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) service was created to provide essential health screenings for at risk children. Despite requirements that states provide timely screenings for the majority of those eligible, the program consistently falls short of meeting these goals.

Image

Drought: It Doesn't Have to Leave Us High and Dry (and Unhealthy)

Nearly half of the United States is experiencing abnormally dry conditions this year. The public health implications of drought cannot be underestimated: drought can lead to a lack of clean drinking water, food insecurity, poor air quality, water-borne diseases, mental health concerns, wildfire, and poor sanitation. Solutions that prevent non-essential uses of water, increase natural storage of water in the soil and aquifers, or maintain water and lake levels, may help limit the public health impacts of future droughts by increasing the overall supply of useable water.

Public Health Law News Round-Up

Some of the public health law and policy issues in the headlines in recent weeks include Texas' new abortion law, the Supreme Court's decision on the federal eviction moratorium and states' responses; challenges to Florida Governor's ban on mask mandates; gaps in data concerning COVID-19 cases; accessibility of mental health care; and the growing suicide rate among communities of color.

Image

Resources

Image

Back-to-School Legal Trends and Challenges Related to COVID-19

K–12 schools and parents of K–12 students are facing numerous challenges and uncertainties with the widespread return of in-person learning for the 2021–22 school year. While the return of in-person learning is generally positive, the continued pervasive presence of COVID-19 implicates public health concerns related to the spread of the virus. This fact sheet offers a broad-level overview of issues associated with the return to in-person learning during the COVID-19 pandemic. It also serves as a starting point and initial resource for individuals seeking information on what actions can be taken to protect K–12 students, as well as school faculty and staff, from COVID-19 in a school setting.

Webinars

Image

Voting & Health: Opportunities to Expand Inclusion

September 15, 2021 | 2:00 - 3:00 p.m. ET

This webinar, co-sponsored by the Network, APHA, Vot-ER, Healthy Democracy Healthy People, and Roundtable on Population Improvement will review policies and approaches that impact voter registration, outline the current landscape of challenges and opportunities in registering the hardest-to-reach populations and explore innovative ways to promote voter registration, such as automatic voter registration specifically through state Medicaid programs.

Worth Sharing

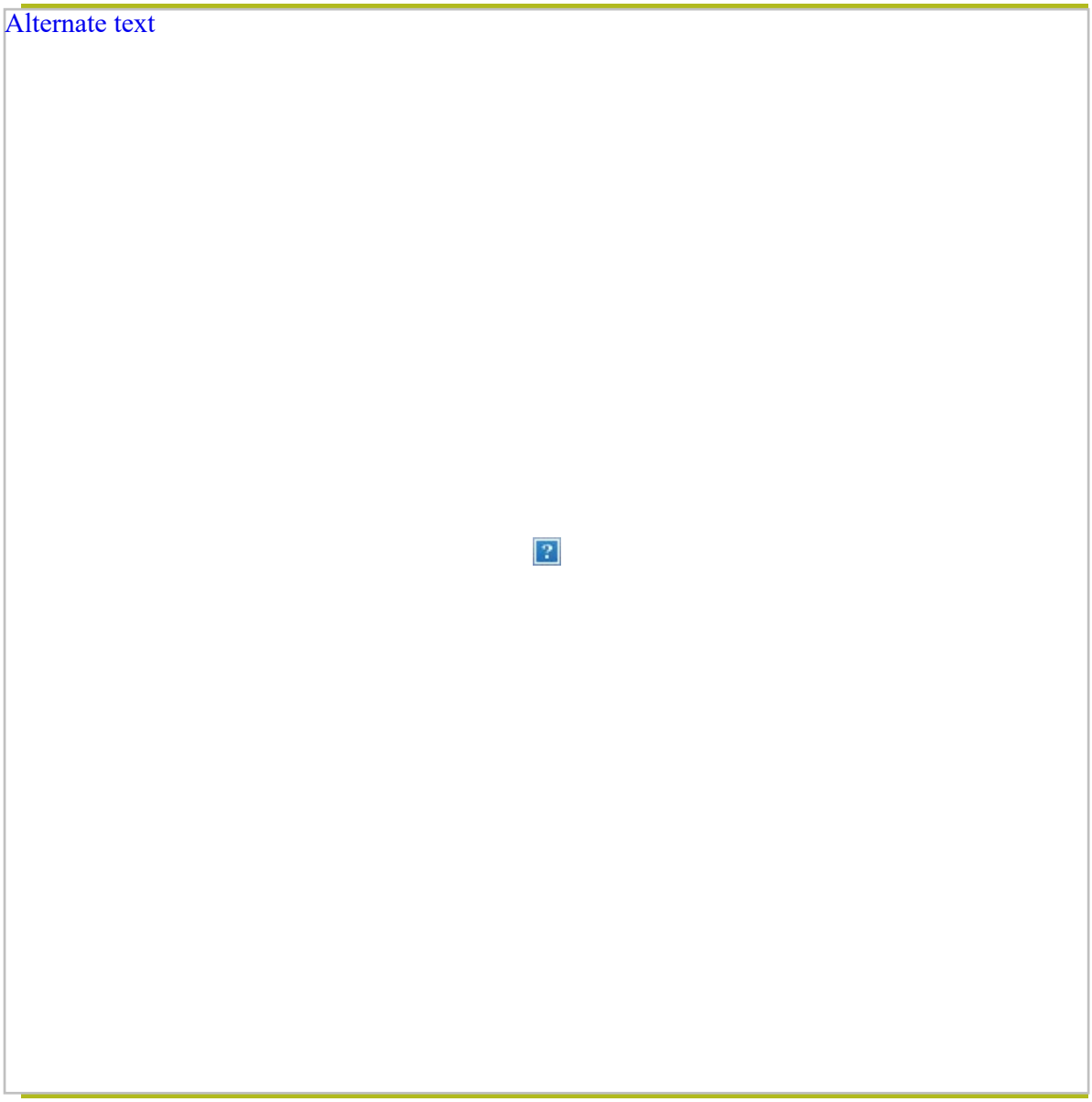
Commentary: Legal Interventions to Counter COVID-19 Denialism

James G, Hodge, director, Jennifer L. Piatt, deputy director, and Leila Barraza, senior consultant at the Network's Western Region Office have coauthored this commentary published in the *Journal Of Law, Medicine & Ethics* assessing a series of legal challenges and pathways under consideration or

in use to counter state-based legal efforts to limit or prohibit the use of known, effective public health powers in response to the continued spread of the Delta variant of COVID-19.

Public Health Law: Concepts and Case Studies

The Network's Donna Levin, Peter Jacobson, Denise Chrysler, James Hodge, Jennifer Piatt, and Corey Davis are among the contributing authors to the recently published book, *Public Health Law - Concepts and Case Studies*. The book aims to make law more accessible, empowering students, public health practitioners, and researchers to see law as simply another tool in their toolbox—just like epidemiology, surveillance, biostatistics, and other traditional public health tools.



Tell Us What You're Working On. We're Ready to Help.

Our law and policy experts can help you identify the key considerations central to your unique challenges and provide law and policy pathways you can leverage to make a difference.

Image

Request Assistance →

Thank you!
Your interest in the work of the Network is important. Together, we can advance law as a tool to improve public health. **Please forward the Network Report and encourage others to join the Network!**

The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, readers should consult a lawyer in their state.

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Infectious SARS-CoV-2 in Exhaled Aerosols and Efficacy of Masks During Early Mild Infection

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Summary: Cases exhale infectious viral aerosols. SARS-CoV-2 evolution favors more efficient aerosol generation. Loose-fitting masks moderately reduce viral RNA aerosol. Ventilation, filtration, UV air sanitation, and tight-fitting masks are needed to protect vulnerable people in public-facing jobs and indoor spaces.

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Abstract

Background: SARS-CoV-2 epidemiology implicates airborne transmission; aerosol infectiousness and impacts of masks and variants on aerosol shedding are not well understood.

Methods: We recruited COVID-19 cases to give blood, saliva, mid-turbinate and fomite (phone) swabs, and 30-minute breath samples while vocalizing into a Gesundheit-II, with and without masks at up to two visits two days apart. We quantified and sequenced viral RNA, cultured virus, and assayed sera for anti-spike and anti-receptor binding domain antibodies.

Results: We enrolled 49 seronegative cases (mean days post onset 3.8 ±2.1), May 2020 through April 2021. We detected SARS-CoV-2 RNA in 45% of fine (≤5 µm), 31% of coarse (>5 µm) aerosols, and 65% of fomite samples overall and in all samples from four alpha-variant cases. Masks reduced viral RNA by 48% (95% confidence interval [CI], 3 to 72%) in fine and by 77% (95% CI, 51 to 89%) in coarse aerosols; cloth and surgical masks were not significantly different. The alpha variant was associated with a 43-fold (95% CI, 6.6 to 280-fold) increase in fine aerosol viral RNA, compared with earlier viruses, that remained a significant 18-fold (95% CI, 3.4 to 92-fold) increase adjusting for viral RNA in saliva, swabs, and other potential confounders. Two fine aerosol samples, collected while participants wore masks, were culture-positive.

Conclusion: SARS-CoV-2 is evolving toward more efficient aerosol generation and loose-fitting masks provide significant but only modest source control. Therefore, until vaccination rates are very high, continued layered controls and tight-fitting masks and respirators will be necessary.

Key words: SARS-CoV-2; exhaled breath aerosol; face masks; airborne infection; SARS-CoV-2 variants

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Introduction

The World Health Organization[1] and U.S. Centers for Disease Control and Prevention[2] recently acknowledged the growing scientific consensus that inhalation exposure is an important route of SARS-CoV-2 transmission[3,4]. The totality of evidence from epidemiologic and outbreak investigations, combined with data on the size distribution of exhaled aerosols and corresponding quantitative models, is compelling[4]. However, culture of the virus from exhaled aerosols, and direct measures of the efficacy of face masks as source control when worn by actual patients have been lacking. Previous reports of infectious virus[5,6] and viral RNA concentrations in room air[7,8] do not provide a clear picture of how much virus infected persons shed into the air. These gaps lead to uncertainty in estimates of exposure, derived from retrospective analysis of outbreaks[9]. New variants also appear more transmissible, but more quantitative data is needed to discern what that means for implementing effective non-pharmaceutical interventions – still a mainstay of infection protection.

We collected exhaled breath aerosol samples from polymerase chain reaction (PCR)-confirmed COVID-19 cases infected with SARS-CoV-2, including alpha and earlier variants, circulating in a university campus community using a Gesundheit-II (G-II) exhaled breath sampler[10,11]. We measured concentrations of SARS-CoV-2 RNA and recovered infectious virus from respiratory swabs, saliva, and aerosols, analyzed the effectiveness of face masks as source control, and examined the impact of the alpha variant on aerosol shedding.

Materials and Methods

This study was approved by the University of Maryland Institutional Review Board and the Human Research Protection Office of the Department of the Navy. Electronically signed informed consent was obtained and questionnaire data were collected and stored with REDCap[12].

We recruited participants with active infection (defined as positive qRT-PCR for SARS-CoV-2 in respiratory swab or saliva samples) May 2020 through April 2021 from the University of Maryland College Park campus and community though a) daily symptom reporting and weekly pooled saliva testing cohort of 238 volunteers, b) direct recruiting of recently diagnosed cases from local clinics and campus, and c) frequent testing of close contacts of cases for two weeks following last contact. Cases and contacts completed online consents and a questionnaire (see Supplemental Methods) before in-person confirmation of consent and specimen collection at the University of Maryland School of Public Health. For contacts, we collected a blood specimen at the first visit and measured oral temperature, blood oxygen saturation (SpO_2), and collected a mid-turbinate swab (MTS) from each nostril and a saliva sample, at approximately two-day intervals.

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Cohort members with a positive saliva sample, recently-diagnosed cases, and contacts with a positive test during follow-up were invited for viral shedding assessment visits on two days separated by one day. Venous blood was collected at the first visit; MTS, saliva, phone/tablet swab, and 30-minute G-II exhaled breath samples were collected at each visit[10,11]. To test the effectiveness of masks as source control, we asked participants to provide paired breath samples at each visit, first while wearing a mask and then without[13]. We provided a surgical mask at one visit and, to test masks in general use by the public, we tested the mask brought by the participant at the other; order of mask type was randomized to avoid bias. Cases studied before September 2020 were asked to repeat the alphabet three times within the 30-minute sampling period, as previously described [13]. Subsequent cases were asked to shout "Go Terps" 30 times and sing "Happy Birthday" loudly three times at 5, 15, and 25 minutes into each 30-minute sampling period. Participants with more severe symptoms sometimes opted to give only one 30-minute breath sample; for these participants, sampling without a face mask was given priority.

Symptom evaluation

Symptoms were self-reported and measured on a scale of 0-3 and composite scores were sums of individual symptom scores for systemic, gastrointestinal, lower respiratory, and upper respiratory symptoms as previously described[10], see Supplementary Information [SI] for additional details.

Sample preparation

MTS and phone/tablet swabs were eluted in 1 mL of Universal Transport Media (BD). MTS from both nostrils were combined. G-II coarse and fine aerosol samples were concentrated, resulting in a 1-mL final sample volume as previously described.[10] One aliquot each of MTS and saliva samples were kept at 4 °C for immediate qRT-PCR. All other samples were stored at −80 °C until further analysis.

Laboratory analyses

Specific laboratory analysis details can be found in the SI. Cohort saliva was processed using the SalivaDirect method[14]. For all other samples, nucleic acids were extracted with MagMax Pathogen RNA/DNA Kit (Applied Biosystems) on KingFisher Duo Prime (Thermo Scientific), following manufacturer protocols specific to sample type. Viral RNA was detected and quantified using the TaqPath COVID-19 Real Time PCR Assay Multiplex and coinfection of samples was determined using the TaqMan Array Card (both Thermo Scientific). RNA copy numbers are reported per mL for saliva and per sample for all other sample types. The limit of detection (LOD) was 75 copies/sample and the limit of quantification (LOQ) was 250 copies/sample (SI).

Viral infectivity was measured by first propagating virus on Vero E6 cells stably expressing TMPRSS2[15] then transferring the media to A549 cells stably expressing human ACE2 (A549-ACE2, from BEI NR-53522 and a gift from Dr. Adolfo Garcia Sastre). Infected A549-ACE2 cells were quantified using immunofluorescence staining with anti-SARS-CoV-2 nucleocapsid antibody (Sino

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Biological 40143-R004) and Hoechst 33342 (Invitrogen H3570), and imaging with a Celigo Imaging Cytometer (Nexcelom) (Figures S1, S2). Plasma was analyzed for IgG, IgM, and IgA antibodies to SARS-CoV-2 using a modified protocol described by Stadlbauer et al., 2020[16]. MTS and saliva samples were sequenced at the Walter Reed Army Institute for Research or the University of Maryland Institute for Genome Sciences. SARS-CoV-2 lineages and mutations were determined using PANGOLIN and Nextstrain tools[17,18].

Statistical analysis

We included analysis of all actively infected cases recruited from the campus and surrounding community over the course of one year. To ensure comparability of with and without mask samples in the analysis of mask efficacy, we included only paired same-day samples collected with and without a face mask from the same person and controlled for numbers of coughs during each sampling session.

Data curation, cleaning, analysis, and visualization were performed using R Studio and R (version 4.1.0)[19], with R packages lme4, lmec, and ggplot2[20]. We made group comparison between seronegative (no detectable antibody) and seropositive cases using two-sample t-test for continuous variables and Fisher's exact test for categorical variables. To handle censored observations below the limit of detection, we applied linear mixed-effect models with censored responses[21,22] and included nested random effects of subject and sample nested within subjects. The geometric means and standard deviations of viral RNA copy numbers for all sample types and the effect of the predictors of viral RNA shedding were estimated from the model. Deidentified data and code for the accepted manuscript will be made available on github.

Results

Sixty-one people with active SARS-CoV-2 infection (recent onset and positive PCR for MTS or saliva) were enrolled in breath testing: 3 from a weekly saliva testing cohort, 43 from 55 recently diagnosed COVID-19 cases, and 15 from among 62 contacts of cases followed to detect early onset of infection (Figure S3). Eight people (13%) with active infection had either IgM or IgG antibodies to SARS-CoV-2 spike protein at the first breath testing visit and four were unable to give a venous blood sample.

The 57 participants with known serologic status at the time of breath sampling (49 seronegative, 8 seropositive) were enrolled from zero to 12 days post onset of symptoms or first positive test (Table 1, Figure S4). All cases were asymptomatic or mild at the time of study. The seronegative cases included all participants with singing experience and alpha-variant infection – there were no other significant differences based on serologic status. No volunteer was taking antiviral medication at the time of breath sample collection and no co-infections were identified.

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Seronegative cases

Among seronegative participants, 4 (8%) were infected with the alpha and none with delta or other variants associated with increased transmissibility[23] (Table S1). Symptoms tended to be more pronounced at the first shedding visit, two participants were febrile at the second shedding visit (Figures S5-S6), and three were asymptomatic. Each of the 4 seronegative alpha variant cases had detectable concentrations of viral RNA in all MTS, saliva, fomite, and aerosol samples (Table 2). Among the remaining seronegative participants, we detected viral RNA in all MTS, 99% of saliva, 49% of fomite, 19% of coarse-, and 31% of fine-aerosol samples. The geometric mean concentrations of viral RNA were significantly greater for all sample types collected from alpha variant cases.

Exhaled breath viral RNA from seronegative cases without masks

Viral RNA content of 30-minute breath aerosol samples was similar to the amount of RNA recovered from participants' mobile phones (Table 2). The frequency of detection of viral RNA in aerosols was greatest 2-5 days post onset of symptoms or first positive test (Figure S7) but was not a significant predictor of the quantity of viral RNA in the aerosols (Table 3). Viral RNA in MTS and saliva were moderately correlated (Figure S8: ρ=0.46) but only RNA in MTS was a strong predictor of viral load in aerosols (Table 3, Figures S9, S10). The quantity of viral RNA in the fine-aerosol fraction was 1.9-fold (95% confidence interval [CI] 1.2 to 2.9-fold) greater than in the coarse-aerosol fraction (not shown).

Effect of alpha variant infection on viral RNA shedding from seronegative cases

Alpha variant infection was associated with significantly greater amounts of viral RNA shedding than infection with earlier strains and variants. In bivariate analyses of samples collected without masks (Tables 3 and S3), the alpha variant was associated with significantly greater viral RNA shedding than wild-type and other variants not associated with increased transmissibility. Fine-aerosol shedding remained significantly greater for alpha variant infections (18-fold, 95% CI, 3.4 to 92-fold) after adjusting for the increased viral RNA in MTS and saliva, the number of coughs during sampling sessions, and symptoms (Table 3). We also analyzed the impact of alpha variants on shedding using the larger data set, including samples collected with and without masks. After controlling for the effect of masks and numbers of coughs during sampling, alpha variant infection was associated with a 100-fold (95% CI, 16 to 650-fold) increase in coarse- and a 73-fold (95% CI, 15 to 350-fold) increase in fine-aerosol RNA shedding (Table 3).

Effect of masks on viral RNA shedding from seronegative cases

We observed statistically significant reductions in aerosol shedding regardless of mask type after adjusting for number of coughs during sampling sessions: 77% (95% CI, 51% to 89%) reduction for coarse and 48% (95% CI, 3% to 72%) for fine aerosols (Figure 1). Surgical masks did not perform significantly differently than others (Table S5), and mask performance was not significantly different for alpha variant infections (Table 3). The types of face masks brought by participants varied and progressed from single-layer homemade cloth masks to more substantial double-layer cloth masks, surgical masks, double masks, and a KN95 over the course of the year (Table S4).

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Seropositive cases

Eight participants had antibodies to SARS-CoV-2 spike protein at the time of breath sample collection. Seropositive cases tended to cough more than seronegative cases (Table 1) but none of the exhaled aerosol samples from seropositive cases had detectable viral RNA (Table S6).

Virus cultures

Among samples subjected to virus culture, we detected infectious virus (Figure S2) in 50 (68%) of 73 MTS and 20 (32%) of 62 saliva samples from seronegative participants (Figure 2, Table S2a). The RNA concentration associated with a 50% probability of a positive culture was 7.8×10^5 for MTS and 5.2×10^6 for saliva (Figure S11, Table S7). None of the 75 fine-aerosol samples collected while not wearing face masks were culture-positive. Two (3%) of the 66 fine-aerosol samples collected from participants while wearing face masks were culture-positive, including one from a person infected with the alpha variant 2 days post onset and one from a person with a Nextstrain clade 20G virus 3 days post onset. Fomite and coarse-aerosol samples subjected to culture were negative.

Discussion

Alpha variant infection yielded one to two orders of magnitude more viral RNA in exhaled breath when compared with earlier strains and variants not associated with increased transmissibility. Our observation of increased aerosol shedding, even after controlling for the increased amounts of viral RNA in the nose and mouth, suggests that evolutionary pressure is selecting for SARS-CoV-2 capable of more efficient aerosol generation.

We recovered infectious virus from two exhaled breath fine-aerosol samples, approximately two-thirds of MTS, and one-third of saliva samples. Logistic regression analysis of the MTS and saliva samples suggests that there is a small but measurable probability that each RNA copy represents an infectious viral particle consistent with previous dose-response models of infectious viruses[24]. The probability of detecting infectious virus in our cell culture system may be as high as 10^{-4} per RNA copy in saliva samples with 10^2 copies. We recovered infectious virus from one of the two fine-aerosol samples with $>10^4$ RNA copies per sample, where the estimated probability of a positive culture was 8% per sample, based on the regression model. The other culture-positive aerosol sample was one of 98 aerosol samples below the 75-copy limit of detection for RNA. This observation is consistent with a previous report of infectious SARS-CoV-2 in an aerosol sample with very low RNA copy numbers[5], and may suggest that virus particles in respiratory aerosols contain fewer defective virions than MTS, or that the fluid is less likely to interfere with viral cell attachment and entry than are nasal secretions and saliva. It is likely that human airway epithelium is more susceptible to infection than laboratory cell cultures[25].

Loose-fitting face masks, including surgical masks and those in daily use by the study participants, produced significant, albeit modest, reductions in the amount of viral RNA in exhaled breath, supporting their use as source control. Consistent with previous studies of influenza, SARS-CoV-2 viral RNA was shed more abundantly in fine than coarse aerosol and masks were more effective at

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blocking release of coarse aerosol[10,13,26,27]. The effectiveness of face masks for blocking release of fine aerosol (1.9-fold) was similar to the effectiveness we previously reported for influenza (2.8-fold). However, the 4.3-fold (or 77%) reduction in coarse aerosol was significantly less than the 25-fold reduction previously observed for influenza shedding[13]. This discrepancy likely arose because the more vigorous and extended vocalizations in the current study would be expected to maximize leakage around loose-fitting face masks. Face masks worked equally well for containing alpha variant and "wild-type" aerosol shedding.

Viral RNA aerosol collected from 22 COVID-19 patients in Singapore using a G-II measured similar RNA copy numbers and overall rates of positive breath samples (59% versus 51% here) during singing and loud talking as observed here[28]. A majority (68%) of the cases studied in Singapore were infected by variants associated with increased transmissibility, while 18% of infections were not variants of concern or interest, and each case was sampled on only one day. By comparison, our sample included more "wild-type" infections and sampling days per person allowing analysis of the impact of variants on shedding. One delta variant was studied in Singapore and none in this study. The shedding rates detected using the G-II in both studies, however, were lower than those reported by Ma et al. using a sampler that requires subjects to blow through a narrow straw[29]. Ma et al. and our data are in agreement that among persons infected with "wild-type" strains, a minority (26% and 31%, respectively) shed detectable levels of viral RNA into aerosols. However, our data on alpha variant infections and the data from Singapore suggest that this is changing and most cases may now be shedding viral aerosols more frequently. We have yet to enroll cases with the delta variant and study them using the Maryland protocol to test the expectation, based on our current findings, that delta will be associated with an additional large increase in aerosol shedding.

Our study had several limitations. Although we attempted to identify and test cases early through weekly testing of a cohort and intensive follow-up of close contacts, most cases were still studied several days after onset of symptoms or first positive test. This likely resulted in missing the most contagious period[30–33]. Furthermore, all cases were mild at the time of testing and only two went on to have moderate severity and require hospitalization. As a result, our data may not represent the upper end of the spectrum of shedding. The types of face masks worn by participants changed over the course of the study, as did the quality of surgical masks that we could purchase. Therefore, we cannot report on the efficacy of specific loose-fitting masks. This work does, however, provide information on the average amount of source control provided by community masking. Finally, logistical considerations required that we freeze samples between collection and culture, with potential loss of infectiousness[34], especially for dilute aerosol specimens.

Overall, our results demonstrate that people with mild or asymptomatic SARS-CoV-2 infections released infectious aerosols in their exhaled breath. Face masks provided significant source control suggesting that community-wide masking even with loose-fitting masks can reduce viral aerosols in indoor air by half, making a significant contribution to reducing the spread of COVID-19. Our data also suggest that the virus is evolving toward more effective dissemination through aerosols and

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demonstrate that infectious virus can escape from loose-fitting masks. With the dominance of newer, more contagious variants than those we studied, increased attention to improved ventilation, filtration, air sanitation, and use of high-quality tight-fitting face masks or respirators (e.g., tight-fitting ASTM F3502-21 level-2 face-coverings or respirators) for respiratory protection will be increasingly important for controlling the pandemic. This will be especially true where vaccination rates are low, vaccine is not available, and for people with poor immune responses or waning immunity. Therefore, our data support community mask mandates and tight-fitting masks or respirators for workers in healthcare but also in all workplaces where people are sharing indoor air or have frequent public contact.

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Disclaimers and Funding

Material has been reviewed by the Walter Reed Army Institute of Research. There is no objection to its presentation and/or publication. The investigators have adhered to the policies for protection of human subjects as prescribed in AR 70–25. The View(s) expressed are those of the authors and do not necessarily reflect the official views of the Department of Health and Human Services, the Departments of the Army, Navy or Air Force, the Department of Defense, or the U.S. Government. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position or policy of these agencies and no official endorsement should be inferred.

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Potential conflict:

TT reports support from IARPA, NSF, and NIH, and a leadership role with COV-IRT, outside the submitted work. SW and MF report payments to their institution from NIAID, BARDA, DARPA, Gates Foundation, Aikido Pharma, Emergent, Astrazeneca, Novavax, Regeneron, and the CDC, outside the submitted work. MF reports royalties/licenses from Aikido Pharma for antiviral drug patent licensing, consulting fees from Aikido Pharma, Observatory Group, for consulting for COVID19, and participation on Scientific Advisory Board for Aikido Pharma, outside the submitted work. PJBdM reports consultancy fees paid directly to Dr. Bueno de Mesquita for advising on SARS-CoV-2 transmission and engineering control measures in buildings from Optimized Thermal Systems and consultancy fees paid directly to Dr. Bueno de Mesquita for advising on strategies to reduce SARS-CoV-2 transmission during film production from PandemicProofProductions, outside the submitted work. All other authors have no potential conflicts of interest.

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Tables

Table 1. Characteristics of the study population

	Antibody negative	Antibody positive	All with serologic tests	*P-value*[a]
Number of participants	49	8	57	-
Number of exhaled breath sample visits[b]	78	15	93	-
Female, N (%)	18 (37)	2 (25)	20 (35)	0.70
Age, mean years ± SD	23.7 ± 9.5	24.9 ± 8.4	23.8 ± 9.3	0.73
Age group, N (%)				-
<18	1 (2)	0 (0)	1 (2)	
18-45	45 (92)	8 (100)	53 (93)	
>45	3 (6)	0 (0)	3 (5)	
White, N (%)	40 (82)	5 (62)	45 (79)	0.16
BMI, mean ± SD	24.6 ± 4.5	27.3 ± 4.8	25 ± 4.6	0.12
Chronic respiratory illness[c] N (%)	12 (24)	1 (12)	13 (23)	0.67
Ever smoker N (%)	2 (4)	1 (12)	3 (5)	0.37
Has taken singing lessons/part of a choir N (%)	4 (8)	0 (0)	4 (7)	-
Alpha Variant N (%)	4 (8)	0 (0)	4(7)	-
Days post onset[d] mean ± SD (range)	3.8 ± 2.1 (Day 1 to 10)	5.9 ± 3.8 (Day 0 to 12)	4.1 ± 2.5 (Day 0 to 12)	0.18
Coughs per 30 min, mean ± SD (range)	1 ± 3 (0-17)	3 ± 8 (0-24)	1 ± 4 (0-24)	0.098
Loss of taste/smell N (%)	13 (27)	4 (50)	17 (30)	0.22
Median upper respiratory symptoms (IQR)[e]	2 (1 - 3)	3 (1.5 - 4)	2 (1 - 3)	0.17
Median lower respiratory symptoms (IQR)	0 (0 - 1.2)	0 (0 - 1)	0 (0 - 1)	0.82
Median systemic symptoms (IQR)	1 (0 - 3)	1 (0 - 2.5)	1 (0 - 3)	0.60
Median gastrointestinal symptoms (IQR)	0 (0 - 1)	0 (0)	0 (0-1)	0.36
Temperature, mean Celsius ± SD	37.2 ± 0.4	37.2 ± 0.2	37.2 ± 0.3	0.80
Oxygen saturation (SpO_2), mean ± SD	97.9 ± 1	97.5 ± 1.1	97.8 ± 1	0.25

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BMI, Body mass index; IQR, Interquartile range;

[a] Group comparisons were made between antibody negative and positive cases using two-sample t-test for continuous variables and Fisher's exact test for categorical variables.

[b] 57 volunteers provided breath samples and sera at the initial shedding assessment visit; 34 of them provided exhaled breath samples at the 2nd shedding assessment visit approximately 2 days later; four volunteers who did not provide sera at the first visit were excluded.

[c] Chronic respiratory illness = volunteers with any Chronic obstructive pulmonary disease, Asthma, Other lung diseases.

[d] Days since start of symptoms or first positive test if asymptomatic or presymptomatic to first breath sample; 3 subjects reported no symptoms.

[e] Symptoms at the time of each sample collection visit. Sixteen symptoms were rated from 0 to 3 with a maximum possible composite score of 15 for upper respiratory, 9 for lower respiratory, 12 for systemic symptoms and 12 for gastrointestinal symptoms.

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Table 2. Viral RNA from cases seronegative for SARS-CoV-2 antibodies at the first assessment

Sample Type	Variant	Case[a]	Cases with ≥1 positive sample[b] N (%)		Samples	Positive Samples[c] N (%)		GM (95% CI)[d]	Maximum RNA copies[e]
			≥LOD	≥LOQ		≥LOD	≥LOQ		
Mid-turbinate swab	Alpha	4	4 (100)	4 (100)	6	6 (100)	6 (100)	3.8×10^8 (3.3×10^8, 4.4×10^8)	2.9×10^9
	Other	45	45 (100)	45 (100)	74	74 (100)	73 (99)	3.8×10^6 (1.4×10^6, 1.0×10^7)	5.1×10^9
Saliva	Alpha	4	4 (100)	4 (100)	6	6 (100)	6 (100)	1.9×10^7 (2.7×10^6, 1.3×10^8)	5.2×10^8
	Other	45	44 (98)	44 (98)	74	73 (99)	70 (95)	2.1×10^5 (8.1×10^4, 5.4×10^5)	3.9×10^8
Fomite	Alpha	4	4 (100)	4 (100)	6	6 (100)	4 (67)	560 (530, 590)	1.7×10^4
	Other	45	28 (62)	14 (31)	74	36 (49)	17 (23)	46 (17, 120)	1.2×10^6
Coarse (>5 µm) Aerosol	Alpha	4	4 (100)	2 (50)	6	6 (100)	3 (50)	140 (28, 730)	5.1×10^4
	Other	45	11 (24)	5 (11)	72	14 (19)	5 (7)	7 (3.2, 15)	2.6×10^4
Fine (≤5 µm) Aerosol	Alpha	4	4 (100)	3 (75)	6	6 (100)	4 (67)	580 (450, 740)	5.4×10^4
	Other	45	18 (40)	8 (18)	72	22 (31)	9 (12)	18 (9.1, 34)	2.8×10^3

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[a] Participants with a mid-turbinate or saliva samples positive for SARS-CoV-2 viral RNA by qRT-PCR and seronegative for SARS-CoV-2 spike protein antibody at enrollment and who provided at least one 30-minute sample of exhaled breath.

[b] Number of participants with at least one sample ≥ limit of detection (LOD) or ≥ limit of quantification (LOQ) (Supplementary.

[c] Samples positive and ≥LOD had at least one replicate with confirmed amplification after inspection and quality control (LOD ~75 RNA copies with 95% probability of detection) and ≥LOQ if the mean of replicate assays was ≥250 RNA copies.

[d] GM = geometric mean. The GMs were computed, accounting for samples below the LOD, using a linear mixed-effects model for censored responses (R Project LMEC package) using data for all samples of each sample type with nested random effects of samples within study participant.

[e] The largest quantity of RNA copies detected based on the mean of replicates qRT-PCR aliquots.

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Table 3. Predictors of viral RNA shedding among seronegative participants

	Coarse Aerosol (>5 µm)			Fine Aerosol (≤5 µm)		
	Without Face Mask N=49, n=78[a]		Paired ± Mask N=46, n = 69	Without Face Mask N=49, n=78		Paired ± Mask N=46, n = 69
	Unadjusted	Adjusted[b]	Estimate[c]	Unadjusted	Adjusted	Estimate
Alpha Variant	67 (6.7, 660)	3.6 (0.35, 36)	100 (16, 650)	43 (6.6, 280)	18 (3.4, 92)	73 (15, 350)
Face mask	-	-	0.23 (0.11, 0.49)	-	-	0.52 (0.28, 0.97)
Age	1.4 (0.44, 4.4)	-	-	1.7 (0.74, 3.7)	1.7 (1, 2.8)	-
Day post onset[e]	0.79 (0.53, 1.2)	-	-	0.97 (0.76, 1.2)	-	-
Log mid-turbinate swab	480 (40, 5700)	36 (3.5, 370)	-	13 (4.3, 42)	7.3 (2.5, 21)	-
Log saliva	4.6 (1.4, 15)	1.5 (0.55, 4.3)	-	2.8 (1.2, 6.5)	0.96 (0.47, 2)	-
Number of coughs	1.2 (0.92, 1.5)	1.2 (1, 1.5)	1 (0.93, 1.2)	1.2 (0.96, 1.5)	1.2 (1, 1.3)	1.1 (1, 1.3)
Upper respiratory symptoms	2.4 (0.91, 6.1)	-	-	1.7 (0.83, 3.6)	0.75 (0.44, 1.3)	-
Lower respiratory symptoms	0.99 (0.36, 2.7)	0.4 (0.13, 1.2)	-	0.64 (0.3, 1.4)	-	-
Gastrointestinal symptoms	2.3 (1.1, 5.2)	1.2 (0.55, 2.4)	-	1.7 (0.94, 3.2)	1 (0.61, 1.7)	-
Systemic symptoms	5.7 (2.5, 13)	2.4 (0.97, 6.1)	-	2.1 (1.1, 4)	1.1 (0.59, 2)	-
Alpha Variant x Face mask	-	-	0.62 (0.15, 2.7)	-	-	0.7 (0.2, 2.4)

Effect estimates and their 95% confidence intervals are shown as the ratio of RNA copy number of samples: with alpha variant to without alpha variant, with mask to without mask, or as the fold-increase in RNA copy number

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for a 10-year increase in age, 1-day increase in day post-symptom onset, and an interquartile range change in symptom scores, mid-turbinate swab and saliva RNA copy number. All analyses were controlled for random effects of subject and sample nested within subjects and for censoring by the limit of detection using a linear mixed-effects model for censored responses (R Project lmec-package).

[a] N = Number of participants, n = number of samples for without face mask analysis and number of pairs of same day with and without face masks samples for paired analysis of the effect of face masks.

[b] The adjusted estimates accounted for potential covariates resulting in greater than 10% change in the estimates of the main exposure variable – "Alpha variant"

[c] The effect of mask on samples adjusted for Alpha variant and number of coughs counted during sample collection

[d] Face masks included both surgical masks provided by the investigators and masks currently being used by participants on the day of testing; surgical masks and participant provided masks were not significantly different (Table S5).

[e] Days since start of symptoms or first positive test if asymptomatic or presymptomatic to breath sample; 2 subjects had no symptoms

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FIGURES LEGENDS

Figure 1. Viral RNA shedding in paired with and without face mask samples. Viral RNA measured during 69 same-day paired sampling events with and without mask from 46 seronegative cases. Samples with no detected viral RNA were assigned a copy number value of one. Exhaled breath aerosols were obtained in 30-minute sampling durations. "+mask" = sample collected while wearing a face mask. MTS = mid-turbinate swab, Fomite = swab of participant's mobile phone.

Figure 2. Viral RNA content and culture results of samples from all sampling events for seronegative cases. Samples with no detected viral RNA were assigned a copy number value of one. Exhaled breath aerosols were obtained during 30-minute sampling events and included unpaired with and without face mask samples. Five fine aerosol samples with face mask and three fomite samples were not available for culture. A subset of MTS, saliva, and coarse aerosol samples were subjected to culture. MTS = mid-turbinate swab, Fomite = swab of participant's mobile phone.

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Figure 1

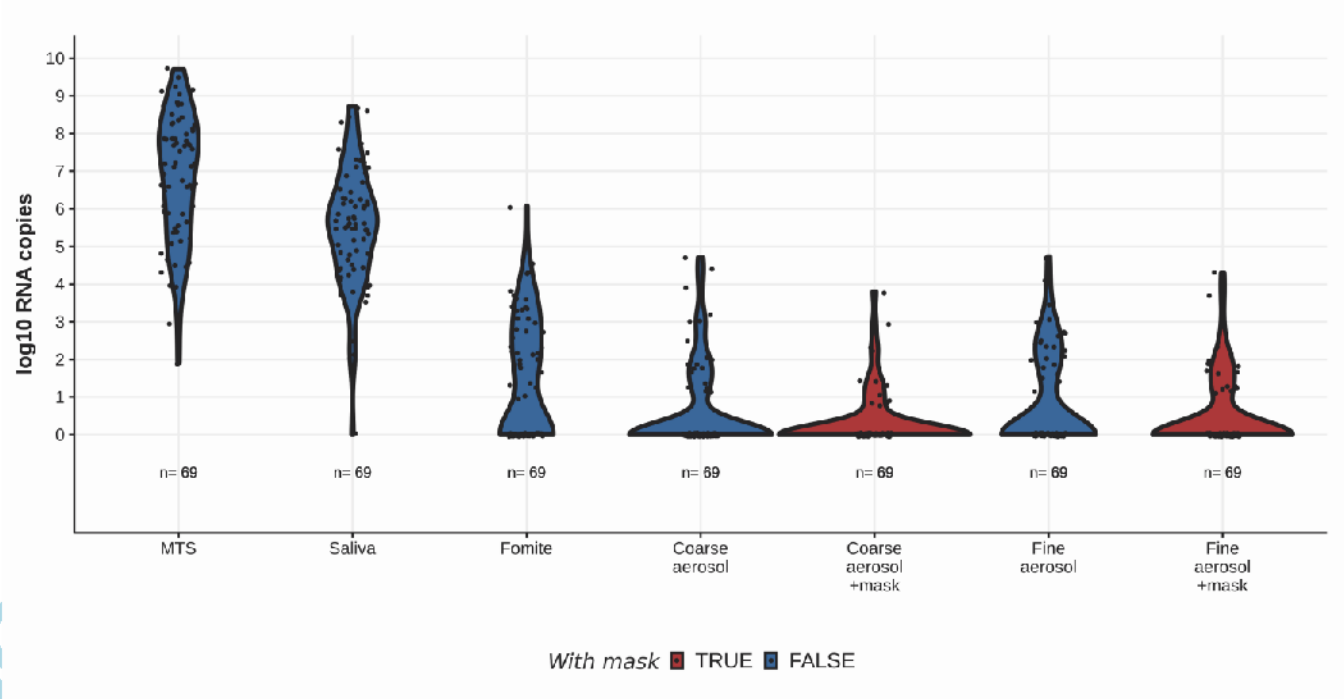

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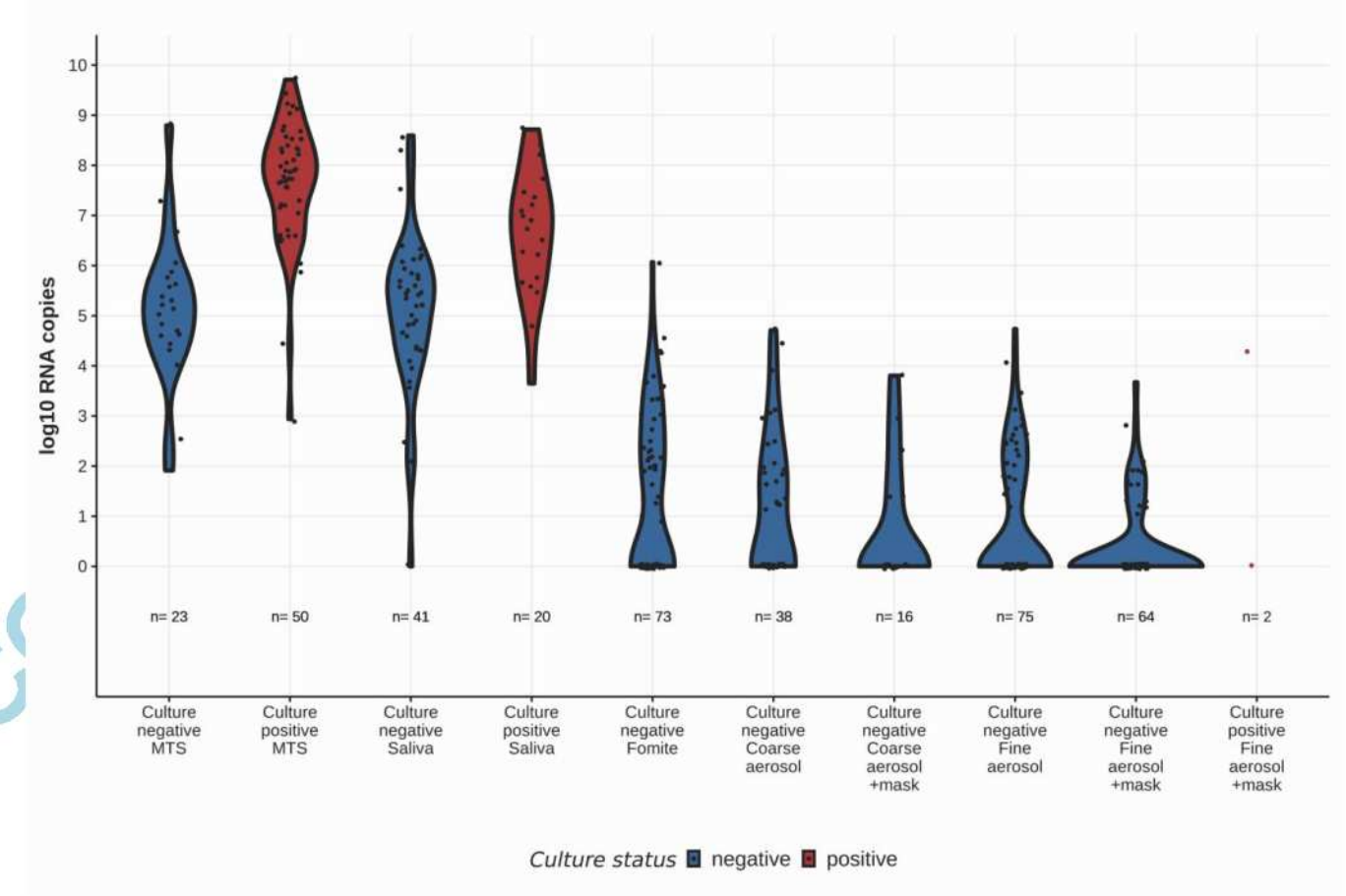
Figure 2



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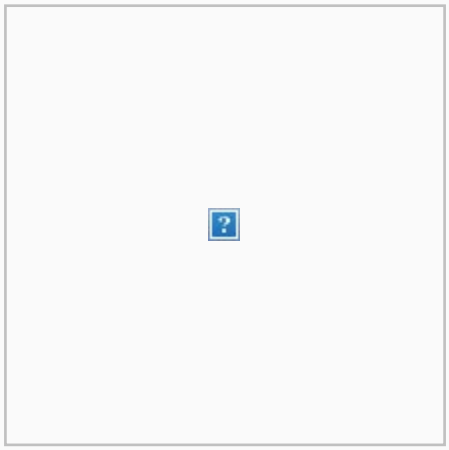
From: Dr. Tom Frieden
To: Dobbs, Thomas E
Subject: Now or Never
Date: Thursday, February 25, 2021 11:41:09 AM

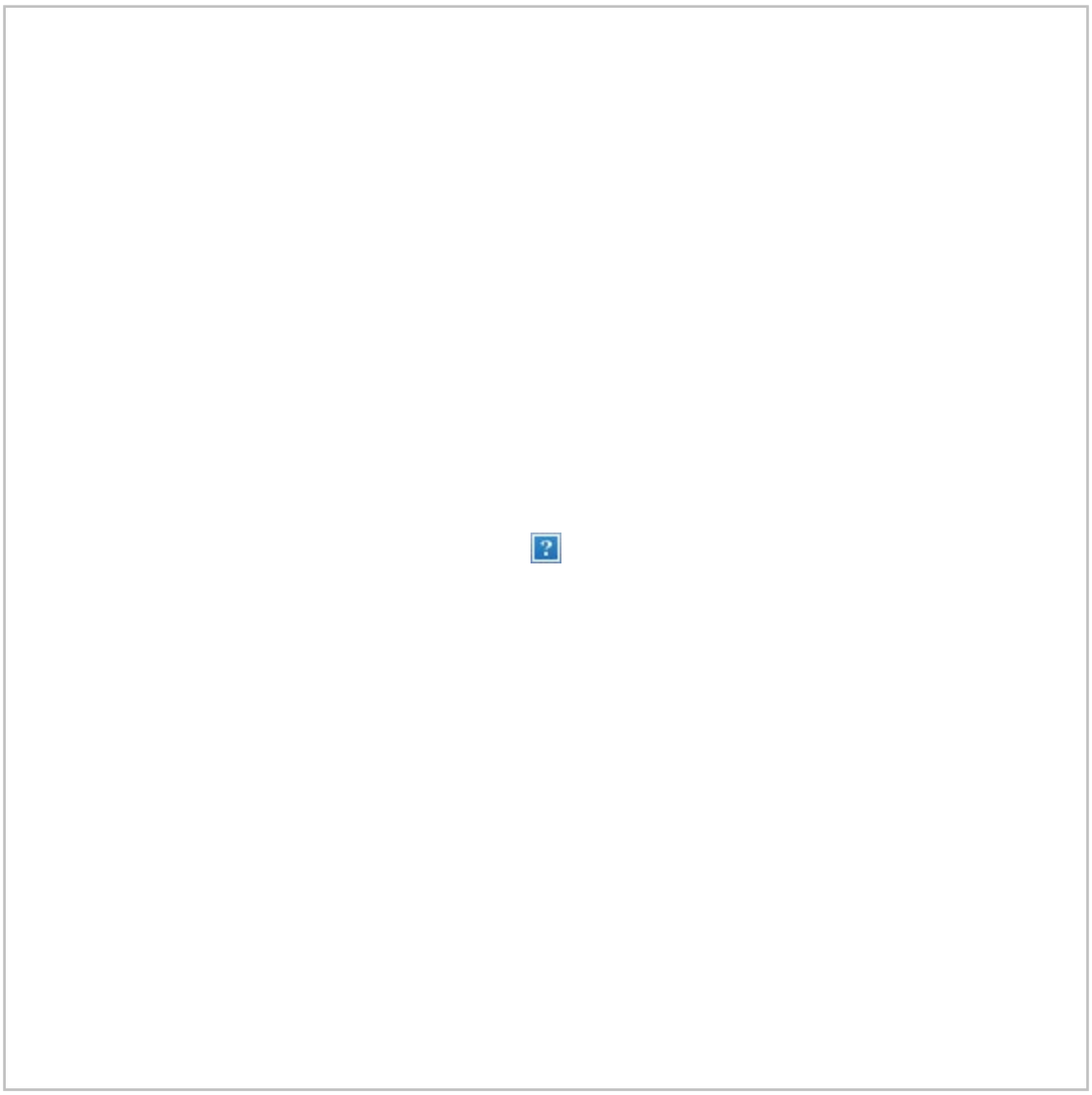


February 25, 2021

Dear Colleague,

One year ago today, based on analysis by experts from around the world at Resolve to Save Lives, we and others predicted, sadly, that a Covid pandemic was inevitable.

In this past year, our team helped the world better understand and more effectively respond to the Covid pandemic that has, tragically, taken so many lives. Covid revealed stark and unacceptable gaps in our public health and primary care systems, and also validated Resolve's approach to help close these gaps.



None of this would be possible without our colleagues at Vital Strategies and the support of our donors. Bloomberg Philanthropies, the Bill and Melinda Gates Foundation, Gates Philanthropy Partners, which is funded with support from the Chan Zuckerberg Foundation, #StartSmall, the CDC Foundation, and the Stavros Niarchos Foundation all provided fast, flexible, and generous support.

Here are nine ways we've worked with partners to meet our goal of improving health using an approach centered on simplicity, speed, and scale.

1. Using 'Science' as a verb.

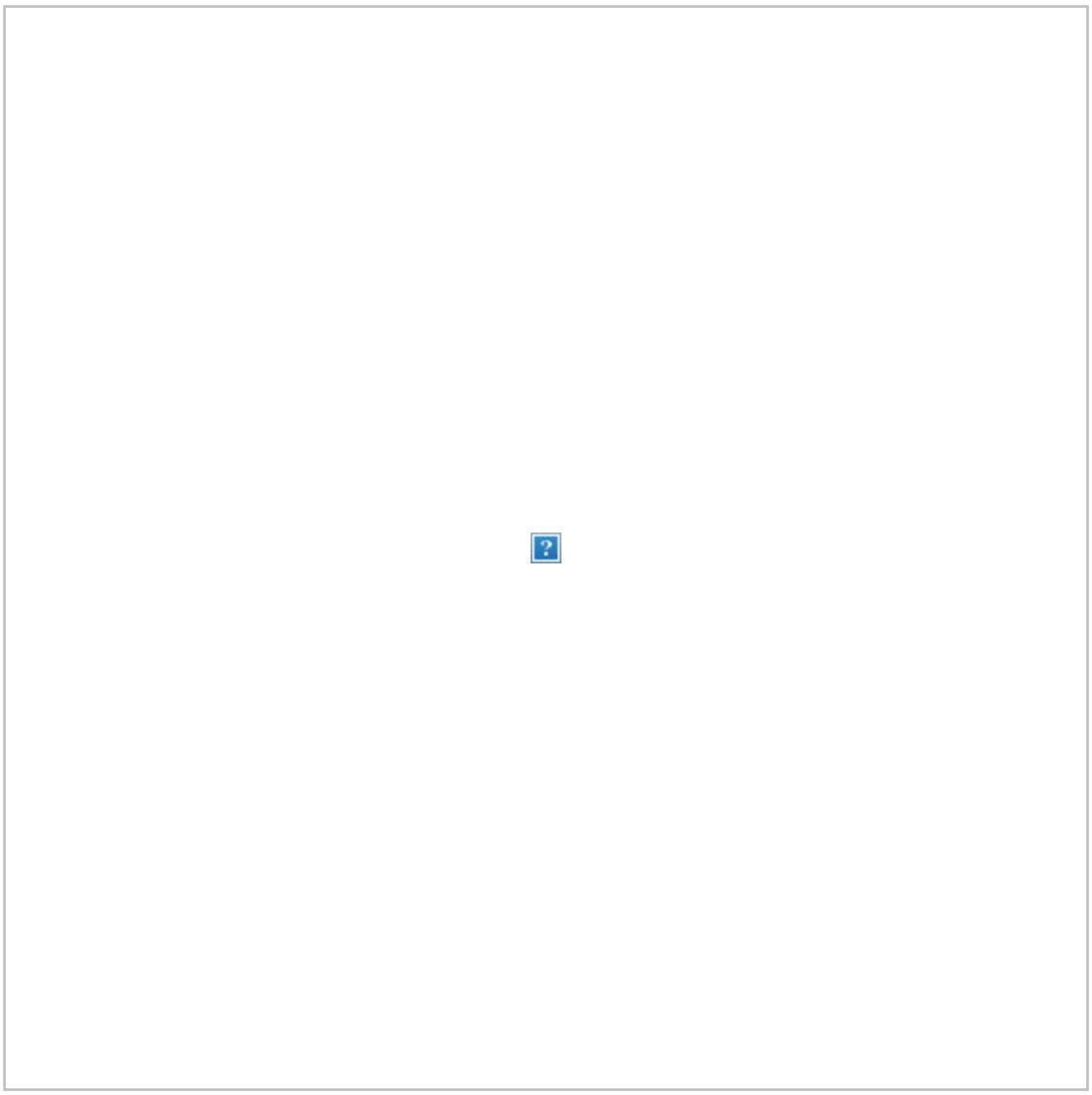
In "*The Martian*," Matt Damon plays a botanist stranded on Mars. He realizes that to get

back home, he's going to have to "science the s--- out of" the problem. Resolve's team of epidemiologists and public health specialists have been learning every day. As the evidence has changed, our approach has not – always base our recommendations on the best available science.

Governments across the United States and throughout the world adopted many of our evidence-based strategies to control the pandemic, including:

- Using an adaptive response to the pandemic, which we released more than a year ago and updated regularly as more information became available. The concept, and most of the details on phased reopening guidance, were adopted by the White House, although unfortunately the strategy wasn't followed.
- Best practice reports on the impact of public health and social measures led to wider adoption of these measures.
- Boxing in the virus to prevent explosive spread and reopen society as soon and as safely as possible.
- Establishing alert level systems to provide a framework to support clear decision-making, improve accountability, and better communicate with the public. Many states and countries adopt this tool, and we partnered with the *New York Times* to make a consistent system across the U.S. available to all.
- Reopening schools while prioritizing the safety of students and their families, teachers and staff, and the entire community.
- Communicating the importance of wearing masks and implementing mask mandates to prevent viral transmission and slow community spread.
- Measuring and reporting essential Covid indicators.
- Implementing, along with our Vital Strategies colleagues, rapid mortality surveillance to better track the pandemic.

Our Prevent Epidemics website had more than a million visits in the past year; our work continues to set the agenda for strong public health systems during and beyond the Covid response.



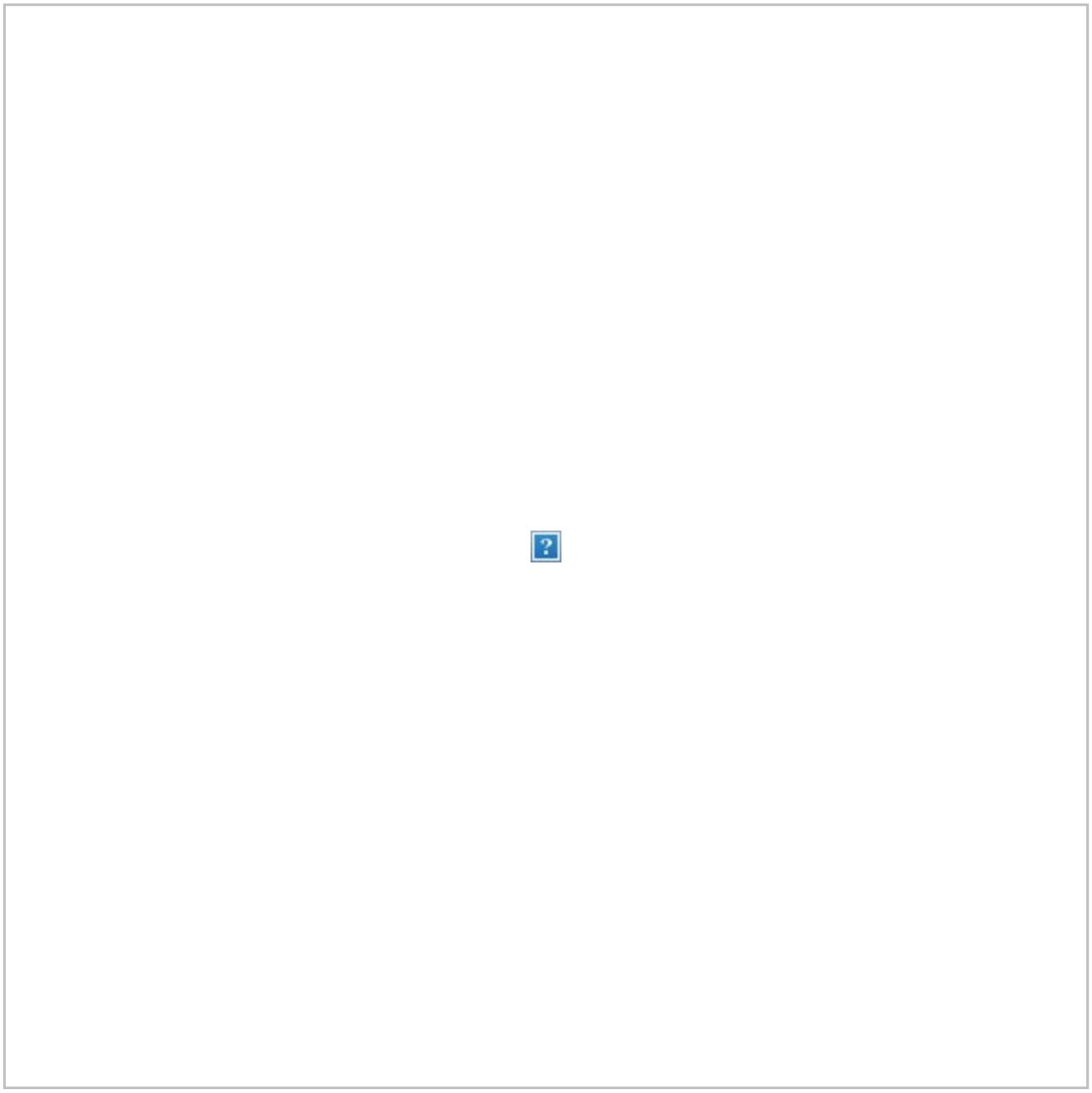
Partnership with the New York Times.

2. Funding to stop outbreaks – provided quickly.

Before and during the Covid pandemic, Resolve provided rapid response funds **to more than two dozen countries in Africa and elsewhere.** A systematic analysis in Nigeria found that time to outbreak response decreased from six to two days after the fund was implemented. Stopping an outbreak in a few days can cost a tiny fraction of what it would cost if allowed to spread for weeks or months. In Nigeria and other countries, these funds are now replenished by government funds.

We established “acceleration teams” of epidemiologists, veterinarians, evaluation experts, and other specialists that helped several African countries use national resources and World Bank funding better. In Uganda, preliminary data suggests that, with our support, the government resolved major weaknesses in epidemic preparedness; it would be the first

country on the continent outside of North Africa to have done so. In Nigeria and Liberia, these teams helped more than double World Bank disbursements within a year.



COVID-19 test preparations in Ogun, Nigeria. Rapid Response Teams in Nigeria were supported by Resolve to Save Lives.

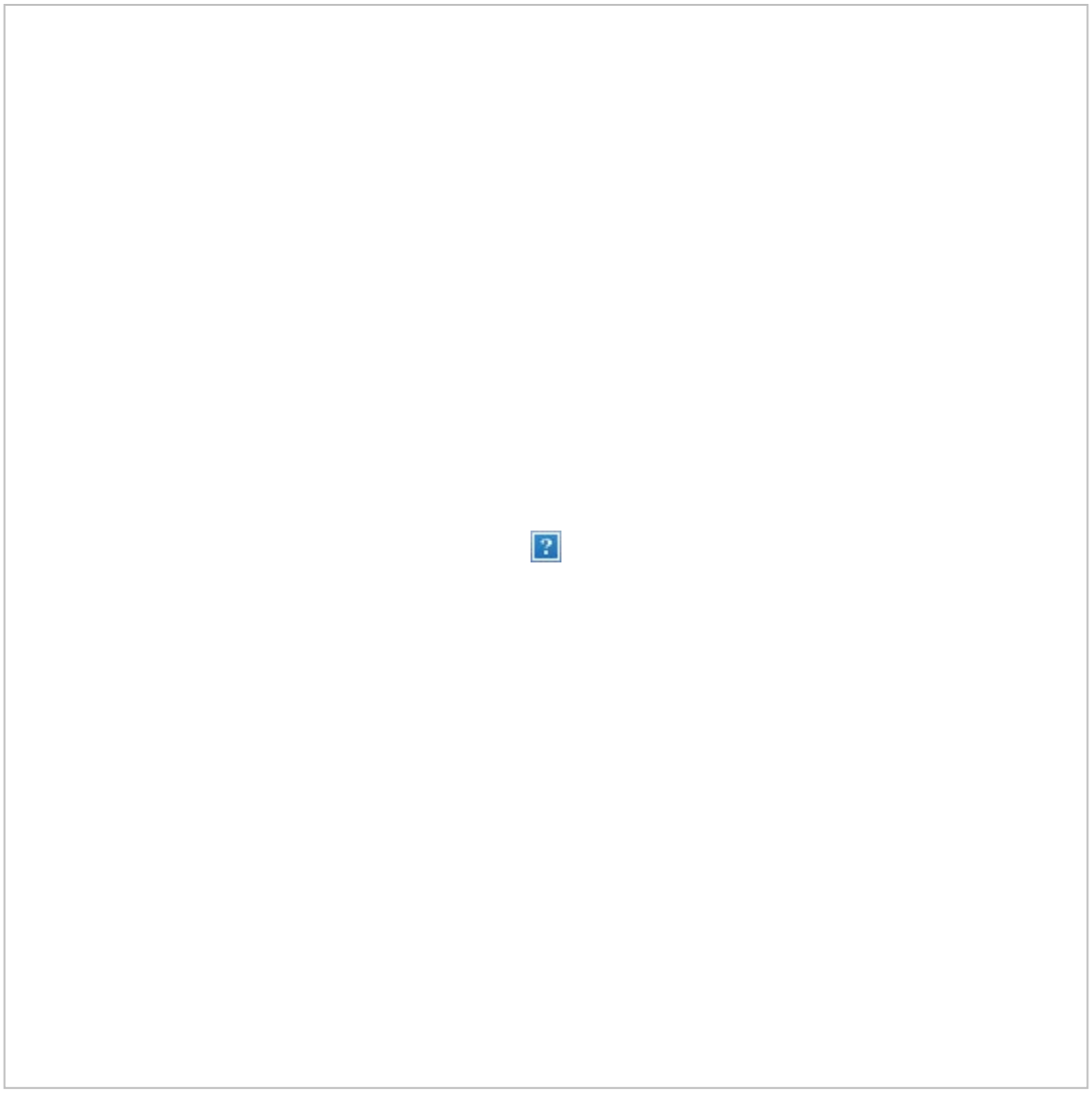
3. Working alongside partners to build capacity.

Collaboration is essential to protect health sustainably. In 2019, our training course, Program Management for Epidemic Preparedness, graduated 25 mid-level managers representing seven countries in Africa. This investment paid off during the Covid pandemic as these individuals and their teams were able to rapidly improve detection and response. Our second training program, planned before and conducted during the pandemic, was held in the Democratic Republic of Congo and helped to align ministry officials and World Bank staff to enable the timely and effective use of $150 million in

World Bank funds for epidemic preparedness.

Our global legal and advocacy teams issued guidance and provided detailed legal consultation to equip cities and countries to rapidly review existing legal frameworks, fill gaps, and ensure that public health and social measures to address Covid were in accordance with legal and ethical best practices.

With input from health departments in the US, we leveraged technology**, applying lessons learned from our successful** Simple app**.** Our digital team developed tools to improve case management and contact tracing for Covid. We supported the Africa Centres for Disease Control and Prevention to improve laboratory systems in Africa, launch a dashboardtracking the pandemic, and more.



Left: Contact tracing team from the Ethiopian Public Health Institute (EPHI) conducting contact tracing at Addis Ketema sub-city.

Right: Health workers perform contact tracing in Malaba, Uganda. Resolve to Save Lives supported COVID-19 response activities in Uganda.

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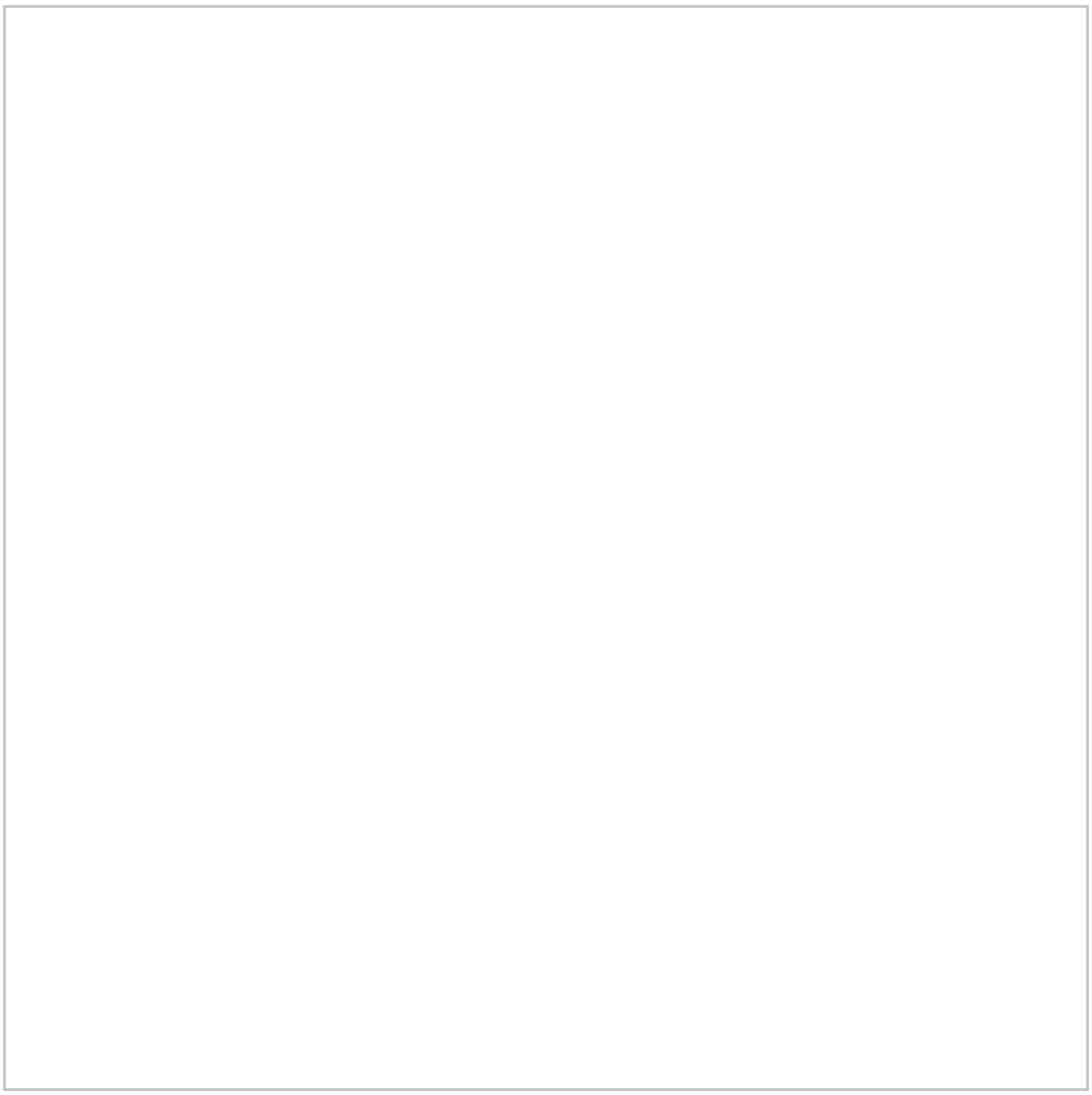
4. Fighting Covid in the U.S. – especially among vulnerable populations.

We started work in the U.S., creating a US Covid Response **team.** Our staff worked with public health departments across the country to strengthen prevention strategies, testing, isolation and quarantine, contact tracing, vaccination, and community engagement, all with a focus on equity. We also joined with other national public health organizations to advocate for improved funding and policies to address this pandemic and prevent the next.

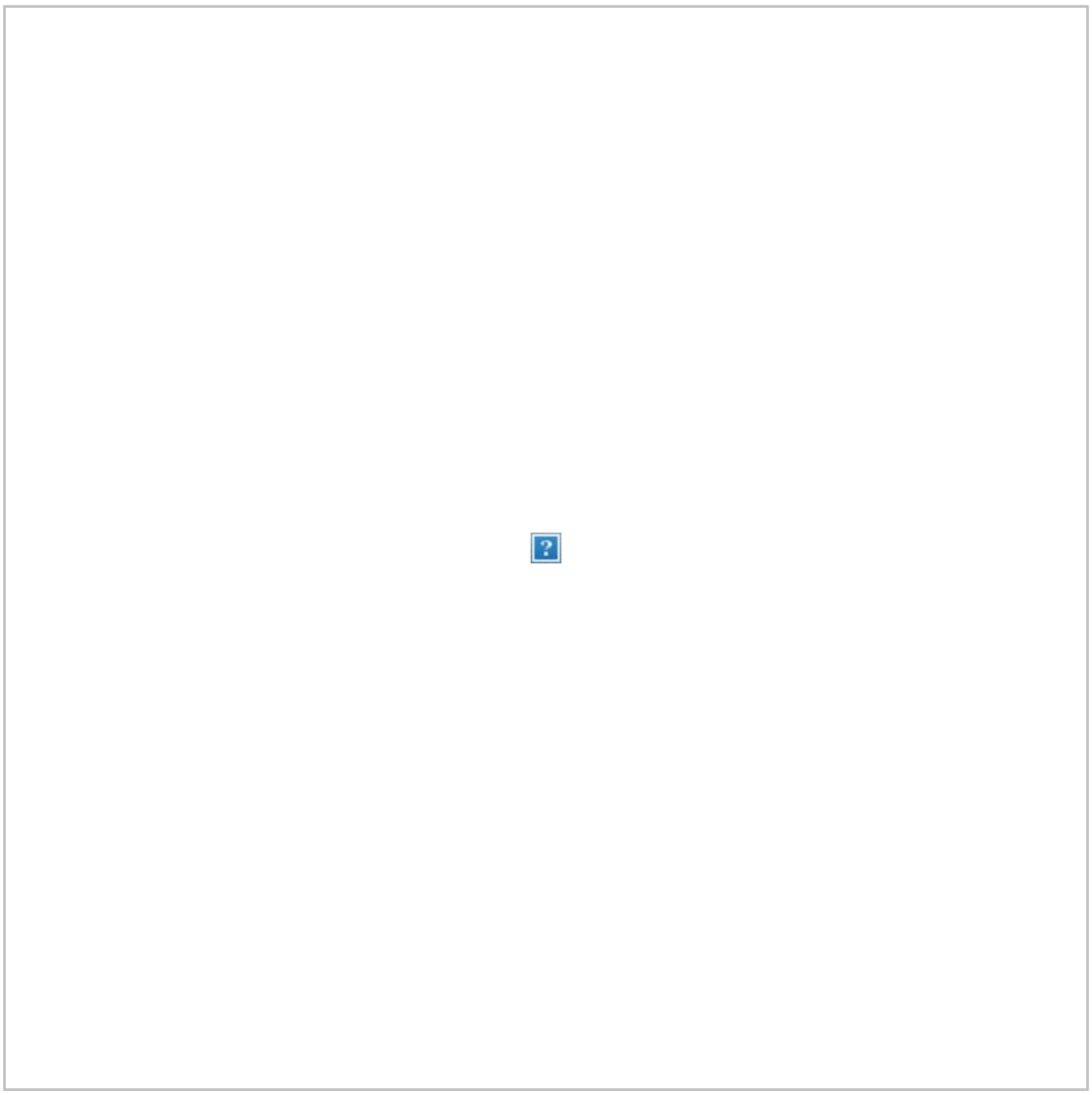
Recognizing the importance of reaching Black communities through faith leaders, we supported launch of the Black Clergy Choose Healthy Life Action Plan, a multi-city initiative to raise awareness of Covid, test those at highest risk, provide services for contact tracing, isolation, and quarantine, promote access to vaccination, and strengthen the infrastructure within the Black church network to end health disparities.



Resolve's Program Advisor in Marion County, Indiana, working at the county's first COVID-19 vaccine distribution center

5. Honoring our health care heroes by protecting them.

As soon as the pandemic hit, we established on-the-ground health care worker training focused on infection prevention and control. Our training was used by more than two dozen partners to train more than 35,000 staff in 7,000 facilities throughout Africa, facilitating safe screening of more than 4 million patients. Learning from this experience, in January 2021, we led a coalition of 17 organizations to publish a report that highlights the risks health care workers face every day and provides recommendations to protect them – and their patients – by making health facilities safer.



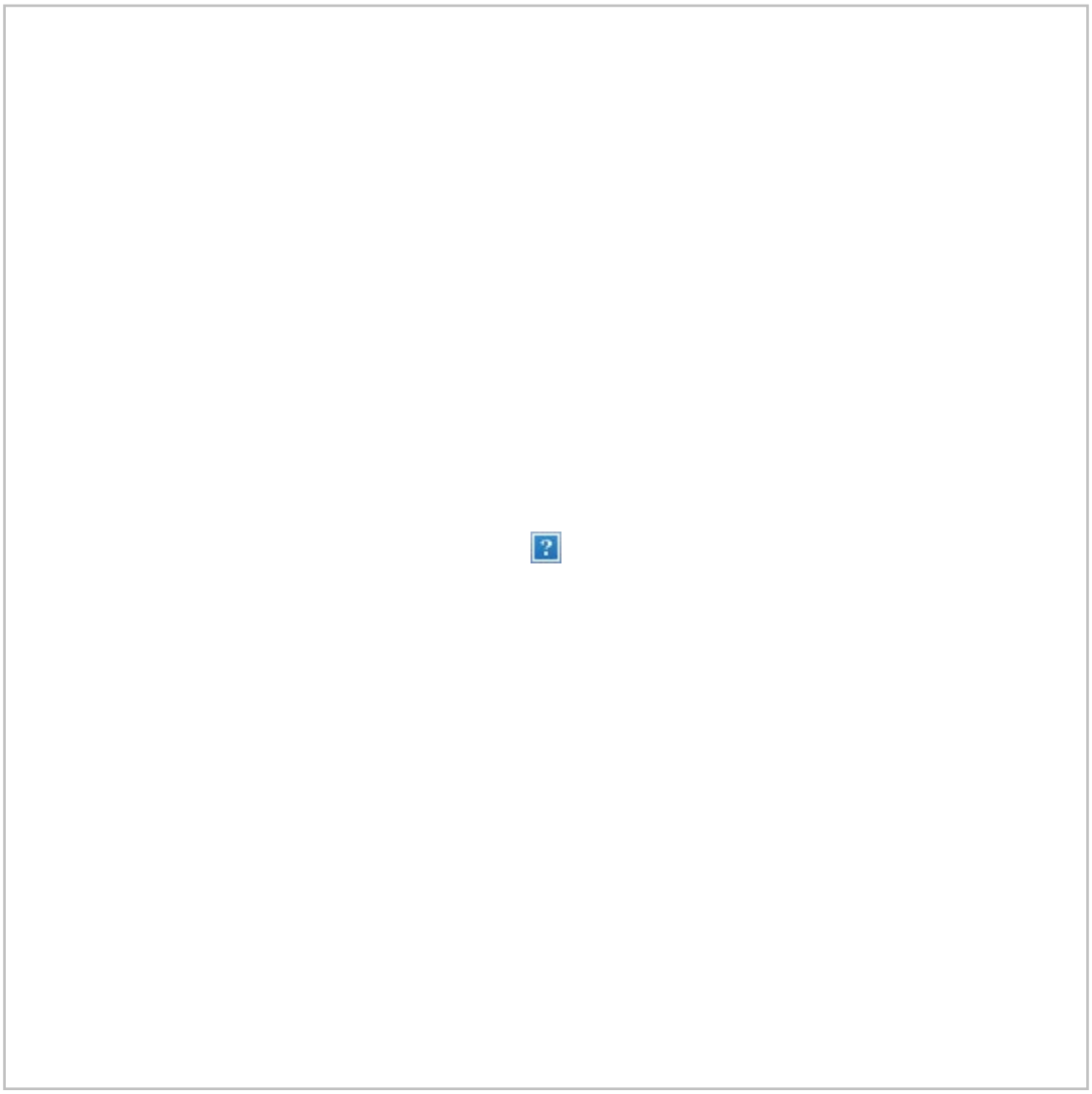
Personal Protective Equipment training in Ethiopia, supported by Resolve to Save Lives. Illustration from the Resolve to Save Lives and partner report Protecting Health Care Workers: A Need for Urgent Action launched January 13, 2021.

6. Basing action on evidence.

We spearheaded development of the Partnership for Evidence-Based Response **to Covid, a public-private partnership that supports evidence-based measures to reduce the impact of the pandemic on African Union Member States**. The partnership collected and analyzed social, economic, epidemiological, population movement, and security data from 20 countries to help determine the impact of public health and social measures.

Our report revealed that while effective in reducing disease spread, the Covid control measures quickly implemented by many member states caused severe secondary

impacts. Many communities across Africa reported difficulties accessing critical health services due to the extra burden placed on health systems, interruptions to medical supply chains, and restrictions on movement. People also reported being hesitant to seek care due to actual or perceived risk of transmission or inability to pay for care. This data led to policy changes to better balance control of Covid with protecting communities' social and economic stability.



Partnership for Evidence-Based Response report launched May 2020.

7. Primary care is primary.

Perhaps the key lesson from the Covid pandemic is the need for primary care to be at the center of health systems. Non-communicable diseases continue to be the leading global causes of death, and we must continue life-saving preventive care and treatment during the pandemic; in addition to saving lives today, this will promote community

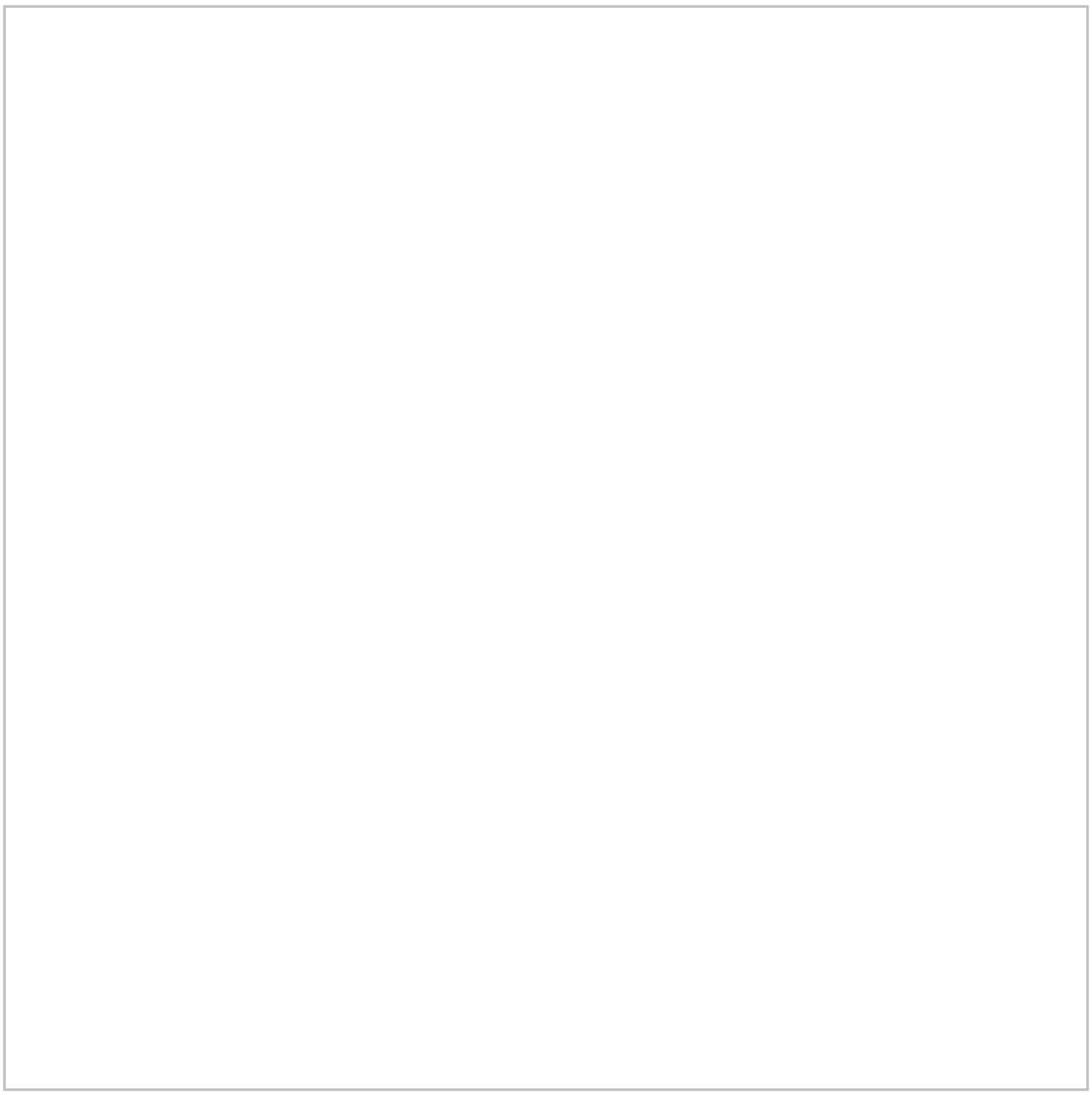
resilience against Covid and future health threats.

Resolve to Save Lives' cardiovascular health team developed guidance on how health systems can maintain life-saving hypertension care and leverage technology in the context of the Covid pandemic. The team produced fact sheets for patients and primary health care providers on how to reduce the risk of Covid transmission, which were translated into more than 15 languages and disseminated by partners around the world.

In countries across the globe, we also promoted simple but innovative patient-centered approaches to increase patient and provider safety during the pandemic:

- Dispensing 3-6 month prescriptions, such as hypertension medications, for stable patients.
- Delivering medications directly to patients.
- Increasing the use of telemedicine and other virtual technologies including phone, email, and text messaging.
- Treating and monitoring at convenient locations in the community.

More than 1.5 million individuals have received hypertension care and treatment through programs supported by Resolve's work. New programs were launched in the Philippines, Ethiopia, Mexico, and Nigeria.

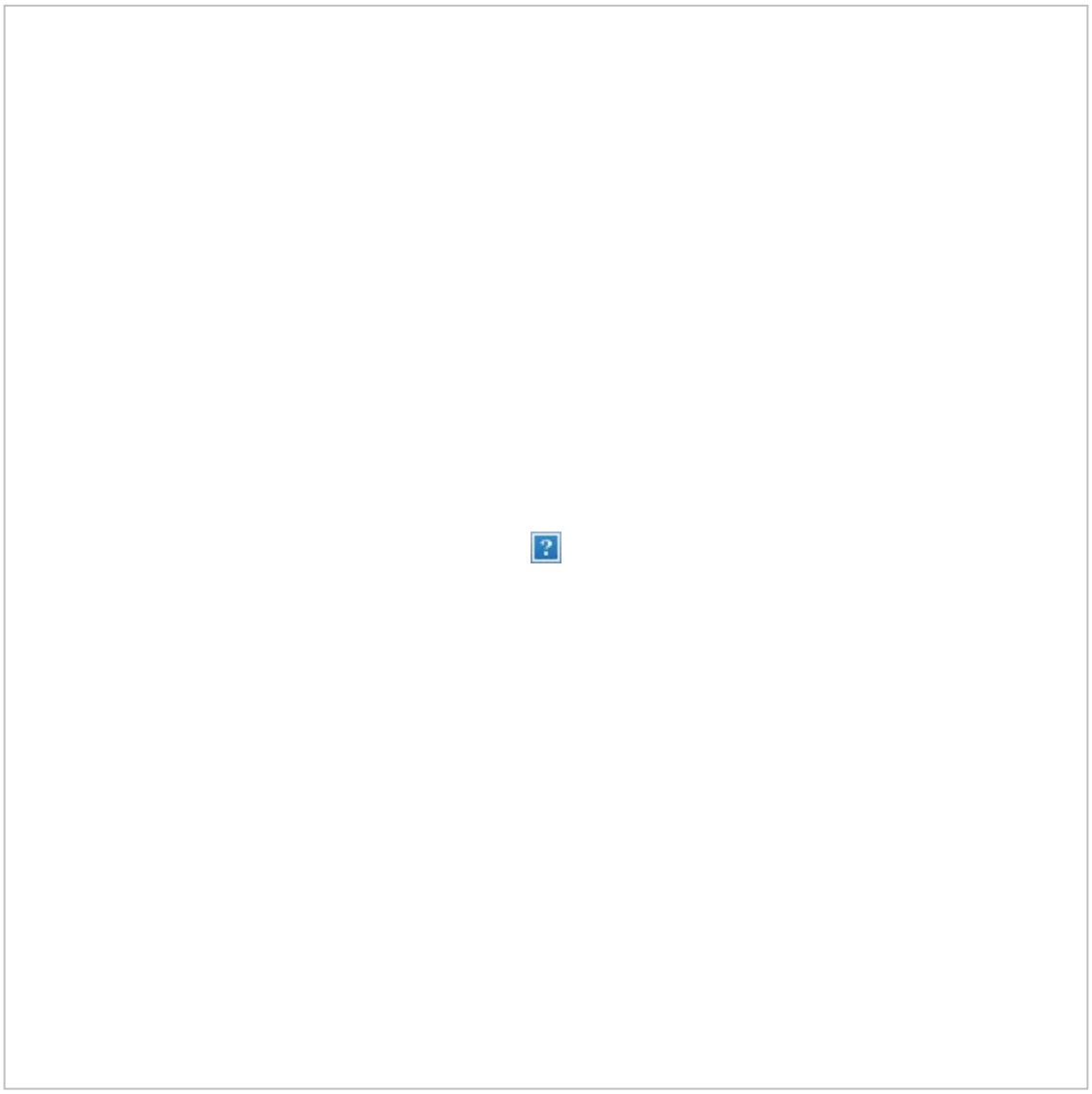


Left: Blood pressure measurement in Thailand before the COVID-19 pandemic.
Right: Community health workers in India deliver medications to hypertension patients.

8. Using policy to save lives.

We continued to advance policy actions to address cardiovascular disease. Global momentum to eliminate trans fat is growing, including an earlier win in Thailand and recent bold action by India to eliminate trans fat by 2022, a stunning victory for healthy nutrition. Turkey and Paraguay also acted to eliminate trans fat, and Nigeria, Bangladesh and the Philippines are now poised to do so. We partnered with the World Health Organization to launch the second annual progress report for the REPLACE initiative to eliminate artificial trans fat. Although 58 countries have introduced laws that will protect 3.2 billion people from trans fat by the end of 2021, more than 100 countries still need to take action to remove this toxic substance from their food supply.

Our team identified seven priority interventions to reduce sodium intake and save lives, including front-of-pack warnings, restrictions on food marketing to children, and taxes on high-sodium foods. We joined WHO to release a policy action framework on public procurement of healthy food, and helped launch four new projects to develop and implement policies on healthy public food procurement in Uganda, Togo, Nepal, and the Philippines. Our partners in Viet Nam and Ethiopia debuted each country's first national mass media campaign designed to encourage people to reduce their salt intake. We are sponsoring studies in China, India, Ethiopia and Thailand to determine the most effective front-of-pack label in order to provide evidence for policy change.



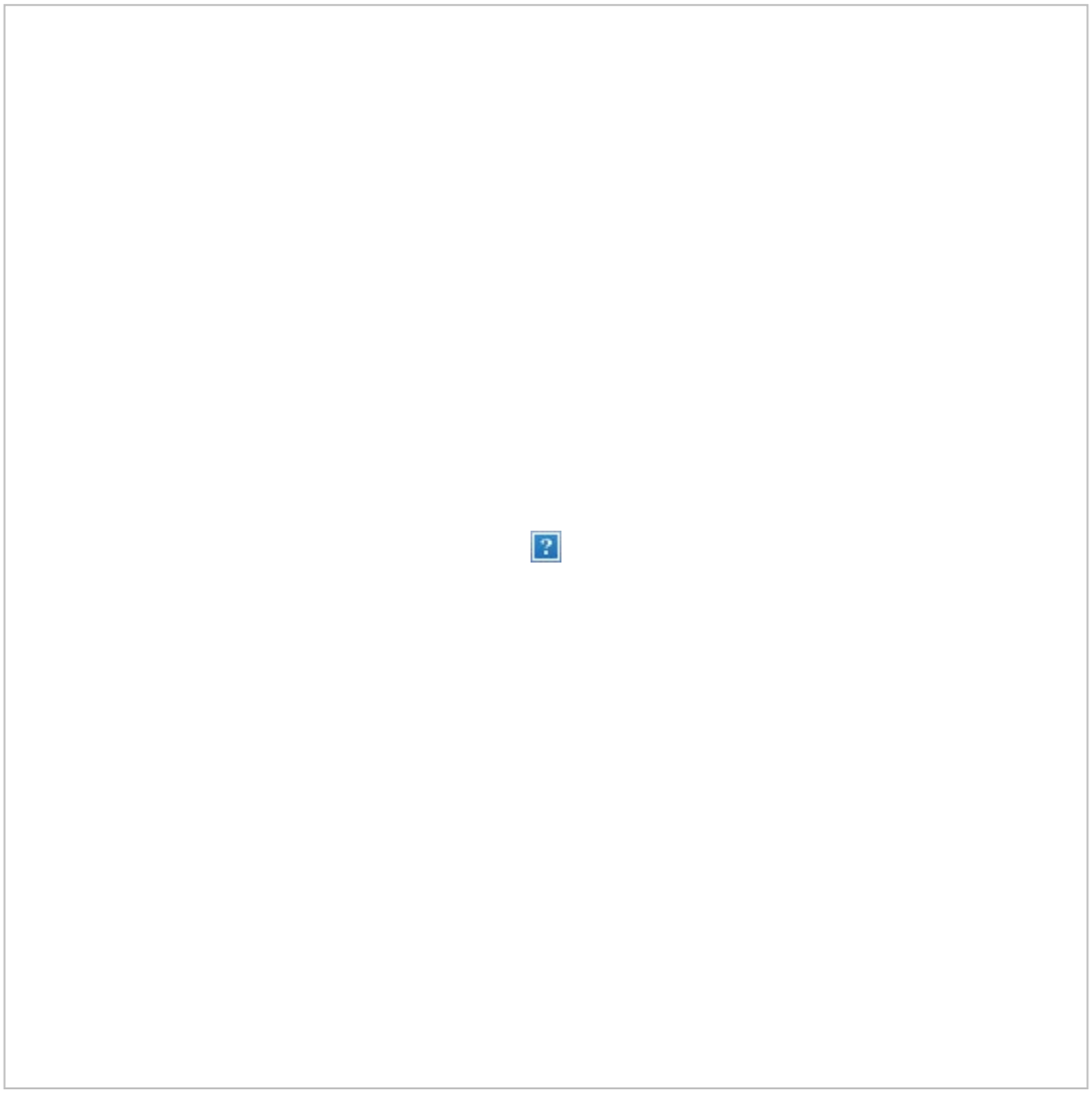
In countries without trans fat regulations, fried foods are a common source of the deadly additive.

9. Spreading truth.

The Covid pandemic was accompanied by an epidemic of competing and often inaccurate information spreading rapidly throughout the world. Our communications team filled a need for real-time, credible public health information by producing high-quality, evidence-based communications materials for diverse audiences.

We produced more than 400 communications products in 25 languages and supported 22 countries and 44 cities with mass media campaigns and the development of effective risk communications strategies. We shared our public health expertise in thousands of media interviews and dozens of peer-reviewed medical journal articles and op-ed pieces in leading global media outlets, and we were mentioned more than 25,000 times in news stories around the world.

Our "3 Ws" strategy – Wear a mask, Watch your distance, and Wash your hands – was disseminated by media outlets and partners worldwide and continues to be at the core of strategies to prevent disease transmission.



The '3-Ws' translated into French.

This moment brings a once-in-a-century opportunity. It's now or never.

Working together, we will take a giant step toward being able to find, stop, and prevent health threats faster in every country through public health systems that are understood, supported, and celebrated. This starts with expanding equitable access to vaccines to end the Covid pandemic. It's both ethically unacceptable and epidemiologically perilous that so much of the world is so far from having vaccine access. Uncontrolled spread anywhere threatens to prolong the pandemic everywhere, and we must scale up not only vaccine access but also vaccine manufacturing capacity in low- and middle-income countries. Beyond Covid, we need a public health renaissance so health threats are detected rapidly by accurate and sensitive tracking systems and laboratory networks, stopped quickly by trained epidemiologists and rapid response teams, and prevented wherever possible, including through ongoing vaccination programs and action to make our environment safer.

Working together, we will partner with governments, health systems, and civil society to make policy and program changes centered on improving equity that increase our personal and community resilience and promote heart and brain health so we live longer, healthier, more productive lives. We will help more countries follow India's trans fat elimination best practices. We will accelerate progress toward Resolve's goal of preventing 100 million deaths from cardiovascular disease in 30 years and achieve the Sustainable Development Goal of a one third reduction in today's leading killers by 2030.

Working together, we will make primary care central to our health systems – building teams, supporting patients, and holding all accountable for achieving the health that health care can deliver and for ending health disparities. By establishing accessible, responsive care systems, we'll find health problems when they emerge, prevent illness, injury, disability, and premature death, and accelerate a virtuous cycle toward healthier and more productive societies.

We resolve to work with partners to strengthen the hands of public health and primary care around the world so that, together, we build this healthier future.

Thank you for joining us.

Tom Frieden
President and CEO
Resolve to Save Lives, an initiative of Vital Strategies

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From: Roy Hart
To: Dobbs, Thomas E; Edney, MD, Daniel
Cc: Natalie Keller
Subject: RE: MSPHI Data Conversation Follow Up
Date: Friday, March 11, 2022 9:05:54 AM
Attachments: image002.png
image004.png
Empowering Communitites with Data.pdf
NNPHI-E2A-Kresge-Report-Web.pdf

Natalie,

Thanks very much for sending the information that we discussed Tuesday.

Dr. Dobbs and Dr. Edney, at the risk you feeling bombarded with information, I want to share 2 additional documents that are directly relevant to the conversation. The first is focused on the importance of sharing data with communities and it really gets to the critical aspects of how and why we should share information. The second is a very recent document prepared by the National Network of Public Health Institutes (NNPHI) with support from the Kresge Foundation that includes a description of public health data systems in the context of opportunities to strengthen public health infrastructure.

Thanks very much and have a great weekend.

Roy

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10 YEAR ANNIVERSARY
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From: Natalie Keller
Sent: Thursday, March 10, 2022 3:49 PM
To: Thomas.Dobbs@msdh.ms.gov; Daniel.Edney@msdh.ms.gov
Cc: Roy Hart <rhart@msphi.org>
Subject: MSPHI Data Conversation Follow Up

Hi Dr. Dobbs and Dr. Edney,

Thank you for your time on Tuesday. I really appreciate the space you gave us to present the whole context of our idea. I'm attaching **the longer plan document** we developed with the steering committee and a **2 pager** pulled from the longer document. I appreciate your input and feedback around demonstrating this idea into more concrete terms before moving forward.

In pursuit of that, I'm sending along two examples of data visualization website. The first website is a local resource, Gulf Coast Community Exchange, funded through the REACH grant in Gulf Coast MS counties. It leverages some local and national datasets. The second website is known as CHORDS. This website utilizes FQHC data and mapping to demonstrate prevalence in the Denver metro area. Our vision for a website encompasses ideas demonstrated in both examples. We want to leverage local data as CHORDS has done successfully but utilizing newer technology for updating data closer to real-time. Additionally, we want a dynamic website interface that is easily utilized by non-experts. Our plan for incorporating these ideas into our own platform is detailed on pages 11 and 12 in the longer document.

Other good examples we would draw from: Arizona's Environmental Public Health Tracker (love the county-level reports with easy to understand explanations), Hope Rising's Substance Use Website (trove of local resources and personal touches), and Tri-County Health Department (issue-by-issue breakdowns).

Essentially, our project is investing in a data resource for community members. The other facets of the project, data literacy education and partnerships with larger health organizations, are part of our larger framework and strategy to address health issues in Mississippi by supporting individuals planning their own community-level projects. This principle of transparent data and distribution is essential in empowering local initiatives especially for marginalized people who are not in positions of power.

In our vision and approach, we are matching up with CDC's Data Modernization Initiative. In their Strategic Implementation Plan (p. 4), the first objective of priority 1 is "Develop a shared vision." Hopefully, that's what we're doing right

now!

Take a look at these documents, explore these website, and let us know next steps!

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Empowering Communities with Data: Role of Data Intermediaries for Communities' Data Utilization

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ABSTRACT

Data have significant potential to address current societal problems not only at the federal and state levels, but also in smaller communities, in neighborhoods, and in the lives of individuals. While the proposition for this potential is that data are and will be shared with and reused by and for communities at different levels, not all data are not systematically or routinely shared for reuse with communities due to social, structural and technical infrastructure barriers. Data intermediary organizations can play a significant role in removing existing barriers while unlocking the potential of data for all, particularly for communities with limited human or financial resources, limited access to existing data infrastructures, and underserved populations. Considering the significance of the data intermediary organizations on local communities, this study aims to explore the role of intermediaries that usually facilitate community members/organizations' data utilization. The findings of this study reveal that data intermediary organizations play four major roles that are crucial in communities' data utilization: (1) democratizing data, (2) adding value to existing data, (3) enhancing communities' data literacy, and (4) building communities' data capacity. This study has several important implications to offer a solution to overcome the challenges of data reuse at the local level.

KEYWORDS

Data reuse, open data, data infrastructure, data intermediaries, data curation

INTRODUCTION

Data have significant potential to address current societal problems (e.g., education, health, economic development, and the environment) not only at the federal and state levels, but also in smaller communities, in neighborhoods, and in the lives of individuals. Many have argued that data have value as a source for community economic development, disaster planning, and decision-making in citizens' daily lives (Kassen, 2013; Levin & Schneir, 2015). In the report *A World that Counts, Mobilizing the Data Revolution*, the United Nations Secretary-General's Independent Expert Advisory Group (IEAG, 2014) underscored the significance of data particularly for underdeveloped countries or neighborhoods, arguing that "data are the lifeblood of decision-making" (p. 4) and that the recent data revolution has created opportunities to design, monitor and evaluate effective policies for communities.

While the proposition for this potential is that data are and will be shared with and reused by and for communities at different levels, much data—including, particularly, data collected by university and research institutes—are not systematically or routinely shared for reuse with communities (Research Data Alliance [RDA] Data for Development Interest Group, n.d.; Urquilla & Shelton, 2015). Government data are traditionally shared with citizens, and while recent open data initiatives accelerate this tradition, Douglass et al. (2014) pointed out that there are still structural and technical infrastructure barriers to be overcome for data to be fully accessible and easily usable. Research data are usually shared within scientists' own communities of practice, although researchers often share data interpretations to support community development. The IEAG (2014) pointed out that unequal access and use of data limit the role that data can play in the realization of sustainable development and argued that it is critical for all stakeholders (e.g., government, regional institutions, public/private data producers, academics, and citizens) to work to create a more equitable data ecosystem.

Data intermediary organizations can play a significant role in removing existing barriers while unlocking the potential of data for all, particularly for communities with limited human or financial resources, limited access to existing data infrastructures, and underserved populations. Van Schalkwyk, Canares, Chattapdhyay, and Andrason (2016) emphasized the importance of these data intermediaries in open data ecosystems, as they can connect different stakeholders and facilitate the flow of data. However, despite the significance of the role and impact of data intermediary organizations on local communities, these groups have been paid little attention in scholarly works, and little is known about how data are utilized among local communities and at the neighbourhood level (Van Schalkwyk et al., 2016).

This study aims to explore the role of data intermediary organizations that usually connect community members/organizations

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with data sources and provide partnerships and consultations to support communities' data utilization (Yoon, 2017). We adopt our definition of data intermediary organizations from Van Schalkwyk et al. (2016), broadly defining such groups as agents positioned between two other agents in a data supply–demand chain and that facilitate the use/reuse of data. By uncovering the role of data intermediary organizations and analyzing the services they provide to the populations they serve, this study contributes to our understanding of how local communities utilized data to have meaningful impacts on their communities. The findings of this study have several important implications to offer a solution to overcome the challenges of data reuse at the local level.

LITERATURE REVIEW

A growing body of literature discusses the power and value of data to enhance data-enriched citizen and public engagement in policy- and decision-making relevant to citizens' daily lives (Gurstein, 2011; Kassen, 2013; Levin & Schneir, 2015). Keserű and Chan (2015) argued that open data not only impact economic development, but also increase state or institutional responsiveness, reduce levels of corruption, build new democratic spaces for citizens, empower local and disadvantaged voices, and enhance service delivery and effective service utilization. Levin and Schneir (2015) also underscored the importance of making reliable public data accessible to anyone, anytime, for any purpose, as such data have the power to help citizens make better decisions for their communities.

In the U.S. context, several cases demonstrate the potential of data reuse for community members. Chicago's open data portal driven by open government data initiatives resulted in several citizen-initiated projects that developed tools to serve Chicago's diverse community by improving the transparency of local governments' political processes (e.g., chicagolobbyists.org) and maintaining local neighborhoods as safe, open, and healthy green spaces for the local community (e.g., Mi Parquet Project; Kassen, 2013). Often, local organizations lead these projects. For example, the Green and Healthy Homes Initiative (GHHI) in Baltimore utilized health and housing data to provide healthy homes for communities and advocate for increased efforts to prevent lead poisoning (Urquilla & Shelton, 2015). These cases show how different community members (e.g., city planners, local government officers, economic developers, non-profit educational consultants, foundations and corporate organizations, and the public, including parents with concerns about childcare and school systems) can utilize or reuse data on regional areas and population groups collected by the private and public sectors to better understand the factors influencing their communities.

This emerging interest in using data for the community has sparked several discussions regarding how to make data open and sharable, many of which call for action on the part of the public sector. However, the movement to make data fully accessible and easily usable still faces several challenges, such as structural and technical infrastructure barriers (Douglass et al., 2014). In this context, several studies have explored the concept of intermediaries as agents capable of removing some of these barriers (e.g. Van Schalkwyk et al., 2016). The concept of Intermediaries was first discussed in the context of information and communication technology (ICT) as bridging or support organizations that link different agents by transmitting information from one to another (Brown & Kalegaonkar, 2002; Sapsed et al., 2007). They were later explored in different organizational contexts, such as business and e-government, as agents for diffusing services (Janssen & Zuiderwijk, 2014; Sein & Furoholt, 2010). In the context of open data, Van Schalkwyk, Willmers, and Czerniewicz (2014) reported that data intermediaries play several possible roles, such as increasing data accessibility and utility, serving as 'keystone species' in data ecosystems, and democratizing the impacts and use of open data. Several other studies have echoed the potential and significance of intermediaries in the contexts of government data (Chattapadhyay, 2014), developing countries (Davies, 2014; Van Schalkwyk et al., 2014), and broadly in ICT (Diaz Andrade, & Urquhart, 2010) and demonstrated intermediaries' crucial role in linking different agents in open data supply chains, including grassroots communities (Van Schalkwyk et al., 2016).

While the interest in and need for data intermediaries is growing, little empirical research has been conducted to understand their roles and the processes of data diffusion and utilization in local communities. By empirically investigating the roles and functions of data intermediary organizations, this study contributes to understand one facet of data utilization at local communities.

METHODS

This study takes qualitative approach to explore the role of data intermediaries. We broadly define a data intermediary as an organization that facilitates the (re)use of data to impact communities. The project team interviewed one to three key staff at nine data intermediary organizations across the U.S. We used several strategies to identify data intermediary organizations in different U.S. cities. As previous research has suggested that community research centers often help community members/organizations with their data needs—and, thus, serve as a form of data intermediaries (Yoon, 2017)—we first conducted a Google search using several key words, such as *community research center* and *community research institute*. Using this strategy, we identified approximately 50 community research centers that existed as non-profit organizations or were affiliated with universities. We also reviewed the 42 partner organizations across 30 cities included in the National Neighborhood Indicators Partnership (NNIP, http://www.neighborhoodindicators.org/), a collaborative effort by the Urban Institute (http://www.urban.org/)

and local partners to further the development and use of neighborhood information systems in local policy-making and community building. We carefully reviewed each organization's website for information regarding their missions, services offered, and past projects. After assessing each organization's fit for this study, we then chose data intermediary organizations in small, medium, and large cities (e.g., Grand Rapids, MI; San Antonio, TX; and Boston, MA) that agreed to participate in the study. Since one organization dropped out during the interview process, we interviewed a total of 15 staff members (one to three per organization) from a total of nine organizations.

We conducted a semi-structured phone interview with our participants following pre-developed interview protocols. The interview questions covered the organizations' missions, the role of the staff, types of services to support communities' data utilization, the interviewees' experiences working with community members/organizations, and challenges associated with support communities' data work. All interviews were audio-recorded and fully transcribed by professionals. The sample sets of data were inductively analyzed to develop a set of codes representing emerging themes. Then, the rest of the data were deductively coded following the developed coding scheme. A qualitative data analysis tool, Nvivo, was used to code the transcripts and analyze the data. The inter-coder reliability among the project team members was 93%, and we had more than 90% agreement for all codes except one, which still achieved an acceptable 86% agreement rate. As this study aims to "understand and describe as accurately as possible the phenomena" (Groenewald, 2004, p. 5), we followed a phenomenological and interpretive analysis approach (Smith, Flowers, & Larkin, 2009).

RESULTS

The nine participating organizations were drawn from small, medium, and large cities across the U.S. (Dallas, TX; Columbus, OH; Boston, MA; San Antonio, TX; Grand Rapids, MI; New Haven, CT; Indianapolis, IN; Milwaukee, WI; and Providence, RI). Four were independent non-profit organizations, and five were university-affiliated organizations. Six organizations were part of the NNIP network. The sizes of the organizations varied from 7 to 30 staff members, with average staff of 15. Of the 15 staff who were interviewed for this study, 4 were male and 10 were female. Their ages ranged from 30s to 60s. Table 1 provides basic demographic information about the participants, including their education levels and years of experience at the organizations. In the following section, we present the participating organizations' primary missions and services, as well as some of the challenges they have faced in fulfilling their missions.

Organization	Staff	Age	Gender	Position	Years at the Organization	Level of Education
O1	S11	30s	F	Program management	2.5	MS
	S12	30s	F	Co-director	5	PhD
	S12	40s	F	Co-director	4	PhD
O2	S21	40s	F	Director	4	PhD
	S22	30s	F	Director of research	2.5	PhD
O3	S31	50s	M	Director	10	PhD
O4	S41	50s	M	Senior director	6	PhD
	S42	50s	F	(Former) research associate	5	PhD
O5	S51	30s	F	Director	5	PhD
O6	S61	30s	M	Executive director	9	BA
O7	S71	50s	F	Director of collaborative research	22	MLA
	S72	30s	M	Research analyst	1	MA
O8	S81	60s	F	Director	1.5	PhD
	S82	30s	F	Data analyst	1.5	BA
O9	S91	30s	F	Research associate data analyst	2	PhD

Table 1. Demographic information

Organizational Missions and Serving Communities

An organization's mission is crucial in justifying its existence, differentiating it from other organizations, facilitating organizational innovation, and helping it achieve intended performance (McDonald, 2007). The ways in which the staff explained their organizational missions reflected the ways in which they perceived these missions in relation to their job responsibilities. From their descriptions of the missions, we found that data were either explicitly or implicitly related to the intermediary organizations' overall missions. Staff from most intermediaries related that their mission was to "strengthen communities with data" by "connecting the communities with data" (e.g., easy access, data aggregation, and analysis) and/or by "helping the communities to make a better decision with data" (O2, O5, O6, O7, O8, O9). Staff from two organization specifically stated that they contributed to "the democratization of data" through different types of data services for public use (O8, O9). Other staff emphasized how their organizations bridged communities and different partners (e.g., academics, business, etc.) by promoting collaborations and community research (O1, O3, O4). One staff member from O4 underscored the organization's mission to support community development by serving as "an information resource for community members." Although these three organizations (O1, O3, O4) did not explicitly mention data in their missions, data were inherently associated with their projects and community services. For instance, S11 discussed the significance of data in all projects, noting that data helps

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community organizations gain a better understanding of their communities at large.

Most organizations tended to focus their services on their regional geographic areas, such as their neighborhoods, counties, and cities; however, some stated that they also served other cities in and out of the state. Their clients or partners were predominantly non-profits (e.g., community foundations, advocacy organizations, community service organizations like the YMCA, etc.) and local government or quasi-government entities, but they also occasionally worked for business associations and individual companies, "although that's less common" (S41).

Emerging Data Needs for Communities

The staff interviewed for this study experienced emerging data needs with their targeted communities. To meet these needs, they interacted with and used a wide range of data. Many reported working with publicly available data published by various government organizations, such as the Department of Education, the Department of Health, and the Bureau of Labor Statistics. Census data and the American Community Survey were among the sources commonly mentioned, but the interviewed staff also utilized data from local agencies to learn more about health, economic indicators (income, unemployment, etc.), housing, education, and business. Though the majority relied on open data, several requested private, proprietary data for specific community projects.

From the staff members' perspectives, one reason for communities to utilize data is to understand their neighborhoods in order to "make community decisions based on data" (S22), such as developing community-specific programs or services. Data are "important in looking at trends and opportunities" (S91) because data "help [community organizations] understand what the needs of their constituencies are and how best to position themselves for the future" (S41). Several echoed the need for data "to set new goals for [community] programs" (S91) or "to start a new initiative" (S51). These initiatives pointed to community efforts to make decisions based on data. Data were also crucial in "adjust[ing] some of [the community organizations'] services if [the communities] have determined that the data show that they're really not having the same impact that they anticipated" (S91). Often, this need was tied to the organizations' program evaluation or outcome measures, since understanding the impacts of their programs guided the organizations to change what they had been working on and how.

Communities' data needs were also highly associated with communities' efforts to apply for grants and secure funding. Staff from almost all intermediaries mentioned the importance of grants for community organizations, most of which are small, non-profit, and in great need of financial support. Data provided evidence of the impact of the community organizations' proposed projects; therefore, community organizations increasingly tried to "visualize these data or to create data tables that they can use for grant applications" (S91). S91 further explained that grant agencies require data for project/program measures, meaning that community members "are asked to be very data fluent in not only their grant applications, but also their grant reporting. […] They're being asked to demonstrate their impacts in terms of quantitative outcomes." Sometimes, funders required community organizations "to do an external evaluation […] to prove that the program is working" (S61), creating another strong data demand on the community side.

Community Data Services

To meet their communities' various data needs, the surveyed intermediary organizations provided different types of data services. The depth and breadth of the services they offered varied depending the intermediary organizations' missions and scales.

Support Data Reuse

Supporting communities' use of secondary data was one of major areas in which most data intermediary organizations offered services, which could be fee-based or pro bono, depending on the scale of the work and the intermediary's service model. One way of supporting data reuse was to simply help "citizens, non-profits, [and] government agencies have easy access to data and knowledge that comes from that data" (S22). Staff from the majority of intermediaries noted that community members occasionally knew what data they needed and wanted, but more often were "not so familiar with pulling secondary data" (S22) and did not know where to search.

The data intermediaries also offered more sophisticated levels of service to support data reuse through data aggregation or integration. Many intermediaries either compiled or aggregated publicly available data by importing or integrating the data into their own system, which S71 described as an activity "adding value" to enhance data utilization. S21 said "a lot of people [from the community] were intimidated" when using secondary data because, even though such data are publicly available, "they are not necessarily publicly available in a ready to use format" (S71). Intermediary organizations took data from various sources, re-organized datasets to meet communities' needs (e.g., by geography or neighborhood), broke geographic data down into smaller geographies, made the data clear and easy to explore, and dug down into the neighborhood level for local stakeholders. S61 described this process as transforming data "from nothing to useful for something," noting that publicly available raw data are often not user-friendly to community members.

Data tools were essential in supporting communities' data reuse. Several intermediaries developed data tools from their data aggregation and integration efforts to facilitate communities' data utilization. S71 said that "provid[ing] tools to community members to help them really compile the information that's of interest to them […] is a very important" piece of a data intermediary's work. While the functions of such tools differed across the intermediaries, common features included interactivity and the capability to present the data at the local level. Using the tools, community members "could select interested indicators as well as geographies and instantly map relevant information" (S22), functionalities that significantly supported the communities' data utilization. The tools also allowed communities to break data down to the neighborhood level, allowing community members to "build an index and look at comparisons between neighborhoods and trends over time" (S51). Being able to dig into data at the local level was crucial for communities' data reuse, as data at the state and federal level were often too general to accurately represent communities' current situations. Intermediary organizations also offered free training sessions to "teach people how to utilize those tools" (S51, S71) to maximize the benefits to the communities.

Collect Local Data

Several intermediaries were actively involved in collecting local data that accurately represented their communities, largely due to the lack of existing secondary data at the local level. S41 pointed out the "deficiencies in the [existing] data," stating this was why intermediary organizations had to "go out and [collect] primary data." S61 echoed that "often you can't get that granularity of data [at local level] from a government agency." The fact that publicly available data rarely provided enough information on a small scale was one of challenges hindering communities' data utilization. S81 said that the lack of data representing local communities was the major issue in supporting communities' data work, leading intermediaries to collect data to complement existing data.

Help with Analysis and Interpretation

While some intermediaries stated that they "don't do analysis" (S51), several others engaged with the analysis and interpretation process when asked to do so by their clients (i.e. community members). S91 said, "most of the smaller [community] organizations, […] they just don't have the capacity to analyze [data] themselves." When the intermediaries analyzed data for the communities, they typically did more than simply share the numbers in written reports. Instead, they "visualize [the data] or map [the results] for [the organizational needs] so that [the community organizations] can then take that output and use [it right away]" (S81). S71 described the analysis process as "a partnership, where we don't just interpret the data and send it back to [the clients], but there's multiple sessions where they're talking about what the questions are, and then a preliminary data analysis is presented, and so it is an interactive process, and there's a lot of collaboration." Further, O7 described "working with [the clients] to understand their needs and their culture, and everything that would go into forming whatever final data project they need" (S71). These reflections show that the intermediaries actively communicated with their clients throughout the analysis process to make sure the clients accurately interpreted and understood the data for their purposes.

Promote Data Sharing and Share Data with Communities

A few intermediary organizations also contributed to the data-sharing landscape by supporting community organizations' data-sharing practices. S91 said that O9 had been working with different organizations that wanted to share data-driven information with members of the community and had "been […] creating data-sharing relationship agencies [that currently do not share their data] to obtain new data sets." Using the data from these agencies, O9 was "linking the data and sharing back out the aggregate to them" as part of its data reuse support. The intermediary organizations also shared the data they collected with the communities. S61 said, "[regarding] our own data, our goal is to make everything public. […] There's some data we released more in an unidentified format or in its original and raw format. […] Pretty much everything we [collect], we make public."

While intermediary organizations occasionally shared raw data, including both secondary data they acquired and primary data they collected, several intermediaries shared data in more "processed" forms, considering the community members' different levels of data literacy and different abilities to search, understand, and interpret data. The most common form of "processed" data was "data reports" with tables and infographics on important indicators that of communities' interests. Often these reports were included in the clients' requests. For instance, they might "compare how [the city] is doing compared to other peer cities on a variety of indicators, such as poverty levels, educational levels, housing, things like that," and were "shared around the community a lot" (S22) through the clients. In other cases, intermediaries produced data reports for general community members or citizens so that any stakeholder could learn about the community and different topics/indicators and use the data for their own purposes. Not all of the intermediaries tracked who accessed and used these reports, but some had a clear understanding of their users, including legislators, community advocates, government officials, and the general public.

Improve Communities' Data Practices

Although it was not common, two intermediaries helped community organizations improve their internal data practices. Community organizations often needed to collect internal data for program evaluation and outcome measures for grant reporting, but not all implemented best practices. S51 ran into "a lot of issues where organizations don't support their own data or don't

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keep [the data] in the same format all the time," generating "more process concerns." O9 helped these community organizations implement the best data organization method to "do or plan out their evaluation plan [early] so that they're not caught at the end of their grant cycle to figure out how demonstrate what their impact was in anything more than an anecdotal fashion" (S91). O1 was more actively involved in community organizations' internal data practices, helping them "curate the data they collect, and the method by which they collect, and the methods by which they store, and their quality assurance and improvement of that, […] and [track] longitudinal patterns" (S13). This was one of the most active forms of data support that intermediary organizations provided communities.

Foster Community Research

A small number of intermediaries actively participated in community research either by independently conducting research "to understand specifically what's going on in [the county]" (S11) or through partnerships with research institutions and community organizations. S61 called this effort "community-engaged research," which could take the form of a survey study "in conduction with the foundations, or hospitals, or health departments, or city offices" to answer community-specific research questions. These community research projects usually produced valuable data specific to the local context and helped to overcome some of the limitations of using secondary data.

Challenges to Support Communities' Data Work

While data intermediary organizations supported communities' data utilization through the various services described above, they also experienced different challenges doing their work. These challenges were associated with several different factors, such as a lack of organizational resources, a lack of local data, a lack of data literacy among community members, and difficulties building a partnership between communities and academic institutions.

Lack of Organizational Resources

Despite growing community demands for data utilization, not all data intermediary organizations were equipped with sufficient financial and human resources to either maintain current services or extend/develop new services for communities. Financial resources were crucial to the intermediary organizations' sustainability, and several mentioned that their business model was "100% self-funded" with no state support (and, thus, fully funded by projects). This limited opportunities for community organizations that could not afford a service fee, although some intermediaries noted that they did smaller-scale "pro bono work" (S21) for smaller communities. Limited financial resources could also limit the development of a new service or the extension of an existing service. As S71 mentioned, these "resource constraints prevent us from working on [new area because] we don't have the funding to [do all the work]." For smaller intermediaries, a lack of human resources was the factor limiting their community data support, as no single staff member can have all different types of expertise and data skills. S61 said, "the staff time and staff level of expertise" also mattered for collecting and working with complex data.

Lack of Local (Neighborhood) Data

While data intermediary organizations shared some common challenges relating to data reuse, such as difficulties accessing secondary data, difficulties aggregating data due to interoperability issues, and difficulties working with sensitive data (Lucero et al., 2015; Yoon, 2016), one notable challenge that staff from all intermediaries identified was a lack of data representing local areas or neighborhoods. Although all staff utilized publicly available data for community data work, they agreed that "the public data are fairly general, and usually the scope is fairly large (S41)." Many noted that there were no data available on particular topics (e.g., health data, unemployment data) at the neighborhood or small-town level. Alternatively, they used or let communities use "data at a zip code level to portray what's going on in their neighborhood," even though such reports are "just basically generally wrong" (S81) because "zip codes are not necessarily related to neighborhood[s]" (S21). S21 said this made community members really "angry […] and the people in a particular neighborhood within that zip code are like, 'that's so not true' because their shared daily experience is different than what the data suggested, and so they're freaking out." This was the major challenge the intermediaries faced when supporting communities' data work, and it was also why data intermediaries needed "to figure out a way to develop our own [data]" (S41). In addition, publicly available data were "notoriously old, [and] it was really common to find data that would be six years old [or] a couple-year lag" (S42). Usually, communities needed current, up-to-date data representing current community problems; in such cases, old data were not particularly useful.

Community Members' Data Literacy Skills

One critical issue relating to interactions with communities was differences in community members' data literacy skills. Many intermediary staff mentioned that different levels of data literacy influenced how they communicated with both their clients and the general public. S72 said, "general citizens are probably not being very accurate in terms of interpreting [data]," which can be a challenge when working with them. Intermediary organizations shared the results of data analyses and/or interpretations in formats "designed to be digestible" (S61). Data reports also aligned with these efforts. Still, a lack of data literacy could hinder intermediaries' communication processes. As S11 shared, "it's hard for [community members] to understand what goes into analyzing and cleaning data. Our community partners get frustrated when they have a request and they don't understand

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why we can't generate it that second, why it might take a few days."

Building a Partnership between Academic Institutions and Communities

For those intermediaries that had tried to build or already built a partnership between communities and academic institutions to support communities' data work or community research, a distance between the two entities often posed a challenge. A partnership with university researchers can have great benefits for communities' data work because academic researchers are experts in topical areas or domains. S42 described one case in which he was "a little suspicious about the motivation for doing the community need assessment [requested by one community organization]." When he consulted with experts from a local university, one of them "flat out said, 'It's a fad, and this is what's going on politically' because they had done years of research on the area." He said the researchers immensely helped to clarify where to look for data sources while crystalizing the real problems to address using the clients' data sources. However, there was still a degree of distance between communities and academic institutions because the two parties tended to have different motivations and needs. Academic researchers tended to focus on education and research; thus, "they push a publication, research design […] that would be required and understandable in [an academic] environment" (S81). By contrast, communities "may not see much value in research itself […] They may be struggling with day-to-day challenges […] and don't see any short-term or immediate benefits from [academic research]" (S31). S81 also found that, "sometimes, data people [from academia] are not very respectful of the [community members]." When academic researchers lacked a deeper understanding of communities' needs, community members found their collaboration intrusive.

DISCUSSIONS

This study explored data utilization at the local community level through the work of data intermediary organizations. The findings of this study reveal that data intermediary organizations play four major roles that are crucial in communities' data utilization: (1) democratizing data, (2) adding value to existing data, (3) enhancing communities' data literacy, and (4) building communities' data capacity.

Democratizing Data

Data democratization involves helping all citizens access and understand data. Although only two intermediary organizations in this study identified data democratization as one of their missions, all intermediaries contributed to democratizing data in practice. Easy access to data when needed at any given moment is an important first step towards data democratization, as previous research has suggested that access to data is the single most important component of successful data reuse (Yoon, 2016). Most intermediaries tried to improve communities' access to data. However, democratizing data means more than just ensuring easy access. Intermediary organizations were actively involved in helping communities make sense of data, ensuring that data could be easily understood and interpreted for the purpose of the communities' data utilization. Aggregating different data sources, breaking data down into desired units (e.g., neighborhood, county), developing self-service data tools for analysis and reuse, and visualizing data were all initiatives in which intermediary organizations engaged to support communities' understanding of data. These efforts align well with the goal of data democratization, which is to expedite decision-making processes, eliminate barriers to accessing or understanding data, and uncover opportunities for organizations (Marr, 2017).

Adding Value to Existing Data

A second critical role that intermediary organizations play is adding value to existing data. Not all of the intermediaries seemed to be aware of this role, though S71 acknowledged that their work added value to data and data utilization. However, whether intermediaries are aware of this role or not, adding value to existing data significantly contributes to open data curation. Value-adding activities are the hallmark of data curation and perhaps the most meaningful and uniquely necessary step in supporting data reuse and utilization. The Digital Curation Center (DCC, n.d.) defined digital (data) curation as the effort to "maintain, preserving and adding value to digital data throughout its lifecycle," as well as to "enhance the long-term value of existing data by making it available" for current and future use. Data intermediary organizations may not contribute to curation of the complete data lifecycle, for example, as the interviewees rarely mentioned long-term data preservation or data sustainability. However, they notably contribute to several other curation components, particularly relating to maximizing access and data preparation. In the context of intermediaries' support of communities' data access, access does not simply mean connecting communities with data by identifying appropriate data sources. The studied intermediaries were also involved in the discovery process, during which they requested data on behalf of communities, suggested potentially good sources, and consulted with local domain experts to find good data sources. Further, much of the intermediaries' work was related to enhancing accessibility and understandability through thorough data preparation. Data preparation is known to be one of most difficult, time-consuming, and knowledge-intensive challenges in data curation. When obtaining data from different sources, the intermediaries had to address issues of interoperability, as well as to clean, merge, aggregate, and integrate data with their data system to make the data more accessible, easily retrievable, and understandable. Such steps enriched the data for communities' further use and analysis. When community members accessed data through their intermediaries' systems, the data were well-prepared for consumption and contained complete and self-explanatory information. Since the ultimate goal of data curation is to support

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current and future use/reuse of data, the role that intermediaries play in curation cannot be underestimated.

Enhancing Communities' Data Literacy

Data literacy is known to be fundamentally important for extensively using data for decision-making (Cruosoe, 2016). In the context of communities' and individuals' data utilization, data literacy is generally understood as "the knowledge of what data are, how they are collected, analyzed, visualized, and shared, and the understanding of how data are applied for benefits or detriments" (Crusoe, 2016, p. 27). Staff from the intermediaries noted that it was important to have a certain level of data literacy to ensure smooth communication during the process of working with communities. Often, a lack of such skills was a barrier to data utilization. Data literacy skills were also critical for communities because they needed to interpret data "based on their understanding of their community" (S71). Due to the importance of data literacy for both the intermediary organizations and the communities themselves, many intermediaries either directly or indirectly educated communities on data literacy. For example, they asked about communities' data needs and perspectives on data, which helped them understand the process of data utilization, and debriefed them on the data analysis and the results, thereby helping communities understand the data and draw accurate conclusions for decision making. Many staff discussed how this process was iterative and collaborative. Several intermediaries also offered the training sessions relevant to data, including training on the data tools they had developed and, less commonly, trainings on secondary data. Since general citizens and community members had few opportunities to develop their data knowledge and skills, intermediaries' contributions to data literacy education are critical and a good fit for the niche.

Building Community's Data Capacity

Overall, data intermediary organizations significantly contribute to building communities' data capacity. In a way, the simple existence of data intermediaries helped communities be less intimidated by data utilization. This represents one important step in introducing communities to the power of data. By using the data services offered by data intermediaries, communities can become more comfortable with data and perhaps become aware of the need to develop further data literacy skills to fully benefit from data. Further, some data intermediaries were aware of their communities' lack of capacity to use and interpret data, and they sought to address these issues. This approach was reflected in both the collaborative nature of intermediaries' work with communities and their efforts relating to data education. The intermediaries' intentions to build community capacity is illustrated in the following statement:

> S71: "we don't wanna just do things for [the community] and walk away. We want to be showing them how to do it. Obviously, some people, they're not interested in knowing the whole thing, but you have to be interested […] our goal is to increase their ability to do similar things in the future, or at least a few steps forward and maybe adapt to just being more experienced in [data work."

Greater community capacity for data utilization would be a great asset for society, as it would enhance communities' ability to utilize data to empower communities. Ultimately, such capacity will support the goal of open data and data reuse in the community context, which will improve the lives of communities and individuals.

Despite the multifaceted roles that data intermediaries play in helping with communities' data work, the findings also illustrated that there are still many barriers to be improved for intermediaries to support communities and make data really useful for communities. It is worth noting that data intermediaries are not and should not be the only player in communities' data work, and collaboration and/or partnership with other data infrastructures is necessary to overcome some of the barriers and generate synergy to support communities' data utilization. Intermediaries were limited to existing financial and human resources, which made them unable to serve as many community as they wanted. This could include smaller communities that may not be able to afford the service fees, although intermediaries offer a pro-bono service for these organizations. In addition, the need to educate community members about data literacy skills emerged in this study; not all intermediaries had enough capacity to provide a formalized training session to the communities. Educational institutions (e.g., local universities) and local information organizations (e.g., public libraries) can share some of the responsibilities of educating communities about data literacy, and can help with communities' interaction with data, considering their expertise in education, community engagement and services. These collaborations and partnerships will complement the services provided by data intermediary organizations while meeting the needs of communities that intermediaries cannot fully afford. The best method and model for these partnerships should be investigated further by considering each entity's capacity.

CONCLUSION

As the findings demonstrate, data intermediary organizations pay several important roles that affect communities' data utilization. By democratizing data, adding value to existing data, enhancing communities' data literacy, and building communities' data capacity, data intermediaries contribute to empowering communities with data, particularly regarding the communities' decision making relating to important community problems and improving community members' everyday lives.

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While this study reports new findings about the role of data intermediaries and data utilization at the local community level, it also has several limitations. First, because the study focused exclusively on intermediaries, the findings reflect only intermediaries' perspectives regarding communities' data utilization. Most of the staff who participated in this study were highly skilled in the realm of data. Speaking directly to community members, who would have much more diverse backgrounds and levels of data skills, is necessary to fully understand how data are used and what kinds of challenges communities face in using data to make a real impact.

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Challenges and Opportunities for Strengthening the US Public Health Infrastructure

Findings from the Scan of the Literature

MAY 2021

National Network of Public Health Institutes

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ABOUT NNPHI

Mobilizing more than 40 public health institutes throughout 32 states along with ten university-based regional training centers and 40 training affiliates, the National Network of Public Health Institutes (NNPHI) supports national public health system initiatives and strengthens public health institutes to promote multi-sector activities resulting in measurable improvements of public health structures, systems, and outcomes. NNPHI also serves as the National Coordinating Center for Public Health Training – NCCPHT. To learn more about NNPHI, visit www.nnphi.org.

ABOUT THIS REPORT

The US public health system's infrastructure serves as the foundation for planning, delivering, evaluating, and improving public health. Public health services depend on basic infrastructure such as up-to-date information systems, health professionals who are competent in cross-cutting and technical skills, and public health organizations with the capacity to assess and respond to community health needs. This summary report was completed to better understand current weaknesses and challenges that are impacting the US public health system's infrastructure and to identify opportunities for addressing these issues.

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FOREWORD

As COVID-19 continues turning our world upside down, never before in recent history have our public health efforts been more needed, more relevant, and more important. At the same time, we must recognize that we are not only fighting a pathogen – we are also experiencing myriad impacts of systemic racism that increasingly drive health and racial inequalities. History will show that we are indeed living in a time of tremendous social change.

The pandemic is shining a light on the inequities we have known for our lifetimes. And for so many in the US and around the globe, this pandemic has shattered lives, and continues to rip apart families, increase food and housing insecurity, exacerbate behavioral health challenges, and cause many other hardships that impact morbidity and premature mortality.

There are also some positive social changes unfolding in response to our experiences, including a deeper public awareness of how structural racism results in shorter life expectancy and increased violence against people of color.

The lessons we are learning from a global pandemic pose many important questions. What are the strengths and weaknesses of our public health system? How do we build our agencies and communities back better? What are the best roles and functions of governmental public health? How can the private, nonprofit sector best be leveraged to support public health improvements and extend reach of government's impact? How do we achieve a healthy balance between the right to protect health while respecting individual freedoms? What changes in public health law are needed to ensure adequate protections in every community, tribe and territory exist? What innovations in public health policy and practice will best advance health and racial equity? How do we strengthen, support, and grow our public health workforce? How do we support a new generation of public health leaders?

We must also consider that while new funding approved by Congress in 2021 is sorely needed, we simply cannot fund our way out of the conundrum we face as a nation increasingly hostile to public health intervention. We must find new ways of engaging individuals and communities from all walks of life so that we begin to build back better by planting new seeds that will grow in greater of support of healthy human development. ***Government alone cannot do this work; it must be a multisector approach that engages all aspects of society.***

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I. INTRODUCTION

This report summarizes the findings of a scan of peer reviewed and gray literature which was completed to better understand current weaknesses and challenges that are impacting the US public health system's infrastructure and to identify opportunities for addressing these issues. In the report, public health infrastructure is defined as the foundation for planning, delivering, evaluating, and improving public health. We acknowledge that all public health services depend on basic infrastructure given that they require up-to-date information systems, health professionals who are competent in cross-cutting and technical skills, and public health organizations with the capacity to assess and respond to community health needs (Turnock, 2004). Federal agencies, for instance, rely on the presence of solid public health infrastructure at all levels to support the implementation of public health programs and policies and to respond to health threats, including those from other countries. We also acknowledge that while a strong infrastructure depends on many organizations, health departments are considered to be the main players.

The search for publications was initiated by first conducting a total of five interviews with key informants in the public health field to better understand how infrastructure is defined, to identify key challenges, to obtain citations and leads for the search, and to collect recommendations of experts in each of the domains to potentially serve on the Technical Expert Panel (TEP). Appendix A includes the list of key informants who participated in the interviews. From these conversations, we identified eight domains that collectively make up the system's infrastructure. We started with traditional domains such as workforce, financial resources, data, and cross-sector partnerships.

We expanded the domains to accommodate the ever-changing landscape of public health and added laboratories, technology, public health law, and health equity. Exhibit 1 illustrates the eight domains that were identified and used to organize our search for literature.

Within each of the eight infrastructure domains, we searched for national and regional needs assessments that were completed within the last six years (starting with 2015). Our strategy was to identify and review needs assessments that were completed at the national and regional levels first. Subsequently, we searched for local needs assessments and literature that addressed key challenges that were referenced by key informants as well as the needs assessments. The challenges and solutions were then categorized by infrastructure domains.

The findings presented below are not meant to serve as a comprehensive list of challenges or weaknesses and solutions but do represent the most commonly cited and most urgent challenges identified by key informants, the TEP, and the literature.

EXHIBIT 1: Key Domains Representing the US Public Health Infrastructure

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II. FINDINGS

Public Health Workforce

There is a severe and consistent shortage of public health workers and the deficits are growing due to high turnover rates and losing workers to retirement. Nearly half of public health workers are considering leaving their organization within the next five years, including individuals who will retire and individuals who will completely leave the public health field. Since 2014, there has been a 41% increase in public health workers planning on leaving their jobs (de Beaumont Foundation et al., n.d.). The public health sector also faces shortages in several career fields including epidemiologists, public health nurses, public health physicians, laboratory scientists and technicians, and environmental health workers (Perlino, 2006). These shortages are due, in part, to high turnover rates caused by lack of advancement, workplace environment, job satisfaction, lack of support, and inadequate pay (Perlino, 2006). Other reasons for leaving include threats and attacks against workers (Mello et al., 2020) and stress from overwhelming responsibilities (Bogaert et al., 2019).

The most cited reason for leaving is the lack of satisfaction with pay. This is the largest barrier as budget constraints for public health limit the number of positions and opportunities for competitive salaries (Bogaert et al., 2019). Exacerbating these shortages in personnel is that the average age of the public health sector is 47 years old and 45% of the workforce is eligible for retirement (Bogaert et al., 2019).

RELEVANT POLICY

THE PUBLIC HEALTH WORKFORCE LOAN REPAYMENT PROGRAM *established by the Secretary for Health and Human Services promotes the recruitment of public health professionals at local, state, and tribal agencies. $100 million was appropriated for the program in FY2020. This policy encouraged more students to pursue public health by providing loan forgiveness opportunities.*

Many public health professionals lack degrees in public health and have entered the workforce with little or no training specific to public health. Only 14% of the public health workforce has formal public health training and less than 1 in 4 public health managers and executives have formal training. Additionally, 4.2% of employees in local and state health departments have degrees in public health (Erwin et al., 2019). Thus, most employees working in public health entered the field with little experience in the field. The low-level of training and education limits health departments' capacity and capability in conducting public health work (Erwin et al., 2019) and requires time and resources to be redirected to training public health professionals.

Health departments have made efforts to provide training programs for their staff, but health departments lack funds to provide professional training and lack coverage for staff members to attend trainings during work hours. Staff members are further discouraged from pursuing training programs due to long travel distances, lack of free time, and limited Internet access to online training. These barriers have discouraged health department leaders from providing professional development and training given the difficulty of managing busy schedules and increasing work demands which show a small return on their investments (*Strengthening New York's Public Health System for the 21st Century: Report of the Public Health Infrastructure Work Group to the Public Health Council, 2004*). With a small percentage of public health staff entering the field with proper training and education in the field, they are at a disadvantage in implementing effective and impactful public health programs.

Staff members are further discouraged from pursuing training programs due to **long travel distances, lack of free time, and limited Internet access to online training.**

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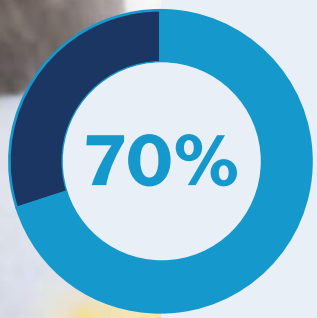
HIGHLIGHT

THE MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT OF 2008 is a federal law that prevents group health plans and health insurance plans from imposing limitations on those who seek care for mental health conditions and substance use disorder. This policy improved access to mental health care, but there are still limitations in access to care.

Severe and chronic shortages of public health mental healthcare providers who specialize in the treatment of children has forced parents into long wait lists and to pay out of pocket for mental health care. Most mental health disorders appear during adolescence, but they are often first detected later in life (Patel et al., 2007). Identifying mental health disorders early will ensure that adolescents receive the treatment they need. However, more than half of children in the United States with a treatable mental health disorder do not receive treatment from a medical professional as the need for child psychiatrists has gone unmet due to provider shortages and because many mental health professionals require out of pocket payments. Seventy percent of counties in the United States do not have a single child psychiatrist. The limited supply of child psychiatrists is unable to keep up with the demand for mental healthcare. Historically, there has been a shortage of child psychiatrists among racial and ethnic minorities as well as youth living in impoverished or rural areas (McBain et al., 2019).

The shortage of providers stems from the significant amount of time it takes to train for child and adolescent psychiatry. After medical school, a candidate studies 4 years for general psychiatry and moves onto a 2-year fellowship in child and adolescent psychiatry. Medical students are less motivated to pursue child psychiatry due to the limited funding for fellowships and the exclusion of CAP in loan forgiveness programs (Schaff, 2016).



of counties in the United States do not have a single child psychiatrist.

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Community health workers are an underutilized source of medical care for disadvantaged populations who are not properly integrated into the healthcare system, limiting their effectiveness in improving healthcare outcomes at the community level. Community health workers (CHWs) are a valuable asset to the healthcare system. They work in their own communities to combat ethnic and racial disparities in healthcare (Phalen & Paradis, 2015). CHW programs face implementation barriers which decrease the impact CHWs have on the healthcare system. The standards for CHW training vary from state to state and only a few states require CHWs to attend a state-certified training program. Many CHWs receive informal, on the job training while others take CHW courses at community colleges and community-based agencies (American Public Health Association, 2014). The lack of well-defined guidelines and variance in standards across states can result in high rates of turnover. In a Harlem Regional Stroke CHW program, one third of CHW candidates dropped out during the 6-month training (Kangovi et al., 2015).

CHW services are often delivered by community-based programs such as church-based programs which are not integrated within the healthcare system (Kangovi et al., 2015). Without formal connections to clinical providers, community health workers face limitations in their care and their disease-specific interventions. Additionally, community health workers receive unstable categorical grant funding which further limits their work (Kangovi et al., 2015).

Teaching public health in middle and high school can expose students to public health early, increasing the chances that a career in public health is contemplated, understood, and ultimately adopted.

Students in middle and high school are typically not exposed to the field of public health and may be misinformed about the role of it plays in their lives. Adding public health curricula can teach students about the importance of public health so they can begin to form a potential future career option that many do not consider until well into their academic careers (McClamroch & Montgomery, 2009).

A high school summer enrichment program, Telluride Association Sophomore Seminar (TASS) was offered at the University of Michigan and Indiana University. The goal of the program was to strengthen skills for a college environment and the curriculum included infectious disease epidemiology. Of the 16 students that participated in the program, a total of 10 reported adding public health to their future career plans (McClamroch & Montgomery, 2009). Also, the Robert Wood Johnson Foundation (RWJF) implemented a Young Epidemiology Scholars (YES) program for high school students which allowed them to conduct

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research projects on public health challenges and then present their research to a panel of judges (Bracken, 2014). The majority of participants (74%) indicated that their experience in the YES program influenced their career plans and were planning on pursuing work in public health (Tsukamaki, 2007).

Additionally, the CDC has created a fellowship aimed at high school STEM teachers to train them to bring public health sciences to middle school and high school classrooms. One of the Science Ambassador fellows partnered with the Broad Institute of Harvard and MIT to pilot a learning module for students called Operation Outbreak (CDC). The learning module was used to create pandemic simulations, which was implemented in middle schools and high schools across the nation (Centers for Disease Control and Prevention, 2019). The learning module helped illustrate key players in pandemics such as the government, military, and the media and taught students' skills used by CDC disease detectives such as rapid decision making, teamwork, and communication (Mecham, 2019). Training teachers in public health would foster engaging initiatives and activities for students, educating and inspiring them to pursue careers in public health.

74%

of high school students that participated in the Young Epidemiology Scholars (YES) program indicated that their experience influenced their career plans and were planning on pursuing work in public health.

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Community colleges offer fertile ground to influence a motivated, racially and ethnically diverse group of students to pursue public health related training and education which could lead to public health work. Community colleges serve recent high school graduates who utilize community college to identify a potential career and 4-year-degree, students who seek associate degrees to prepare for entry level jobs, and individuals of all ages who resume their studies after or while working to enhance their skills through certification programs at more affordable tuition rates than traditional colleges and universities (Riegelman & Wilson, 2014). In addition, community colleges tend to serve a higher percentage of minority students (de los Santos, 2016).

The Society for Public Health Education (SOPHE) partnered with community colleges to create a health education certificate for transfer students with associate degrees to pursue a bachelor's degree program in health education and health administration, and public health and Health Navigator certificate programs for individuals already in the workforce. The certificates provide students with experiential learning experiences at health agencies and health departments which can provide opportunities for students to pursue internship and careers. The certificate makes the transfer process easier for community college students, equipping them with the skills needed for an undergraduate education. Creating public health programs at the community college level encourages more students to pursue the public health field, which can amplify the flow of graduates pursuing public health degrees (Riegelman & Wilson, 2014).

> *Engaging students at the college level through applied experience and mentorship opportunities with local health department workers is vital to creating a public health workforce pipeline and addressing shortages.*

Work practicums and mentorship programs that expose students to careers in public health are effective strategies to create and maintain a strong and stable public health workforce.

Academic institutions have created pipeline programs to encourage students to pursue the epidemiology field. Through partnerships with local and state health departments, students are placed to assist with outbreak investigations and other short term public health projects. Placements provide surge capacity to health departments and provides practical experience for students. Participation in pipeline programs expose students to the benefits of working as an epidemiologist and provides opportunities for networking and mentorship with public health workers in local health departments (Erwin et al., 2019). Engaging students at the college level through applied experience and mentorship opportunities with local health department workers is vital to creating a public health workforce pipeline and addressing shortages.

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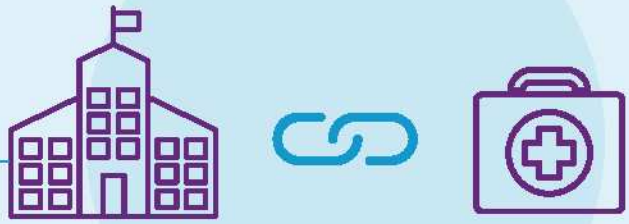
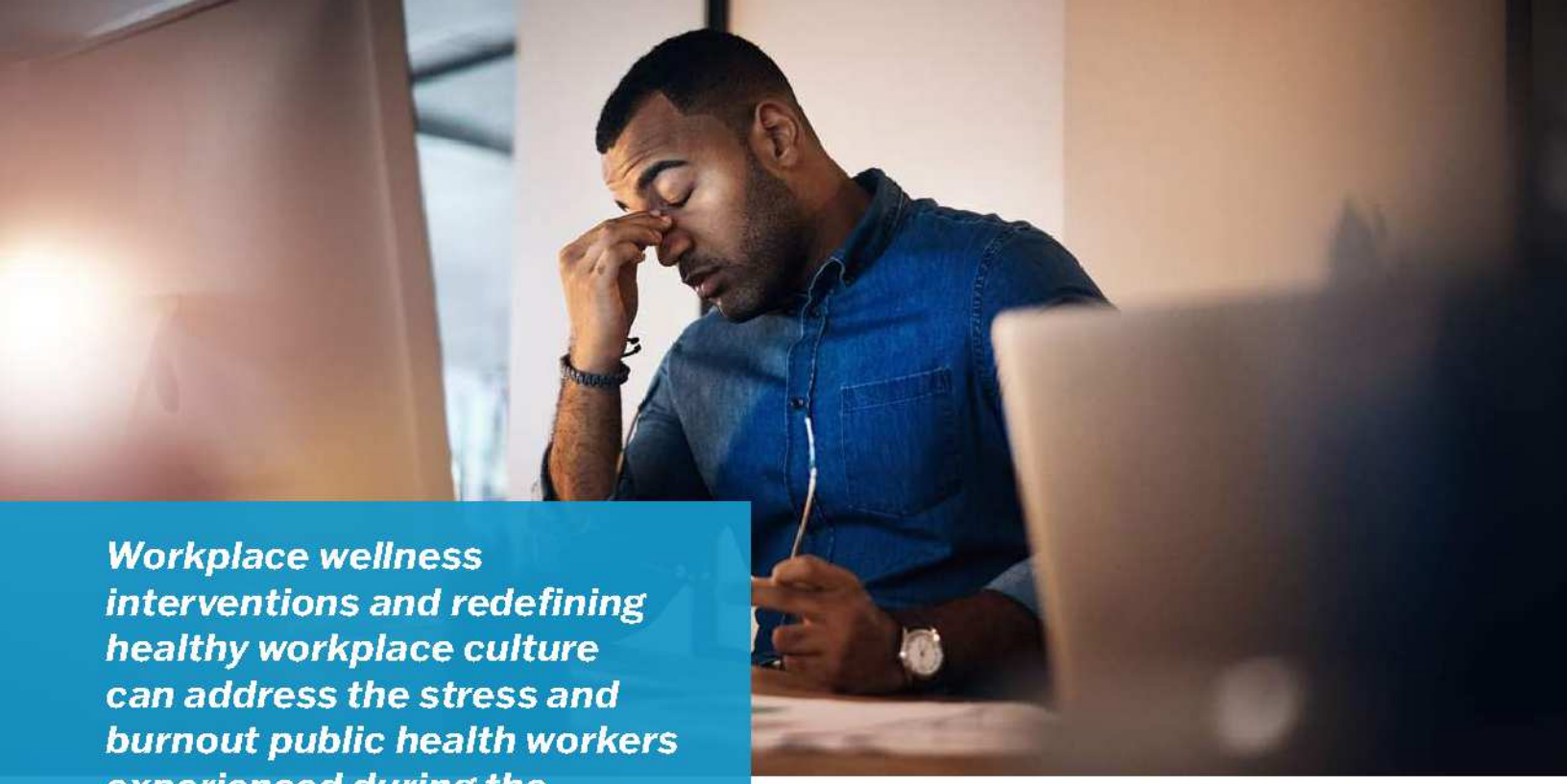
Establishing partnerships between universities and local health departments could provide the workforce with broader continuing education opportunities (Bouye et al., 2016).

Local health departments and universities have partnered together to support continuing education. The New York Department of Health established a Memorandum of Understanding with the State University of New York at Albany School of Public Health to create education opportunities for their staff. These included a public health course, an environmental health course for sanitarians, and a Surveillance Academy that trains the state public health work force employed to conduct hospital and nursing home surveillance (*Strengthening New York's Public Health System for the 21st Century: Report of the Public Health Infrastructure Work Group to the Public Health Council*, 2004). Expanding these partnerships will allow for more health department staff to return to school and to receive formal public health training and degrees. Collaborating with universities makes these opportunities more readily accessible for health department staff.





Workplace wellness interventions and redefining healthy workplace culture can address the stress and burnout public health workers experienced during the COVID-19 pandemic.

Burnout is a work-related stress syndrome resulting from chronic exposure to job stress. Healthcare workers are at particular risk for burnout due to the increased work that resulted from the COVID-19 pandemic as well as severe public health workforce shortages. This has significant negative personal (substance abuse, broken relationships, and even suicide), but also important professional consequences such as lower patient satisfaction, impaired quality of care, and medical errors (Shanafelt et al., 2010; West et al., 2006). The development of adequate coping personal and organizational strategies is essential in dealing with this important problem in contemporary healthcare and requires intentional redefining a health workplace culture for public health workers. Public health organizations can foster a positive environment for their staff by offering staff the ability to influence their work environment, make decisions, and control their work schedules. Work policies that allow for flexible scheduling, childcare, and remote work options have shown to increase employee wellbeing (De Hert, 2020).

Workplaces that provide support to their workers can help reduce burnout and promote better achieve better work outcomes. Mindfulness in Motion is a mindfulness based intervention (MBI) that has been adopted by an ICU facility to bring awareness and relaxation to the work environment. The intervention had a 97% retention rate and increased the resiliency and engagement in work by staff. Social cohesion programs also serve to improve wellness among workers. The Vanderbilt Medical Student Wellness program pairs students with faculty for mentoring, arranges wellness retreats, and puts students together in committees (Global Forum on Innovation in Health Professional Education et al., 2019). Fostering relationships with colleagues can provide emotional support and shared understanding of experiences. Public health leaders can implement wellness interventions which better support their staff and provide them with resources and tools to help ameliorate the stress they face from their job.

Work policies that allow for **flexible scheduling, childcare, and remote work options** have shown to increase employee wellbeing.

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Financial Resources

Public health's invisible role in protecting the nation has resulted in chronic underfunding which has negatively impacted its workforce, data systems, technology, community partnerships, and leadership.

Public health has been underfunded and undervalued at the local, state, and federal levels. Public health cares for the general population by providing clean air and clean water initiatives, sanitation, vaccines, and other methods of controlling against environmental threats and diseases. However, the role that public health plays is hidden compared to the healthcare system that cares for patients individually or advertises new drugs and medical devices. The invisible role public health plays has caused public health to receive little attention, recognition or funding except when there is an urgent public health crisis (Rovner, 2020).

Since 2010, federal funding has dropped to 16% for state health departments and 18% for local health departments. During the last ten years, local health departments have lost 56,260 staff positions due to the constant budget cuts (Weber et al., 2020). Without adequate pay, workers leave the field in search of other opportunities as they struggle to pay back their student loans. Without proper investment, public health will not be able to carry out its core responsibilities to keep the nation safe and healthy.

At the federal level, the Centers for Disease Control and Prevention (CDC) has lacked the funds to adequately support the public health system. The CDC is the nation's leading public health agency. Its mission is to protect Americans from disease outbreaks, disasters, and unsafe food and water, and to reduce the incidence of leading causes of Americans' deaths. To help accomplish its objectives, the CDC supports states, localities, tribes, territories, and community organizations in addressing leading health threats in their communities. Indeed, more than half of its program funding is redistributed to these partners.

The CDC also lacks sufficient dedicated funding to adequately support the cross-cutting, foundational capabilities that form the backbone of comprehensive public health systems at the federal, state, and local levels.

The CDC's budget has not kept pace with the nation's growing public health needs and emerging threats, particularly the rise in substance misuse and weather-related emergencies. The agency has expanded its substance misuse efforts in the past few years, but more resources are needed to address underlying causes. For example, the CDC's State Physical Activity and Nutrition (SPAN) program has been successful in improving nutrition and encouraging physical activity through early care and education. However, the SPAN program only has sufficient funding to be implemented in 16 states (Faberman et al., 2020). The CDC also lacks sufficient dedicated funding to adequately support the cross-cutting, foundational capabilities that form the backbone of comprehensive public health systems at the federal, state, and local levels. Fiscal Year (FY) 2019 program funding for the CDC, as enacted in September 2018, is $7.3 billion. After accounting for interagency transfers and one-time funding, this reflects a $143 million (2 percent) increase over FY2018 — or flat funding in inflation-adjusted dollars (Trust For America's Health, 2020).

It is not just the lack of funding available to public health but the manner in which funds are made available that limits its ability to address new and emerging needs such as updating information systems and policy analysis.

Since 2010 non-defense discretionary funding (NDD) has been declining and in 2019 it reached a record low of 3.1% of the gross domestic product (Center on Budget and Policy Priorities, 2020). NDD funding supports services such as education, public health, medical care for veterans, and medical research. NDD funding has been limited by statutory caps that were set by the Budget Control Act of 2011. Federal appropriations for CDC fell 7% between 2010 and 2021. These reductions have limited CDC's ability to fund state and local health departments (Reich & Windham, 2021). Consistent limited funding from the federal government has left public health chronically underfunded. In addition, categorical funding has led to silos that reduce health department's ability to fund a wide range of needs such as information systems or policy analysis (Committee on Public Health Strategies to Improve Health, 2012).

Federal appropriations for CDC

fell 7 percent

between 2010 and 2021. These reductions have limited CDC's ability to fund state and local health departments.

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A common workaround to chronic underfunding has been cross-jurisdictional sharing (CJS) which allows health departments to pool resources in order to offer an expanded array of services.

Several states have established CJS arrangements for public health functions to address health populations in areas with limited financial resources, staff, and equipment. Only 38% of local health departments (LHDs) have an epidemiologist and only 33% of LHDs have an information specialist. Through CJS, LHDs that lack funding to staff these positions are able to access their expertise (Shah et al., 2016). In Kansas, emergency preparedness regions, multicounty health departments, and other CJS arrangements among different counties have been established (Hartsig, 2017). The most commonly shared services among LHDs were all hazards and response, communications and community partnership development, policy development, and health equity and social determinants of health organizational competencies (Hartsig, 2017). CJS offers a way for LHDs to counteract the limited funding they receive by working with other LHDs to gain the resources that they need to do their job.

Improving communication on the value of public health will allow public health workers and their supporters to better advocate for policies and funding. With the general public and different sectors not fully aware of what public health does or achieves, it is increasingly important for public health officials to effectively communicate the value and role public health plays. Leaders in business, housing, and other sectors associate public health with impractical research and bureaucracy (L'Hôte et al., 2019). Public health officials must share stories of the impact their work has and illustrate the value that public health brings to people's lives. Public health has made several achievements in the past 21st century from the creation of new vaccinations, improved sanitation which has led to a sharp decline in infant and child mortality, among many others (Association of State and Territorial Health Officials, 2016). The impact of public health work is not as immediate and evident as new scientific discoveries, but it is important, nonetheless. This is why public health must document and communicate the ways that public health improves lives and communities (Illinois Strategic Communication Leadership Project, 2016). Public Health Reaching Across Sectors (PHRASES), an initiative of the de Beaumont Foundation, has created a toolkit to help public health workers to better communicate about public health with other sectors (*Motivating The Public To Support Public Health: A Toolkit For Communicating With Non-Experts*, 2020). Utilizing toolkits like PHRASES and creating workshops to improve communication will better equip public health officials with the skills needed to advocate for public health. Communicating and publicizing the role of public health will help the federal government see the importance in properly funding public health.

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Cross-Sector Partnerships

Public health workers are siloed in their work, culture, and language which prohibits them from strategically interacting with other sectors to prevent and solve social problems that result in poor health outcomes. Public health workers often do not work (and do not know how to communicate with) with partners in sectors other than public health (Rudolph et al., 2013). Although public health has an important role in hospitals and private clinics, criminal justice, public schools, and emergency services most health professionals do not have a clear understanding of their counterpart's roles and responsibilities. Open communication, collaboration, information exchange, and consultation between the sectors are of utmost importance in creating effective and trusting relationships.

Public health and criminal justice have often acted independently of one another. However, public health issues are inherent in various aspects of the criminal justice system (Gideon, 2013). Prisoners face a myriad of health problems including elevated rates of mental disorders, substance abuse, as well as airborne and bloodborne viruses (Kinner & Young, 2018). Public health operates on a prevention approach which could be applied to criminal justice research and policy. Early identification of health issues in prisoners and outbreaks and treatment in prison can improve health outcomes and reduce harm to communities when prisoners are released. Working alongside criminal justice to provide services would greatly improve the health status of the populations at-risk and can prevent health issues from spreading to the larger community (Kinner & Young, 2018).

School settings have a great impact on child and adolescent health. Schools provide regular physical activity required for children and adolescents, promote healthy nutrition, and provide health education for risky behaviors. School nurses and counselors also prevent, detect, and treat physical and mental health problems. Schools are already overwhelmed with the breadth of responsibilities that they must take on and require the help of public health workers to increase the effectiveness of school programs to promote health in children and adolescents. The public health workforce must conduct school health research and development and provide professional services to sustain and improve school health programs within their own districts (Kolbe, 2019).

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Local health departments struggle to establish and maintain cross-sector partnerships. Health departments lack the staff, resources, and funding to maintain cross-sector partnerships. Health department staff members are often overworked with the overwhelming needs of serving the local population and struggle to find the adequate time to establish meaningful relationships. Staff members are met with competing priorities and are not able to fully commit to partnership development and maintenance. Public health leaders have noted that they struggled to find the time to build relationships and struggle to participate in community meetings or calls necessary for the development and maintenance of partnerships. High staff turnover is a barrier to maintain long-term partnerships. When organizational points of contact change, organizational priorities soon follow (Ransom et al., 2019). Public health leaders are then left with a loosely defined partnership that requires rebuilding and redefining relationships (Carlin & Peterman, 2019).

Resource limitations were the most commonly cited barrier to cross-sector partnerships. Without sufficient funding, services and programs are not adequately supported and partnerships cannot be sustained over a long period of time. Siloed funding for public health also prevents organizations from investing in cross-sector partnerships as they will focus on maintaining their funding mechanism (Center for Sharing Public Health Services & Public Health National Center for Innovations, 2019).

Health departments lack the staff, resources, and funding to maintain cross-sector partnerships.

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Training public health staff on the development of community partnerships could increase their efficacy in establishing partnerships and expand the occurrence of cross-sector partnerships. Expanding training programs for community partnerships would provide public health workers with the skills needed to establish and maintain partnerships. One of the barriers to increasing partnerships between public health and other sectors of society is that there are communication challenges and gaps in knowledge between public health experts and leaders in other sectors. Leaders in other sectors do not fully understand the role of public health and define health differently than public health professionals (L'Hôte et al., 2019). To bridge the gaps between the sectors, training public health workers in effective communication would enable them to forge these partnerships. The de Beaumont Foundation has created a toolkit, Public Health Reaching Across Sectors (PHRASES), which provides best practices for communication, to help public health experts better describe their work to leaders in other sectors (*Motivating The Public To Support Public Health: A Toolkit For Communicating With Non-Experts*, 2020)

Embracing non-traditional partnerships will allow public health to gain resources, experts, and champions. Collaborations with non-traditional partners such as businesses, faith institutions, universities, hospitals, nonprofits, philanthropy, and schools create opportunities for public health to further their impact in the community and to promote better health outcomes. Partnerships with business provides public health with financial resources, products, staff time, knowledge exports, and property. Additionally, businesses can provide funding towards public health goals and help support community initiatives (Bipartisan Policy Center & de Beaumont Foundation, 2019). Universities and hospitals are anchor institutions which have significant influence and economic and social impacts in their surrounding communities. They are uniquely positioned to use their knowledge and resources to improve the quality of life in their surrounding communities. Partnerships with these institutions provide an array of funding sources which greatly expands community-based efforts. Faith institutions are another key partner that are deeply embedded in the community and can be mobilized to advocate for health care services (Weinstein et al., 2017).

Collaborations with non-traditional partners such as businesses, faith institutions, universities, hospitals, nonprofits, philanthropy, and schools **create opportunities for public health to further their impact in the community and to promote better health outcomes.**

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Data

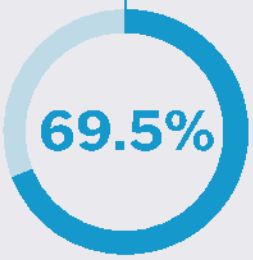
The lack of harmonization between public health information systems and healthcare has led to silos of electronic health data which hinders public health surveillance efforts. Public health agencies house data registries from healthcare providers like childhood immunization, birth defects, and death registries. Additionally, public health agencies collect information from healthcare providers for disease surveillance (Office of the National Coordinator for Health Information Technology, 2017). However, more than 4 in 10 US hospitals report that public health agencies are unable to receive full electronic data sets but only a select number of data elements from some electronic health record (EHR) systems (Holmgren et al., 2020). The lack of full data exchange results in siloed health data that must be manually exchanged for surveillance. Epidemiologists often make requests for data over the phone or through email to medical examiners or coroners and the information is then faxed to health departments for manual input (Hagan et al., 2019). Health providers are often unclear on which data elements need to be sent to health departments and the level of detail needed for proper disease surveillance (Birkhead et al., 2015), and are often not able to submit risk factors such as smoking, blood pressure, diet, exercise, and occupation which limits the scope of surveillance (Hagan et al., 2019). Finally, there is a lack of harmonization of messaging standards between public health and healthcare. Healthcare and public health use different vocabulary in data exchange (Birkhead et al., 2015), limiting real time data exchange which ultimately hinders public health's ability to track emerging threats and conduct proper disease surveillance in a timely fashion.

Lack of data standardization limits public health officials' ability to analyze data received from other systems which leads to inconsistencies in surveillance efforts. There is a significant disconnect in data standards between public health and healthcare. Healthcare systems use multiple information systems, applications, and hardware each with different data dictionaries and data transfer procedures. This complexity in systems leaves health departments with a minefield of potential error which can lead to incorrect data interpretation and an inability to make cross-system comparisons (Birkhead et al., 2015).

State and local health departments lack the capacity to analyze and provide real time data necessary to conduct surveillance work. Local and state health departments have limited capacity to manage and analyze data received from healthcare to inform policy. This is due to reduced public health budgets, outdated informatics systems and technology, and lack of informatics expertise. It has been reported that 30% of health departments do not have inoperable systems and they lack control over the hardware and software they use. Also, only 22% of health departments have implemented EHRs, only 13% conduct health information exchanges, and 69.5% have the ability to extract data from information systems. These tasks are necessary for surveillance, the documentation of immunization records, and understanding of community health. With many health departments unable to complete these tasks, the effectiveness and reach of their efforts are minimized (Drezner et al., 2016). Many of these challenges are due to health departments' lack of informatics expertise and data literacy. Only 20% of local health departments have information systems specialists on staff and many smaller health departments do not have that expertise on staff.

of health departments have implemented EHRs.

conduct health information exchanges.



have the ability to extract data from information systems.

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20%
of local health departments have information systems specialists on staff and many smaller departments do not have that expertise on staff.

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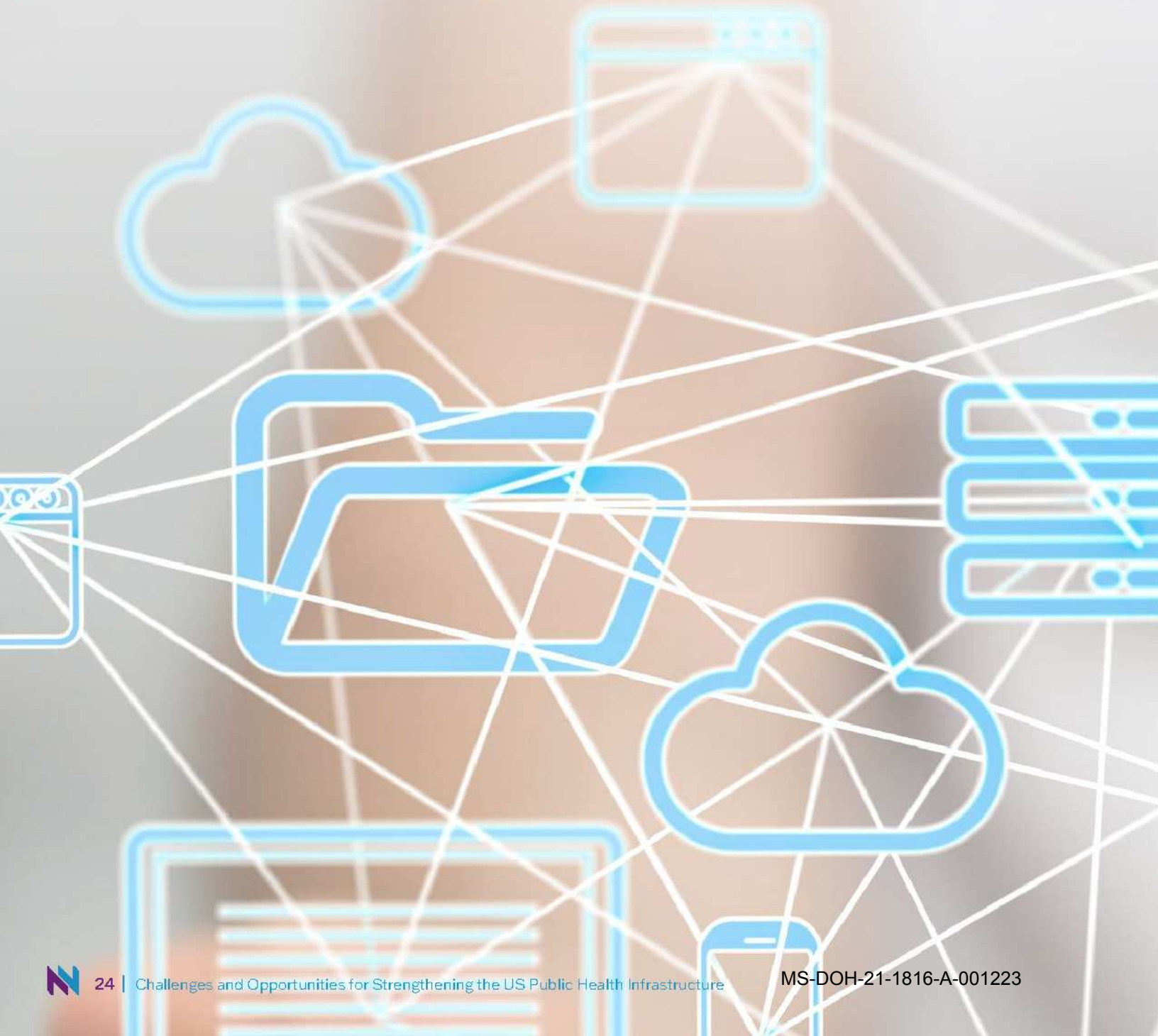
Health providers and researchers do not consistently collect data on sexual orientation and gender identity (SOGI) which leads to limited understanding of the health needs and disparities of the LGBTQ community. Researchers have struggled to operationalize the different dimensions of sexual orientation including behavior and attraction as well as gender identity (IOM Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities, 2011). Gender identity is a diverse spectrum that is difficult to categorize in surveys with a broad range of identities such as genderqueer, gender nonconforming, transgender, and agender. These identities may prefer neutral pronouns such as they/them or zie/hir (Deutsch & Buchholz, 2015). Providers often possess limited competency on LGBTQ identities and provider discomfort has been cited as a common reason for low SOGI data collection in hospitals (Streed et al., 2020).

At the federal level, most governmental data collection efforts do not include SOGI measures. In the past, the Census Bureau edited census responses for LGBTQ married couples. However, the Census has decided that "same-sex husband/wife/spouse/partner" will be included which is a step for the LGBTQ community (Velte, 2020). The federal government has also collected limited SOGI data during the COVID-19 pandemic. Few states have taken steps to collect SOGI data in the COVID-19 pandemic, with only Pennsylvania, Washington DC, Massachusetts, and Rhode Island making strides in collecting SOGI data (Cahill et al., 2020).

An underrepresented population of the LGBT are two-spirited people. Two-spirited people have often been grouped with LGBTQ identities which equates two-spirit identities to Western identities. To engage these populations in research, Indigenous only options could be listed alongside Western terms so Two-Spirit and Indigenous people can see themselves in data collection (Pruden & Salway, 2020).

The continued lack of consistent SOGI data hinders the implementation of public health interventions for vulnerable populations, limits epidemiological understanding of the LGBTQ community, and minimizes the understanding of the health disparities the LGBTQ community faces. Without proper data, researchers, public health officials, and the government will not understand what the LGBTQ community needs.

Efforts to scale up novel programs like the Digital Bridge could unify information exchange between public health and healthcare. The Digital Bridge is a partnership between the CDC and healthcare, public health, and health information technology to create a bidirectional exchange of data and to improve electronic case reporting of health data. Digital Bridge has built a national framework for electronic case reporting (eCR) to standardize tools and reporting from public health and healthcare and to make data extraction from EHRs faster and easier. The framework flags potential disease cases from data in a patient's EHR and creates a report that is electronically sent to public health. This process reduces the manual, paper-based process for healthcare providers and public health professionals, increasing the response to outbreaks (Office of Public Health Scientific Services, 2018). The Digital Bridge has been tested at seven sites in California, Houston, Kansas, Massachusetts, New York City, and Utah (Office of Public Health Scientific Services, 2018). Greater expansion would make public health surveillance seamless and more effective.



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Public Health Law

There is an overall lack of awareness of the legal basis in public health work among the general population that reduces public health's power, influence, and effectiveness. Law creates the framework for public health interventions and is the basis of every solution to public health challenges. Thus, public health officials must understand the intersection of law and public health and recognize their specific legal power to address health inequity. Laws, for instance, mandate disclosure of calories on restaurant menus; promote automobile safety; influence how public health practitioners distribute and enforce vaccination efforts, affect isolation, and quarantine orders; and are used to prohibit smoking in buildings (Leider et al., 2015).

Public health law remains one of the largest knowledge gaps in the public health workforce. Law has not been integrated into public health and as a result has left many public health officials unsure about legal capacity and left them with little legal efficacy (Burris et al., 2016). The top two self-identified areas of need for training among the workforce are how to influence law and policy development and how to understand the effects of law and policy on health. Most public health professionals receive little, if any, legal or advocacy training (Berman et al., 2019). These skills are rarely taught in law or public health schools and professionals enter the workforce unsure of how to advocate for effective policies (Berman et al., 2019).

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The value and need for essential public health law services need to be better communicated at the local and national levels.

Public health officials play an important role in providing legal counsel for elected officials. Public health officials develop policy solutions and work with elected officials to build public support for these solutions. To develop these policy solutions, public health must establish relationships with legislative liaisons, city attorneys, and local boards of health to push these solutions forward. The 5 essential public health law services include ensuring access to evidence and expertise, designing legal solutions to address health problems, engaging communities, and building political will, enforcing and defending legal interventions, and monitoring and evaluating policy (Burris et al., 2016).

5

The 5 essential public health law services include ensuring access to evidence and expertise, designing legal solutions to address health problems, engaging communities, and building political will, enforcing and defending legal interventions, and monitoring and evaluating policy.

Establishing public health law training programs and mentorship programs will allow public health workers to enforce and apply laws to their work.

To address the deficit in law knowledge in public health professionals, trainings have been created to teach the basics of law and the intersection between policy and public health. The Public Health Law Academy was established by ChangeLab Solutions and the CDC's Public Health Law Program (PHLP) to help public health professionals better understand law and incorporate it into their job. The Academy incorporates online tools and training and a facilitator toolkit to prepare mentors. The Public Health Law Academy provides basic courses on topics such as Introduction to Public Health Law, Hot Topics in Public Health Law, and Legal Epidemiology Overview (Ransom et al., 2019). Expanding training programs and courses will teach public health professionals the basics of public health law so they can use policies and the law to improve health outcomes.

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RELEVANT POLICY

THE PUBLIC HEALTH SERVICE ACT *provides legal authority for the Department of Health and Human Services to respond to public health emergencies.*

Providing public health workers with political advocacy training and courses will help them strengthen policies and laws to improve public health outcomes and reduce disparities. Many public health workers lack opportunities to build policy and advocacy skills and do not understand the role they play in developing health policy solutions. Providing political advocacy courses in public health college curriculum and creating training workshops could increase the efficacy of the workforce. The Johns Hopkins Bloomberg School of Public Health offers a course designed to prepare public health students from different disciplines to analyze policy solutions and to determine advocacy strategies. The course offers community-based practice, classroom discussions, and opportunities for students to practice their advocacy skills to solve public health problems. Expanding political advocacy courses and making these courses mandatory will ensure that students possess policy and advocacy skills when they enter the workforce (Hearne, 2008).

The University of South Florida College of Public Health offers an educational workshop on policy aimed at building advocacy skills in public health professionals. The objectives of the workshop were to understand the relationship of federal and state governments in public health law, understanding common good vs. individual freedoms in public health law, and summarize the steps in policy development. Participants in the workshop are provided examples of how public health problems are identified and how to integrate these issues in a health policy agenda (Blenner et al., 2017).

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Laboratories

Public health laboratories (PHLs) are not able to keep up with the capacity of public health surveillance due to budget cuts, staffing vacancies, and outdated technology. PHLs are on the front lines protecting people from disease by providing diagnostic testing, disease surveillance, and research (Association of State and Territorial Health Officials, 2004). PHLs have faced numerous budget cuts which have resulted in the closure of public health labs in states such as Georgia, California, and Michigan. PHLs that are still operating have been forced to cut down on their staff and salaries (Strain & Sullivan, 2019) and have been unable to keep up with equipment upgrades (Association of State and Territorial Health Officials, 2004). Improvements have been made in the volume of testing at PHLs, but the biggest challenge faced is the dearth of laboratory specialists and staff. Thirteen states reported no doctoral-level molecular scientist on staff, and 23 states reported only one. States report that at least two doctoral-level molecular scientists are needed on staff to ensure emergency readiness and proper disease surveillance. The shortage of technology specialists hinders the state's ability to respond to emergencies and to communicate testing results (Scheck & Hing, 2020).

> *"PHLs are on the front lines protecting people from disease by providing diagnostic testing, disease surveillance, and research ... [and] have faced numerous budget cuts which have resulted in the closure of public health labs in states such as Georgia, California, and Michigan.*

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PHLs struggle to recruit staff because most trained personnel prefer to work in the private sector where they can make more money rather than work in the public sector. There is also a low level of awareness of the potential for careers in clinical laboratory science. Most science, technology, engineering, and mathematics programs geared towards adolescents focus on more common professions such as physicians and do not address clinical laboratory positions. Additionally, there are challenges in retaining trained laboratorians. About 15% of the workforce are expected to leave the workforce by 2023. The most frequently cited reasons for leaving include low salaries, limited career mobility, and lack of satisfaction with work environment.

There are testing inequities across public health departments due to testing deserts and disparities between high and low income communities.

The COVID-19 pandemic has highlighted the inequities between higher and lower income communities and more urban and more rural locations. Median travel time to COVID-19 testing sites was longer in counties with lower population density and longer in counties with a higher percent of minority and uninsured individuals, compounding the health disparities these communities face. These inequities were recently addressed an additional $2.25 billion made available to underserved communities through the American Rescue Plan, which has the additionally benefit of increasing asymptomatic testing and surveillance. Also, public health laboratory staff have lower median salary than state health agency staff, further contributing to the potential for staff dissatisfaction and turnover (Association of Public Health Laboratories, 2018).

Memorandums of Understanding (MOUs) between public health laboratories and university laboratories allow university laboratories to share human, financial, and technological resources.

In order to strengthen public health laboratories, partnering with university laboratories would provide them with the resources they need. Academic collaborations improve the data quality of public health laboratories increasing the reach, core competencies and scientific basis of public health laboratories (Erwin et al., 2019). In Hawai'i, the State Laboratories Division recognized its staff shortfalls and piloted a successful internship with local universities to support Clinical Laboratory Improvement Amendments activities (Whelen & Kitagawa, 2013). The program provided valuable insights for future iterations including offering credit through the universities and increasing the intensiveness of the internship to expand the laboratory activities students can participate in.

MS-DOH-21-1816-A-001228

Technology

Access to broadband by public health organizations is not widespread and lack of connectivity limits the scope and quality of services delivered by health departments across the country. An estimated 24 million people in the US live in "digital deserts." Areas of the country that do not have access to broadband. This includes approximately 19 million rural Americans and 1.4 million American Indian/Alaska Natives (Baurely, McCord, Hulkower, & Pepin, 2019). Health departments need consistent access to broadband to conduct their surveillance work and to provide timely and consistent services to communities. Lack of connection or low quality connection limits health departments to interact with healthcare, laboratories, registries, and hinders their ability to provide telehealth services.

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Health misinformation on social media platforms spreads quickly and severely impacts the effectiveness of public health messaging and health behaviors.

The Internet and social media have become a growing resource for health information with 72% of US adults using the Internet to search for health information (Swire-Thompson & Lazer, 2020). The Internet allows public health officials to share information quickly and for individuals to access information at their own leisure. However, false and misleading health information has been reported to spread more quickly than scientific knowledge, negatively affecting decision-making and health behaviors in the general public (Suarez-Lledo & Alvarez-Galvez, 2021). Health misinformation leads to the adoption of inaccurate health beliefs. This can be seen with the misconception that the measles, mumps, rubella (MMR) vaccine causes autism. This misconception has created a negative societal impact, creating distrust in public health and vaccines (Swire-Thompson & Lazer, 2020). In addition, public health officials are not receiving adequate training on health literacy and how to properly communicate with and educate the general public. Without proper health literacy and effective response by public health officials, the general public is at increased risk of believing and acting on false information.

> *False and misleading health information has been reported to spread more quickly than scientific knowledge, negatively affecting decision-making and health behaviors in the general public.*

Telemedicine improves access to care for disadvantaged populations and is a flexible option for healthcare.

Telemedicine has seen a 50% increase in use due to the COVID-19 pandemic. Telemedicine connects patients with healthcare information and communication at a low cost in the comfort of their home. It has been shown to help patients better manage chronic conditions, increase the accuracy of patient records, and enhance access to services. By reducing the amount of travel for patients and providers telemedicine encourages the use of health services by vulnerable populations who may live in a healthcare desert. It also reduces the barriers for psychiatry and increases access to services for clients who may not have been able to access before (Alvandi, 2017).

+50%

Telemedicine has seen a 50% increase in use due to the COVID-19 pandemic.

Promatores(as) de salud are an underutilized source of accurate health information for members of Spanish-speaking communities who have the tools to combat misinformation.

Promatores de salud are trusted community health workers who reside in Hispanic/Latino communities and provide health resources to community members. Their peer-to-peer approach gives them the unique advantage of addressing misinformation in a timely and personal way. *Promatores de salud* have been on the forefront of combatting misinformation on COVID-19 after noticing that the Internet and social media have been key sources for information for Hispanic/Latino communities. *Promatores* programs are demonstrating to be successful because they are able to facilitate open discussions with community members where they are not afraid to ask questions (Zamuido, 2021). Also, the discussions are not hindered by language or cultural barriers and promatoras are able to disseminate important health information in print format to residents that lack internet access (Logan & Castañeda, 2020). Expanding the *promatore* model to other vulnerable populations can serve as an effective way to combat misinformation by working with established workers who are trusted by their communities.

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Health Equity

For public health to deliver its promise to protect and improve the health of people and their communities, equity must be infused into all aspects of public health planning and delivery of services. The ultimate goal of public health is to protect and improve the health of people and their communities by promoting healthy lifestyles, researching disease and injury prevention, and detecting, preventing and responding to infectious diseases. Achieving these goals is not possible without applying an equity lens to the work. Health equity is defined as the state in which everyone has the opportunity to achieve their full health potential. Black/African Americans, American Indians/Alaska Natives, Hispanic/Latino, and Asian/Pacific Islanders face disparities in life expectancy, infant mortality rates, and chronic diseases. Health inequity in the United States results in wasteful healthcare spending, a less productive workforce, and reduces the nation's overall health status (Weinstein et al., 2017).

Public health has a responsibility to help address these disparities by creating a framework for equity. Addressing public health issues such as violence prevention, the HIV and opioid epidemics, and ending the burden of preventable chronic diseases requires public health to take a societal and collaborative approach and to understand the impact of inequity (Weinstein et al., 2017). Consistent with this approach, the American Public Health Association depicts ten essential public health services to address inequities such as racism, oppression, and poverty (Weinstein et al., 2017) and more recently centered equity as part of their overall framework.

Lack of access to the Internet limits minority groups' ability to receive quality care as well as other social services which now makes it a meta social determinant of health. Lack of access to broadband primarily affects minority populations due to financial and geographical barriers. There is a wide disparity in pricing between metropolitan and rural areas, which results in a lower adoption rate of broadband by rural communities. Additionally, rural broadband development is more challenging because of higher investment needs and certain areas are skipped over by broadband network owners through a process called "digital redlining" (Tomer et al., 2020). With minority populations having limited access to broadband, they are at a disadvantage in receiving social services that impact every social determinant of health such as economic stability, social support, and access to healthcare (Tomer et al., 2020).

HIGHLIGHT

Further expanding the implementation of mobile health units has the potential to increase access to health services for disadvantaged populations and reduce health disparities.

Mobile health clinics offer a variety of services ranging from primary care, prevention screenings, and dental services. Underserved populations face barriers to healthcare access such as transportation, financial costs, discomfort with healthcare providers, and cultural barriers. Mobile health clinics address these barriers by providing care at a client's doorstep in their community. Mobile units are able to foster trusting relationships since they provide services in environments clients feel most comfortable in (Yu, Hill, Ricks, Bennet, & Oriol, 2017). Mobile health units have been shown to increase screening rates, assist with chronic disease management, and increase self-efficacy in managing health conditions (Yu, Hill, Ricks, Bennet, & Oriol, 2017). These positive outcomes illustrate the need to further invest in mobile health units to improve healthcare outcomes for vulnerable populations.

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The public health workforce lacks diversity and is ill equipped to address the future needs of a racially and ethnically evolving nation. A diverse public health workforce is needed to adequately handle the needs of a demographically changing nation. Currently, the public health workforce is not reflective of the general population. An estimated 63% of the public health workforce is white and 28% are male (Bogaert et al., 2019). Nonwhite students accounted for 47% of public health degrees awarded. From 1992 to 2016, the percentage of Asian/Pacific Islander students awarded degrees increased from 6% to 14%, Black/African American students from 6% to 11%, and Hispanic/Latino students from 8% to 10%. The workforce is made up primarily of women with 70-73% of women receiving public health graduate degrees (Bogaert et al., 2019). The underrepresentation of certain groups in public health may be due to the financial costs of higher education. In public health, there is a scarcity of available scholarships in comparison to other fields (Leider et al., 2015). Additionally, costs associated with degree programs in the United States, particularly for graduate school, are generally high and can pose a barrier for students and disproportionately affect racial and ethnic minorities (Mays et al., 2008).

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Minority populations are underrepresented in research studies which limits the generalizability of research to the general population. While Black/African Americans and Hispanic/Latino make 12.4% and 15.8% of the US population, only a small percentage participate in clinical trials sponsored by the National Institutes of Health (NIH). One report has estimated that Hispanics make up 7.6% of all research participants in NIH studies. Increasing the participation of all minorities in clinical trials is critical for the production of knowledge about new therapies because having diverse research participants can improve the generalizability of medicine. Additionally, minority participation in clinical trials is an important topic in public health discussions because this representation touches on issues of equality and the elimination of disparities, which are core values of the field.

Also, there are no databases aggregating demographic data from all clinical trials—neither those sponsored by NIH nor those sponsored by the pharmaceutical industry. Examining the entire spectrum of clinical research is important because the goals of clinical trials—as well as the benefits and risks—differ according to a novel therapy's stage of development (Fisher & Kalbaugh, 2011). The low rates of participation can be a result of distrust, provider bias, and low-quality translated research materials. Minorities report high levels of distrust in research trials due to a history of exploitation. Black/African Americans are more likely to believe that physicians would not fully explain details of research participation, fear that physicians would allow them to participate in a study even if serious harm was involved, and generally mistrust physicians/researchers (Fisher & Kalbaugh, 2011). On the part of physicians, research has shown that providers are likely to be affected by biases towards minority populations which can affect the treatment minority populations receive in clinical trials (Fisher &

Minorities report high levels of distrust in research trials due to a history of exploitation.

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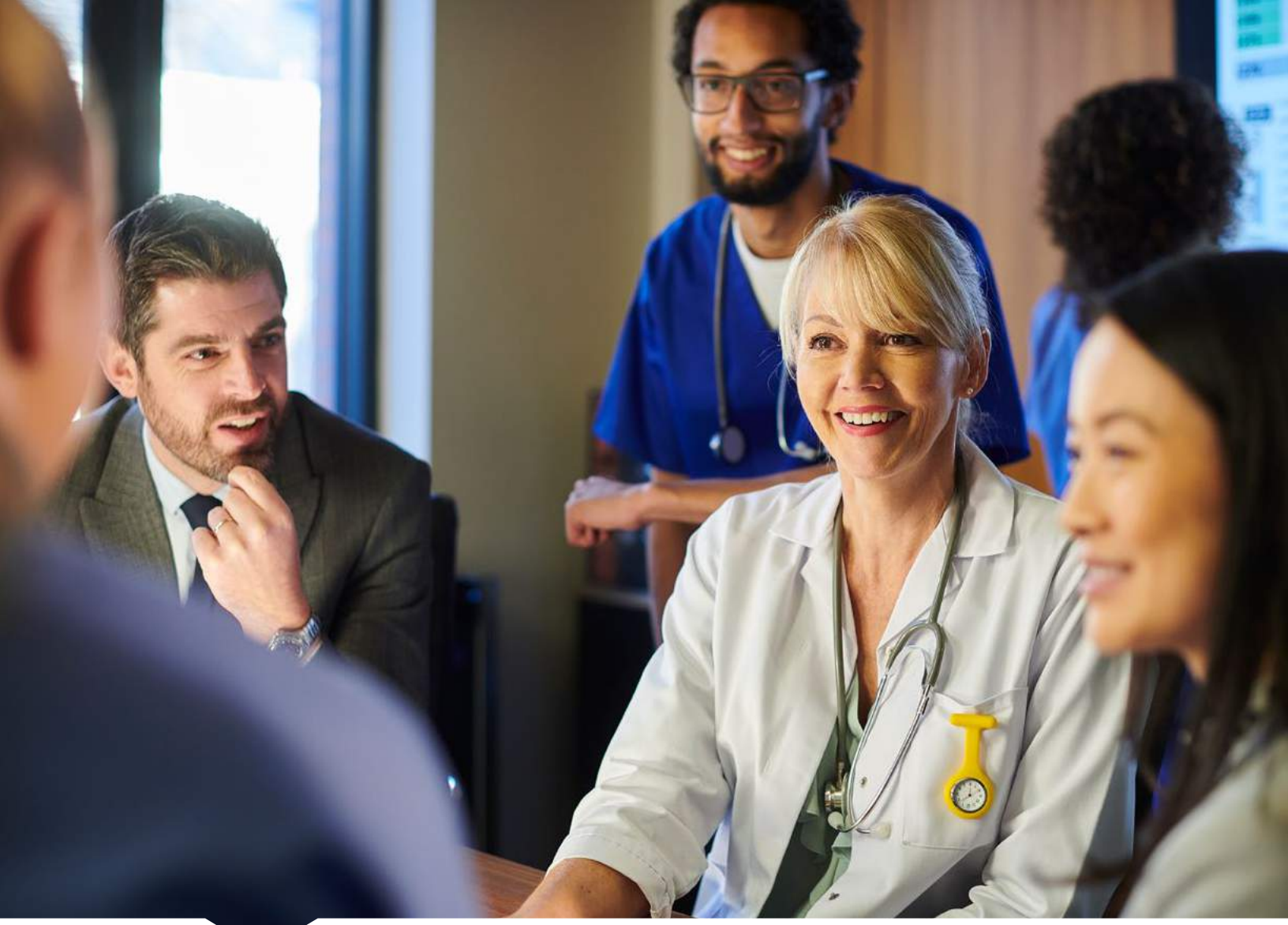
Kalbaugh, 2011). Lastly, the translations of research materials such as informed consent forms often have errors. Translations do not take into account regional colloquialisms in languages such as Hindi, Chinese, and Spanish (Brelsford et al., 2018). Translations incorporate complex and long-winded language and the omission of phrases such as please and other clarifying language. There have also been a number of translation cases where words were imprecisely translated which resulted in altered meaning of words (Brelsford et al., 2018).

In response to the underrepresentation of minority populations, the US Department of Health and Human Service's Office of Minority Health (OMH) released fourteen national standards for culturally and linguistically appropriate services (CLAS) in 2000. These standards were issued to clinicians, organization, accreditation bodies, and state agencies. The standards encouraged services to be compatible with patient cultural beliefs and languages, a diverse workforce, and ongoing self-assessments for cultural competency. In 2016, OMH found that 32 states undertook CLAS activities and incorporated CLAS standards into their strategic planning. And only 9 states adopted CLAS-specific policies, and procedures. Despite the establishment of these standards in 2000, there has not been widespread adoption of these policies (Aggarwal et al., 2017). Implementing CLAS standards into minority recruitment practices will improve the chances that minority populations participate in clinical trials.

Cultural competency training programs for public health workers should be co-produced with community members to improve its effectiveness. In order for public health workers to effectively serve diverse populations they must be trained in cultural competency. Cultural competence training often includes understanding the role of culture in our lives and how it shapes behavior, acceptance of cultural difference, learning to utilize culturally specific practices, and the continuous development and reflection of one's personal prejudices and biases (Jongen et al., 2018). Cultural competency should not just be a onetime training, cultural competency must be fostered and reflected on during the course of a person's life. Constant reflection of cultural competency skills will build a strong workforce with a commitment to eliminating health disparities. Additionally, cultural competency should not just focus on education and knowledge, trainings should prioritize practical skills, application of skills, and assessment of skills. To make cultural competency trainings even more effective, incorporating priority populations will ensure that public health workers are able to understand the communities they work with on a deeper level.

The Health Disparities Field Experience (HDFE) is a partnership between New Mexico State University and the Fred Hutchinson Cancer Research Center to help students understand the unique disparities that exist in the US-Mexico Border area and in Native American tribal lands. Students in the program met with community members, health care providers, and visited rural health clinics and hospitals (Moralez et al., 2020). Direct engagement with the community provides deeper knowledge of cultural competency as public health workers will have greater insight on the disparities and lack of resources priority populations face.



Increasing diversity of the workforce through training programs will enable public health to better meet the needs of the nation. There are many federal agencies that have partnered with universities to offer training programs to recruit underrepresented students and to provide them with skills to enter the workforce. These training programs provide students with leadership training, professional development, and public health research and work experience. At the end of programs, students deliver oral presentations of their work and prepare final papers with the opportunity to submit papers to journals. Students additionally gain the opportunity to network and find mentors who will guide them to public health careers suitable for them and assistance with preparing for graduate programs (Horney et al., 2014). Programs have been established in Historically Black Colleges and Universities (HBCUs) to increase the presence and retention of underrepresented racial/ethnic groups in nursing and to assist students in achieving nursing certification pass rates. Programs include mentoring and academic support and help with career planning and professional development (Mayo, 2019). Training programs are an effort to recruit racial/ethnic minorities and to provide them with opportunities they would not have had before.

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Expanding the promatores(as) de salud model can help better reach medically underserved minority populations and reduce health disparities. *Promatores(as) de salud* communicate health information in a linguistic and culturally relevant way which increases the adoption and effectiveness of health interventions (Sosa et al., 2013). *Promatores* have been shown to effectively reach minority populations which resulted in increased immunization rates and cancer screening rates (Cupertino et al., 2013).

The "Mujeres Interesadas en Cambios por la Salud" is a diabetes prevention program that has been culturally tailored for Mexican American women, led by *promatoras* and aimed at promoting physical activity and healthy eating to reduce the risk of type 2 diabetes in low income populations. The work of *promatoras* helped strengthen communication among participants in the program, increased trust, knowledge, and access to community resources to help with behavior change (Sosa et al., 2013). The *promatore* model can be scaled and implemented to support public health programs in minority communities across the country.

Health equity zones (HEZ) address social determinants of health on a community scale and can help reduce health disparities. Health equity zones are an initiative implemented by the Rhode Island Department of Health. HEZ's are community collaboratives that receive funding through a "braided" funding model (ChangeLab Solutions & Rhode Island Department of Health, 2021). The braided funding stream pools multiple funding streams from the federal, local, and state government, investor, and foundation funding. HEZ's establish programs that address social determinants of health such as community gardens to increase access to healthy food and creating a program to help kids walk safely to school (Newman, 2020). A HEZ is usually implemented in economically disadvantaged areas with documented health disparities (Patriarca & Ausura, 2016). These place-based initiatives target where people live and work, improving their overall circumstances which in turn reduces the effects of social determinants of health. Addressing these disparities requires a community based effort such as HEZ community members having a say in the immediate impacts that these programs have.

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III. CONCLUSION

The development of this environmental scan afforded us the opportunity to hear from many public health experts in the field who have well-formed historical and experiential perspectives of working within the confines of the public health infrastructure. Through their feedback and confirmed by the literature we learned that the chronic underfunding of public health is only the tip of the literal iceberg in terms of what has produced and is currently fueling the challenges. The role of public health has been undermined for years resulting in little investment and funding for public health to carry out its necessary duties. This has severely impacted public health workforce pipeline and health department's ability to modernize labs, informatics, and data systems to identify disease threats. To create a new future for public health, the laws that are needed to support public health departments need to be identified, strengthened and enforced.

The politicization of public health and public health mandates has weakened the public health infrastructure and minimized public health effectiveness.

The political polarization of the COVID-19 pandemic and mask mandates has undermined the authority of public health officials and experts and their ability to keep the country safe (International Federation of Red Cross and Red Crescent Societies & United Nations Children's Fund, 2020). Political polarization of public health has been driven by income inequality, marginalization, and misinformation driven by different forms of media (Gallup, 2019). Public health interventions and public health mandates have been met with controversies due to the limitations on personal autonomy and liberty (Brown, 2010). Public health measures give public health agencies the power to regulate actions and choices in order to protect the nation's health during public health emergencies. Public health officials and governors invoke police powers to order physical distancing measures, stay-at-homes orders, business and school closures, public gathering limits, and other measures to protect the nation's health (Hall et al., 2020). However, the legal authority of public health has been challenged and limited in the courts. Cases have alleged that stay-at-home orders violate freedom and individual rights. In Wisconsin Legislature v. Palm, the Wisconsin Supreme Court struck down the states' renewed stay-at-home order, ruling that the state secretary of health had imposed it improperly. Courts in Ohio and Oregon have followed suit (Hall et al., 2020). Trust and coordination between public health professionals and public authorities is necessary in order to protect the nation's health. Missing from the national dialogue on personal freedom and individual rights is the argument that individuals have a paramount right not lose their lives by being infected by others who put their own desires ahead of others. Infectious disease is not the same as chronic disease, and the entire frame of personal freedom needs to be reconstructed so that we do not repeat the unimaginable number of preventable deaths that are still occurring.

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In conclusion, we learned that the challenges go far beyond the material, brick and mortar neglect that public health has been subjected to for the last few decades.

The physical challenges extend deep into our collective psyche. Public health has been losing a credibility battle that has been fueled by lack of awareness of public health's charge and legal duty. What is needed beyond funding is for the U.S. public to envision a new public health system for the 21st century and beyond that addresses all the challenges and weaknesses that have been brought to public view by the Pandemic of 2019. Another conclusion is that to change the public health infrastructure requires changing the way that public health is taught, and at what critical time it is communicated to young citizens. There are a number of programs described in this document that focus on raising awareness of public health among young students and making opportunities for them to contribute to the solutions that will ultimately address all the challenges that are impacting the stability of our public health system. These programs (most of which were discontinued even after showing that they were effective) have the potential to be replicated and scaled. Another ray of hope is national legislation like the reintroduction of the Public Health Infrastructure Saves Lives Act by Patty Murray. This legislation would establish a core public health infrastructure program at the CDC. The program would award grants to state, local, and territorial departments to ensure health departments have the tools and workforce to target emerging health threats. State, tribal and territorial, and local health departments would receive sustained funding to support their work. Policies and programs like the Public Health Infrastructure Saves Lives Act would pave the way for a strengthened and sustainable public health infrastructure.

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APPENDIX A

Key Informants Interviewed

Gloria Addo-Ayensu, MD

Gloria Addo-Ayensu is the Director of Health at the Fairfax County Health Department in Virginia. In this capacity, she provides overall leadership and direction for public health programs in the county and serves as the official health advisor to Fairfax Board of Supervisors, Health Care Advisory Board and the Human Services Council. She has led a number of regional and state public health initiatives in the areas of health literacy, emergency preparedness, obesity prevention and health equity, as well as served on a number of national committees, including NACCHO's Public Health Preparedness Essential Services Committee and two Institute of Medicine committees on personal protective equipment for healthcare workers to prevent transmission of pandemic influenza or other viral respiratory infections. In 2016 Dr. Addo-Ayensu was a recipient of the A. Heath Onthank Memorial Award, the highest honor the county bestows upon its employees.

Georges Benjamin, MD

Georges Benjamin is the executive director of the American Public Health Association. He came to APHA from his position as secretary of the Maryland Department of Health and Mental Hygiene. Dr. Benjamin became secretary of health in Maryland in April 1999, following four years as its deputy secretary for public health services. As secretary, Dr. Benjamin oversaw the expansion and improvement of the state's Medicaid program. He is board-certified in internal medicine and a fellow of the American College of Physicians, a fellow of the National Academy of Public Administration, a fellow emeritus of the American College of Emergency Physicians and an honorary fellow of the Royal Society of Public Health. In April 2016, President Obama appointed Dr. Benjamin to the National Infrastructure Advisory Council, a council that advises the president on how best to assure the security of the nation's critical infrastructure.

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Michelle Carvalho, MPH, MCHES

Michelle Carvalho is the team Lead for the Education and Training Services Branch at the Centers for Disease Control and Prevention. Michelle has over 18 years of domestic and global community health experience. Ms. Carvalho spent 10 years as the Team Lead for the Cancer Prevention and Control Research Network (CPCRN) of the Emory Prevention Research Center. Her past work includes infectious disease research at the Centers for Disease Control and Prevention (CDC) and faith-based community work in Sao Paulo, Rio de Janeiro, and Recife, Brazil. Since 2004, she has worked on the dissemination of evidence-based approaches through national and state workgroups and local mini-grants programs to translate evidence into practice in Georgia.

Claude-Alix Jacob, MPH

Claude-Alix Jacob is the Chief Public Health Officer for the city of Cambridge, Massachusetts. He has over 20 years experience in public health and has led the operations of the Cambridge Public Health Department (CPHD) since 2007. Most recently, Mr. Jacob served as the Deputy Director of the Office of Health Promotion at the Illinois Department of Public Health. In this position, he oversaw health promotion activities related to chronic disease prevention, oral health education, children's health, and injury prevention. Previously, Mr. Jacob served as the Chief of the Bureau of Disease Prevention and Control at the Baltimore City Health Department and as the Director of Community Affairs at the Sinai Community Institute in Chicago. He has participated on a number of advisory boards including the Baltimore Schweitzer Fellows Program, the National Association of Health Services Executives (Chicago/Baltimore chapters), and Public Allies–Chicago (AmeriCorps). He is the current national chair of the Black Caucus of Health Workers of the American Public Health Association.

Montrece Ransom, JD, MPH

Montrece McNeill Ransom is the Director of the National Coordinating Center for Public Health Training. Ms. Ransom was appointed as a Presidential Management Fellow and worked at CDC for almost 20 years. For the last 10 years of her service, Ms. Ransom led CDC's public health law related training and workforce development efforts. Ms. Ransom is the ABA Health Law Section's 2019 Champion of Diversity and Inclusion Awardee, and the 2017 recipient of the American Public Health Association Jennifer Robbins Award for the Practice of Public Health Law. She is the President-Elect of the American Society for Law, Medicine, and Ethics and serves on the Advisory Committee for the Georgia Campaign for Adolescent Power and Potential.

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APPENDIX B

Technical Expert Panel (TEP) Members

Julia Adler-Milstein, PhD

Julia Adler-Milstein is an Associate Professor of Medicine and the inaugural Director of the Center for Clinical Informatics and Improvement Research (CLIIR) at the University of California – San Francisco. Her research focuses on health IT policy with an emphasis on electronic health records and interoperability. Dr. Adler-Milstein previously was on the faculty at the University of Michigan. She has testified before the US Senate Health, Education, Labor and Pensions Committee, is a member of the National Academy of Medicine, been named one of the top 10 influential women in health IT, and won numerous awards, including the New Investigator Award from the American Medical Informatics Association and the Alice S. Hersh New Investigator Award from AcademyHealth. She has served on an array of committees and boards, including the NHS National Advisory Group on Health Information Technology, the Health Care Advisory Board for Politico, and the Interoperability Committee of the National Quality Forum.

Kathleen Amos, MLIS

Kathleen Amos serves as the Director, Academic/Practice Linkages for the Public Health Foundation (PHF). Ms. Amos coordinates the Council on Linkages Between Academia and Public Health Practice and its initiatives, including the Academic Health Department Learning Community and the Core Competencies for Public Health Professionals; manages performance improvement and competency development and implementation activities; and helps to coordinate Maryland's Mid-Shore Rural Health Collaborative. Ms. Amos joined PHF in 2010 as a Learning Partnership Librarian through the Grace and Harold Sewell Memorial Fund. Prior to coming to PHF, she completed the National Library of Medicine Associate Fellowship Program, gaining specialized training in health sciences information services; engaging in research related to biomedical publishing; and supporting consumer health, health literacy, and public health informatics projects.

Scott Becker, MS

Scott Becker is the Chief Executive Officer of the Association of Public Health Laboratories (APHL), serving in that capacity since 1997. Currently he is leading development of new plans and a funding strategy for APHL's state-of-the-art AIMS platform, which provides data management and messaging services to public health and

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other data exchange partners, and also is pursuing national solutions to transfer electronic health data through extensive participation in the public-private forum Digital Bridge and the "Data: Elemental to Health" Campaign. Earlier in his career, Mr. Becker served as deputy executive director for the Association of Schools & Programs of Public Health (ASPPH). During a sabbatical from ASPPH, he directed a WHO project to integrate HIV/AIDS into health profession curricula. He chairs the Governance Working Group for the Global Laboratory Leadership Program (GLLP), a collaboration with the World Health Organization (WHO), the US CDC and others to develop a competency-based curriculum for laboratory leaders. Additionally, he is a member of the Affiliate Council of ASTHO which he formerly chaired.

Betty Bekemeier, PhD, MPH, MSN, RN, FAAN

Betty Bekemeier is the Director of the Northwest Center for Public Health Practice, where she , leads training activities, serves as content reviewer for the center's nursing trainings, and writes for the Northwest Public Health magazine, among other duties. She is the Kirby & Ellery Cramer Endowed Professor at the University of Washington School of Nursing and Adjunct Professor in the School of Public Health. She is Primary Investigator of the Public Health Activities and Services Tracking (PHAST) Study and conducts practice-based research in collaboration with state and local public health practice partners. Much of her research and leadership in advancing public health systems has been conducted through state Public Health Practice-based Research Networks (PBRN), working directly with public health leaders to provide the evidence needed to most effectively and equitably promote health in communities. Dr. Bekemeier is a Robert Wood Johnson Foundation Nurse Faculty Scholar and an active member and founding member of the Washington State Public Health Practice-Based Research Network and its Executive Committee. She is also a committee member on the Public Health Accreditation Board of Directors Research Advisory Council.

Samantha Cinnick, MPH, CPH, CHES

Samantha Cinnick is a Program Officer at the de Beaumont Foundation, providing program coordination for workforce development initiatives to equip public health professionals with the knowledge, skills, and tools to make their communities healthier. Before joining the Foundation, she was the center coordinator of the Region 2 Public Health Training Center at the Columbia University Mailman School of Public Health. Ms. Cinnick gained experience in city and local governmental public health by interning for the New York City Department of Health and Mental Hygiene's Brooklyn Breastfeeding Empowerment Zone and designing a public health workforce development plan for the US Virgin Islands Department of Health.

Nafisa Cisse Egbuonye, PhD, MPH

Nafisa Cisse Egbuonye is the director of the Black Hawk County Health Department in Iowa. She is a certified infectious disease and surveillance control specialist, who has experience in infectious disease surveillance domestically and globally. Dr. Egbuonye serves on the boards of Allen College, Delta Dental of Iowa Foundation and Grow Cedar Valley, as well as Iowa Public Health Association's Public Health Advocacy Group. She received a National Research Service Award from the National Institutes of Health and a Diversity Fellowship from the Texas A & M University. She received a 20 under 40 award from the Cedar Valley Courier. Dr. Egbuonye is a member of the third cohort of The Kresge Foundation's Emerging Leaders in Public Health initiative.

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Sarah de Guia, JD

Sarah de Guia is the Chief Executive Officer at ChangeLab Solutions. Before joining ChangeLab Solutions, Sarah worked at the California Pan-Ethnic Health Network (CPEHN), first as director of government affairs and then as executive director. Sarah's accomplishments during her tenure at CPEHN include passage of more than a dozen legislative bills to further health equity; critical administrative policy wins to incorporate health equity into land use and planning regulations; and improving the quality of health care for immigrants, patients with limited English proficiency, and communities of color. Prior to working at CPEHN, Sarah was a health program director at Latino Issues Forum and a legislative analyst at the Mexican American Legal Defense and Educational Fund. Sarah sits on the advisory committee for the Office of Health Equity at the California Department of Public Health, the advisory council of the Healthiest Cities and Counties Challenge, the editorial committee of Public Health Watch, the principles alliance stewardship council of Raising the Bar: Health Care's Transforming Role, and the board of directors of the CARESTAR Foundation.

Julian Drix, MPH

Julian Drix the co-lead of the Health Equity Institute at the Rhode Island Department of Health. He previously served as its Asthma Program Manager, where he developed, implemented and evaluated comprehensive asthma interventions that connect public health with the health care system. Mr. Drix is an alumni of the Bloomberg American Health Initiative fellowship program, in which he analyzed complex social and environmental determinants and establish initiatives to advance health equity. He is a member of the Environment Section and Environmental Justice Subcommittee of APHA and was elected by the Section as an APHA Governing Councilor. He is a member of the 2019 class of the 40 Under 40 in Public Health list by the de Beaumont Foundation. Mr. Drix is a member of the second cohort of The Kresge Foundation's Emerging Leaders in Public Health initiative.

Venus Ginés, MA, P/CHWI

Venus Ginés is a 27-year breast cancer survivor who survived cancer for the second time in 2017 after 25 years of survivorship. Ms. Ginés retired as a faculty member at Baylor College of Medicine in Houston, Texas, having taught cultural competence and health literacy as well as conducted research on Latino medical mistrust. From her personal experience with cancer and her sister's untimely death from cervical cancer 9 months after diagnosis, Ms. Ginés founded Día de la Mujer Latina (DML), Inc., in 1997, as a national non-profit organization that celebrates its signature Health Fiestas in 40 states, Puerto Rico, and the Dominican Republic and provides the medically underserved Latina community with culturally and linguistically proficient health education and early detection screening for chronic diseases.

Dawn Hunter, JD, MPH, CPH

Dawn Hunter is the is the Deputy Director of the Southeastern Region Office of the Network for Public Health law. Ms. Hunter has worked in state public health at the New Mexico Department of Health, where she started as a Robert Wood Johnson Foundation Visiting Attorney in Public Health Law through the Network. She is also experienced in training and compliance, organizational policy management, and workforce development. Ms. Hunter started her career in child protective services in Hillsborough County, Florida. She later transitioned into research and development as a microbiologist at the University of South Florida, Center for Biological Defense, with a focus on rapid detection methods for food and waterborne pathogens. She also served as the Senior Director of Policy, Strategy and Legal Services for the Foundation for a Healthy St. Petersburg.

Peter Holtgrave, MPH, MA

Peter Holtgrave is the Senior Director of Public Health Infrastructure and Systems at the NACCHO, where he oversees the organization's Performance Improvement, Workforce Development, Public Health Transformation, and Health Equity and Social Justice portfolios. He previously served as NACCHO's Director of Accreditation and Quality Improvement. Mr. Holtgrave has served as the National Health Manager at the OASIS Institute, a national nonprofit focused on healthy and productive aging, and managed the evaluation of the Healthy Kids, Healthy Communities national initiative, funded by the Robert Wood Johnson Foundation. He held multiple positions at the Boston Public Health Commission, including the Co-Director of Health Education for the Division of Child and Adolescent Health, the Director of the Boston Area Health Education Center, and the Associate Director of the Youth to Health Careers program.

Erika Miller, JD

Erika Miller is the Senior Vice President and Counsel at the Coalition for Health Funding. Ms. Miller has expertise in the intricacies of physician reimbursement and provides guidance to clients as they navigate the evolving area of alternative payment models and health care quality initiatives. She advocates before the legislative and executive branches to innovate within the health workforce programs, like Title VII, and the Medicare graduate medical education program to ensure that there is a physician workforce available to meet the health needs of Americans. Prior to CHF, Ms. Miller also worked in the HHS Office on Women's Health, where she monitored grant awards., and the office of Congressman Steve Rothman of New Jersey, a member of the House Appropriations Committee, where she handled immigration issues.

Denise Octavia-Smith, MBA, CHW, PN

Denise Octavia-Smith is the founding Executive Director of the National Association of Community Health Workers. Prior to NACHW, she was the led the development of the Equal Coverage to Care Coalition at the UConn Health Disparities Institute, served as the Director of Career and Education Initiatives for Central Area Health Education Center, Inc. and was the Training Coordinator for Access Health CT where she developed the statewide training, certification, consumer engagement strategies and continuing education opportunities for 400 culturally and linguistically diverse Navigators, In-Person Assisters and Certified Application Counselors during Connecticut's first open enrollment. Mrs. Smith is a 2018 Robert Wood Johnson Culture of Health Leadership Fellow and a 2016 Universal Health Care Foundation "Leaders in Action" Fellow. Her advisory appointments include the American Board of Internal Medicine, the Connecticut Office of Health Strategy and the University of Pennsylvania Perelman School of Medicine Department of Medical Ethics and Health Policy.

Myra Parker, JD, PhD, MPH

Myra Parker is the Executive Director of Seven Directions, A Center for Indigenous Public Health. She is an assistant professor in the Center for the Studies of Health and Risk Behavior in the Department of Psychiatry and Behavioral Sciences, in the University of Washington School of Medicine. She also serves as Co-Director of the Indigenous Wellness Research Institute's Tribal Protocols and Ethics Division. She is an enrolled member of the Mandan and Hidatsa tribes and has worked on tribal public health program implementation, coordination, and research with tribal communities in Arizona, Idaho, and Washington. Prior to her work in research, she worked for five years in the policy arena within Arizona state government, in tribal governments, and with tribal working groups at the state and national level. Dr. Parker serves as Co-Investigator on an ETHICS project to culturally adapt a human subjects curriculum for tribal communities; a national epidemiology research study grounded in CBPR involving twenty-five tribal colleges and universities; and a NIAAA R01 research study investigating the effectiveness of a culturally-adapted version of the BASICS intervention and a policy intervention.

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Gianfranco Pezzino, MD, MPH

Gianfranco Pezzino is a Senior Fellow at the Kansas Health Institute where he directs the Center for Sharing Public Health Services, a multi-year dollar national initiative funded by the Robert Wood Johnson Foundation. The Center provides access to tools, techniques, expertise and resources that support better collaboration across boundaries by public health departments, allowing them to do more together than they could do alone. Dr. Franco previously served as the Shawnee County, Kansas, health officer. Prior to joining KHI, he most recently served as state epidemiologist and medical director for the bioterrorism program within the Kansas Department of Health and Environment. He is a Fellow of the American College of Preventive Medicine, is board-certified in preventive medicine and public health and is certified in evaluation practice.

Larry Polsky, MD, MPH, FACOG

Larry Polsky is the Health Officer and Director of the Calvert County Health Department in Maryland. Dr. Polsky directs the health department as an agent of the Maryland State Government. With over 30 years of practice, he is a fellow of the American Congress of Obstetricians and Gynecologists. He serves on the board of directors for Calvert Healthcare Solutions, which provides primary care to uninsured Calvert County adults, care coordination for residents being treated for diabetes and high blood pressure, and direct education and enrollment efforts for expanded Medicaid and Qualified Health Products in 3 Maryland counties. Dr. Polsky is a member of the first cohort of The Kresge Foundation's Emerging Leaders in Public Health initiative.

Julie Pryde, MPH, MSW

Julie Pryde is a public health administrator for the Champaign-Urbana Public Health District (CUPHD) in Illinois. She joined CUPHD in 1995 as a Program Consultant in the Division of Social Services and as the Project Director for the IL Region 6 HIV Prevention Implementation Group. In 2001 she became the Director of the Division of HIV/STD/TB Prevention and Management. In 2008, Ms. Pryde was appointed as the first female Public Health Administrator in CUPHD's 70+ year history. CUPHD was created in 1937. Ms. Pryde served as an Investigator for the Home Access' FDA Post-Marketing Surveillance Study. Ms. Pryde has won awards from the Illinois Department of Public Health, The University of Illinois School of Social Work, The Greater Community AIDS Project, IL Public Health Association, and the IL Association of Agencies and Community Organizations for Migrant Advocacy. She currently serves on the NACCHO's Zika Advisory Council, Illinois Immunization Advisory Committee, the University of Illinois, School of Social Work's Field Advisory Committee, and the UIUC Department of Human Development and Family Studies External Advisory Committee. Ms. Pryde is a member of the third cohort of The Kresge Foundation's Emerging Leaders in Public Health initiative.

Monica Valdes Lupi, JD, MPH

Monica Valdes Lupi is the Managing Director of Health for The Kresge Foundation. Ms. Valdes Lupi most recently served as senior fellow at the de Beaumont Foundation, where she advised and led its efforts to amplify and accelerate policy initiatives aimed at developing and advancing a health agenda on critical public health issues such as tobacco control, racial justice and health equity. Ms. Valdes Lupi was also a senior advisor to the CDC Foundation in its COVID-19 efforts. In this role, she guided activities aimed at quickly identifying and supporting critical gaps and needs among state and local health departments in their response and recovery activities. Previously, she served as the executive director of the Boston Public Health Commission, the deputy commissioner for the Massachusetts Department of Public Health and was the first chief program officer for Health Systems Transformation at ASTHO. Ms. Valdes Lupi led ASTHO's work on health equity, Medicaid and public health partnerships, government relations, state health policy, and public health informatics.

Katherine Wells, MPH

Katherine Wells is the Director of Public Health for the Department of Public Health for the City of Lubbock, Texas. Ms. Wells previously worked at the Department of Health Services for the State of Texas, serving as a communicable disease program manager, manager of the Texas HIV State Pharmacy Assistance Program, and a data analyst for the Texas AIDS Drug Assistance Program. She also worked at the National Institute of Health assisting on the Surgeon General's Report on oral health in America. Ms. Wells moved to Lubbock to look at rebuilding Lubbock's public health system, which had been significantly cut back in 2012. Ms. Wells is a member of the third cohort of The Kresge Foundation's Emerging Leaders in Public Health initiative.

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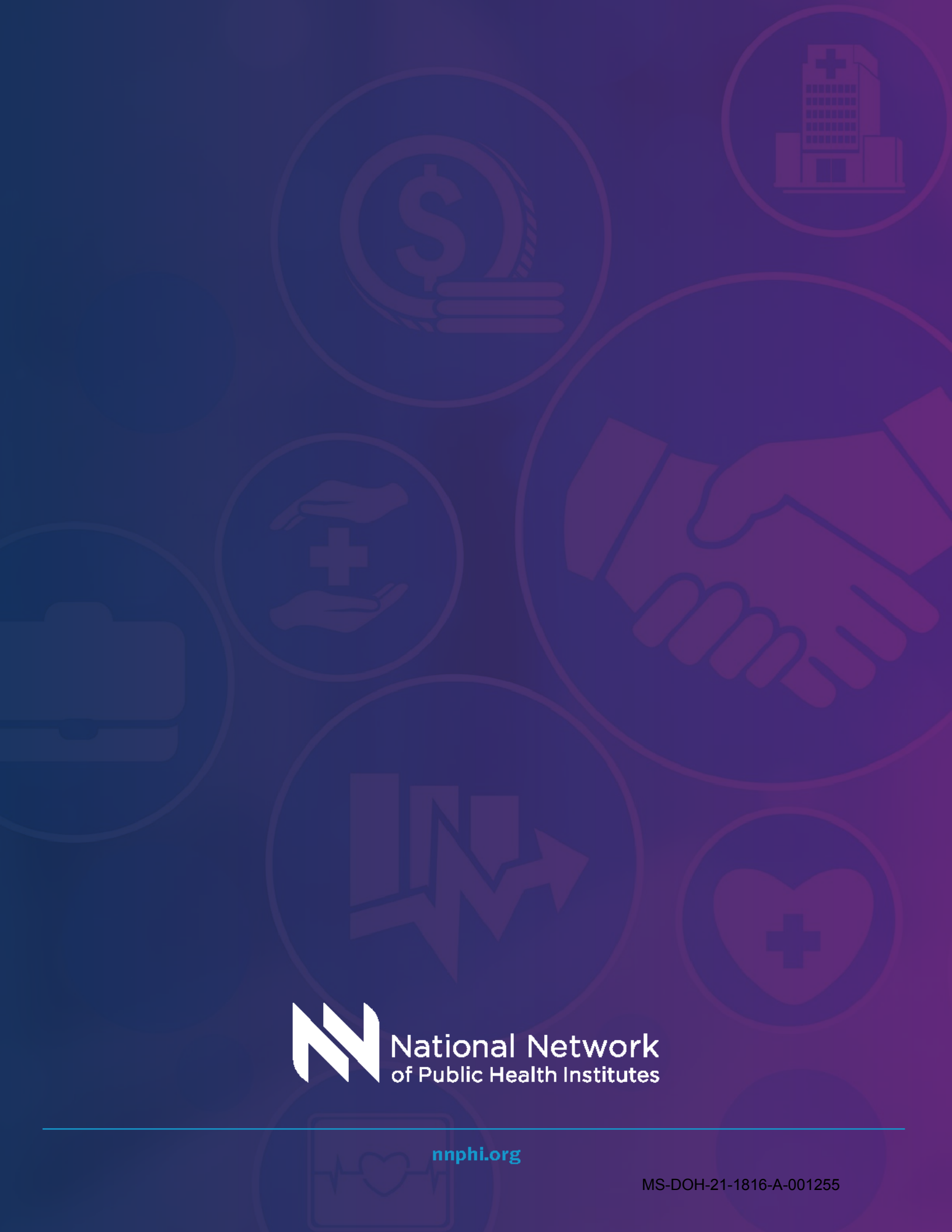

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From:	Kate Heyer
To:	Dobbs, Thomas E
Cc:	Grace Lee; Griffin, Jenny
Subject:	RE: Proposed IDPC agenda and white paper draft
Date:	Friday, November 12, 2021 3:18:22 PM
Attachments:	image001.png DRAFT - Public Health Authority Policy Statement.001.docx

Hi Dr. Dobbs,

Apologies for another e-mail so soon, but I wanted to check to see if you approve my sending the IDPC agenda and this white paper draft. I also received the ***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease*** policy statement draft, which is attached here.

Please let me know your thoughts and I will send the materials to the IDPC for Tuesday's call.

Kate

From: Kate Heyer
Sent: Thursday, November 11, 2021 3:34 PM
To: Dobbs, Thomas E <Thomas.Dobbs@msdh.ms.gov>
Cc: Grace Lee <glee@astho.org>; Griffin, Jenny <Jenny.Griffin@msdh.ms.gov>
Subject: Proposed IDPC agenda and white paper draft

Hi Dr. Dobbs,
Attached please see a proposed IDPC agenda for Tuesday and a draft of the **Preparing for the Next Pandemic/Public Health Crisis: Lessons from the Last Decade and Beyond** white paper. This is our first attempt at framing out a document to respond to the concerns you laid out in the e-mail to leadership in late September, so please do not hesitate to redirect us if we're off base. I've moved things around, so the references are out of order, but I'll wait to fix those until we get feedback on the scope of the document.
When you have a chance to review, please let me know what you think, and I'll share these materials as well as a the draft ***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease*** policy statement with the committee.

I'll also send a facilitator's agenda for you when the IDPC agenda is finalized.

Kate

Kate Heyer, MPH
Senior Director, Infectious Disease Infrastructure and Policy
Association of State and Territorial Health Officials
(571) 318-5490
National Headquarters: 2231 Crystal Drive, Suite 450, Arlington, VA 22202
Regional Office: 600 Peachtree Street NE, Suite 1000, Atlanta, GA 30308

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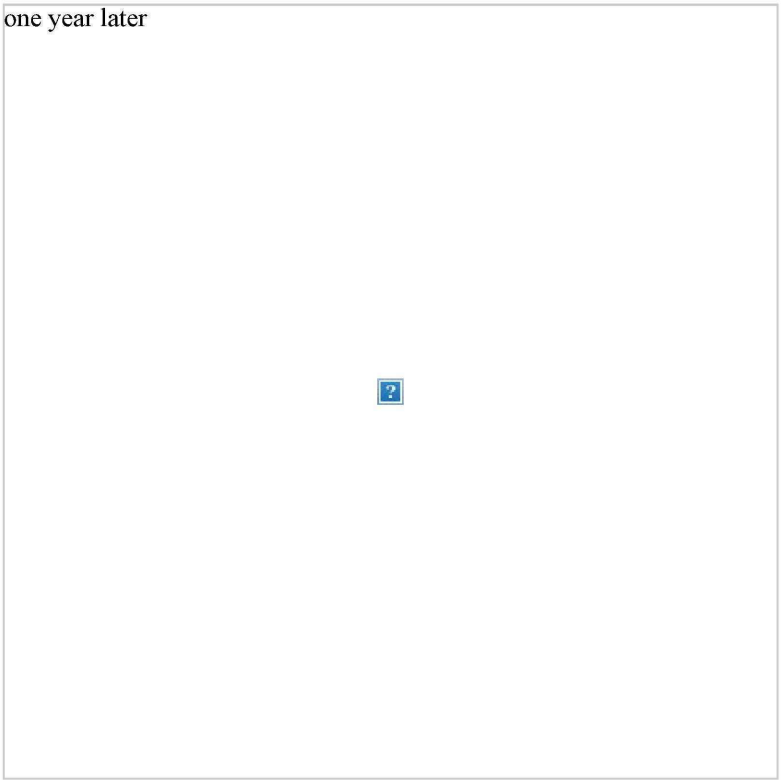
From: Health Law360
To: Young, Dorthy
Subject: 1 Year Later, How Coronavirus Has Changed The Legal Profession
Date: Friday, March 12, 2021 1:16:46 PM

Coronavirus Special Report

Friday, March 12, 2021

TOP NEWS



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Jury trials dropped off sharply during the pandemic, but in-person proceedings may rebound as virus cases wane and courts face pressure to address a litigation backlog, spurring concerns about how to bring people back to court safely.

A Tale Of Two Zoom Trials

The COVID-19 pandemic led most courts to postpone in-person trials or press ahead with safety precautions, but a minority are experimenting with conducting the whole trial experience via videoconference. Here, Law360 talks to two lawyers who tried their cases on Zoom about the format and what role it could play in the long run.

1 Year In, Policyholders See Hope In Virus Coverage Battles

Courts have sided with insurers in most COVID-19 business interruption coverage disputes since the pandemic brought the country to a standstill, but attorneys for policyholders have been encouraged by a growing number of rulings that coverage can be triggered by loss of use of property as well as visible damage.

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Honigman LLP
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Jeffer Mangels
Jenner & Block
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COVID 1 Year In: What Employment Attys Still Don't Know

A growing number of Americans are getting vaccinated every day, and employers are thinking about what returning to workplaces may look like. Here, Law360 discusses what employment lawyers know and don't know about what's to come in the COVID-19 pandemic's second year.

The Defining Pandemic Moments For Health And Life Sci Attys

The coronavirus pandemic's first year tested America's health care and life sciences systems in unprecedented ways and set the stage for profound and lasting changes. Here, attorneys share the moments and lessons that stand out — and what they'll be watching as the pandemic enters its second year.

What COVID Taught Real Estate Attys About Force Majeure

When COVID-19 began rapidly spreading across the U.S., real estate lawyers scrambled to help clients figure out whether force majeure clauses could excuse them from certain obligations, and a year later, much has been learned about their efficacy. Here, Law360 looks at three things lawyers have discovered.

Why A Surge Of COVID Securities Suits Hasn't Happened

The first year of the worldwide reckoning with COVID-19 saw the biotech and pharmaceutical industries get hit hardest by investor actions tied to the pandemic, though the chances of the virus spawning a broader wave of securities litigation seem to be slimming.

COVID Inflamed Damaging Year For Data Breach Victims

Data breach responders are coming up for air after an onslaught of security episodes over the past year, as hackers' evolving tactics collided with unprecedented challenges for organizations responding to the COVID-19 pandemic, cybersecurity lawyers tell Law360.

WHAT IT MEANS FOR YOUR PRACTICE

How COVID Has Reshaped M&A Agreements

Nearly one year into the COVID-19 pandemic, it's clear that even merger and acquisition agreements are not immune to the novel disease, as dealmakers are negotiating more specific material adverse effect clauses and leaning more often on the use of earnouts as part of deal consideration.

Compliance Officers Stretched Thin As Remote Work Goes On

One year into the declaration of COVID-19 as a national emergency, the shift to remote work is stretching compliance officers as they struggle to keep tabs on employees and face steep learning curves with new technological tools, experts tell Law360.

Virus Vaccine Tracking To Keep Focus On Data Privacy

A year after the onset of the COVID-19 pandemic in the U.S., companies are still grappling with questions about how to handle and retain sensitive health information, and emerging efforts to monitor who's been vaccinated will only exacerbate these issues.

1 Year Into Pandemic, These Real Estate Questions Remain

Questions about the future of office space and the viability of hotels are among the unknowns for the real estate sector, one year after COVID-19 began its rapid spread across the U.S. Here, Law360 looks at three lingering questions for commercial real estate a year into the pandemic.

Key Takeaways From The Biggest COVID Real Estate Cases

Major real estate cases brought on by COVID-19 have shown courts are amenable to considering "material adverse change" clauses as means to call off M&A deals, while a pair of tenant-friendly rent dispute rulings also have landlords on high alert. Here, Law360 looks at what's been learned from four key disputes.

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Morgan Lewis
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Munsch Hardt
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Paul Weiss
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Duquesne University
Early Warning Services LLC
Erie Insurance Inc.

For 'Essential' Cannabis Businesses, Pandemic Year A Boom

The pandemic marked a turning point for the cannabis industry, which was facing its first real downturn when state officials chose it as one of the businesses that could stay open amid the closure orders designed to curb COVID-19.

REGIONAL IMPACT

Texas Judges See Lasting Benefits From Pandemic Practices

Virtual hearings are largely what has allowed Texas courts to keep the administration of justice trudging along during a year of the global pandemic, and what started as the short-term necessity of remote proceedings will have lasting impacts on court operations.

How COVID Strengthened Texas As A Bankruptcy Hub

The Southern District of Texas saw a surge in commercial bankruptcy filings during 2020, drawing a caseload second only to Delaware's during the coronavirus pandemic, which attorneys attribute to the accessibility, ingenuity and predictability of a pair of Houston judges who have spent years giving the district a high profile.

5 Pennsylvania Cases That Shaped A Year Of COVID

Pennsylvania's 2020 docket related to the COVID-19 pandemic was a series of flashpoints that reflected the tensions throughout the nation as the courts dealt with emergency shutdown orders, mask mandates and the limits of state power to enforce them.

Ill. Courts Stare Down Backlog As Jury Trials Start To Resume

Navigating COVID-19 has left Illinois courts staring down a massive jury trial backlog of both civil and criminal cases, and when trials resume in the coming weeks, state and federal courts will have a tremendous amount of work to do to clear their dockets.

How Florida's Courts Have Been Forever Changed By COVID

The technological revolution in Florida's legal industry brought on by the COVID-19 pandemic has improved efficiency and saved clients money, but the necessary shift to online interactions has made mentoring young attorneys a challenge, and delays in jury trials are expected to clog up courts in the coming years.

Ga. Probate Judges Want Relief After Year Of COVID Havoc

Georgia probate court judges and clerks, hardest hit by the coronavirus pandemic of any group in the state's legal community, feel mounting frustration over the lack of protections they've gotten from the state in the last year.

'Sorry For The Disruption': A Year Of Remote Court In The UK

It was a lawyer's star turn in a London courtroom lost to a poor internet connection. Such is the world of remote hearings, forced out of courtrooms a year ago amid the pandemic. And while the experience has improved, lawyers say hitches remain.

Lawyers Predict UK's Virtual Hearings May Outlast Pandemic

When March rolled around last year, no one using the English civil courts would have guessed the judiciary was on the verge of going digital. But many practitioners now predict some of the drastic technological changes will be here to stay.

ONGOING CLOSINGS

Coronavirus: The Latest Court Closures And Restrictions

UPDATED March 11, 2021, 4:14 PM EST | As courts across the country take

Financial Industry Regulatory Authority Inc.
Friendly Ice Cream Corp.
GameStop Corp.
Giant Eagle Inc.
HIMSS
Hannaford Brothers Co.
Inovio Pharmaceuticals, Inc.
InterDigital Inc.
International Business Machines Corp.
J.C. Penney Co. Inc.
LVMH Group
LeafLink Inc.
Leafly Holdings Inc.
Lenovo Group Ltd.
LexisNexis Group
Marijuana Policy Project
Massachusetts Mutual Life Insurance Co.
Microsoft Corp.
Mirae Asset Financial Group
Moderna Inc.
NPC International Inc.
National Employment Law Project
Neiman Marcus Group
Panasonic Corp.
Pizza Hut Inc.
RELX PLC
Reddit Inc.
SRS Acquiom Inc.
Simon Property Group Inc.
Skype Technologies SA
Smarsh Inc.
Sorrento Therapeutics Inc.
Taubman Centers, Inc.
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Council of Inspectors General on Integrity and Efficiency

measures to prevent the spread of the coronavirus, some are restricting access and altering their procedures. Click state or court to jump to section.

EXPERT ANALYSIS

1 Year Into Pandemic, It's Time To Rethink Law Firm Billing

The particular tasks for which a law firm client can expect to be billed have become unpredictable in the era of COVID-19, making flat fees and other alternative fee arrangements more attractive for both in-house and outside counsel, says Jessica Hodkinson at Panasonic.

What Companies Should Know About SIGPR Oversight

Brian Miller, the special inspector general for pandemic recovery, discusses what companies and attorneys can do to avoid CARES Act fraud, how his team approaches protecting taxpayer money, and some of the challenges and successes SIGPR faced building an agency from the ground up amid a pandemic.

Delaware Court of Chancery
Equal Employment Opportunity Commission
European Union
Executive Office of the President
Federal Bureau of Investigation
Federal Reserve System
Financial Crimes Enforcement Network
Florida Supreme Court
Food and Drug Administration
Georgia Supreme Court
Government Accountability Office
National Institutes of Health
National Labor Relations Board
Occupational Safety and Health Administration
Pennsylvania Supreme Court
Texas Supreme Court
U.S. Bankruptcy Court for the Northern District of Illinois
U.S. Court of Appeals for the Federal Circuit
U.S. Court of Appeals for the Ninth Circuit
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U.S. Department of Health and Human Services
U.S. Department of Justice
U.S. Department of Labor
U.S. Department of Veterans Affairs
U.S. Department of the Treasury
U.S. District Court for the Southern District of New York
U.S. Environmental Protection Agency
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From: Health Law360
To: Dobbs, Thomas E
Subject: 1 Year Later, How Coronavirus Has Changed The Legal Profession
Date: Friday, March 12, 2021 1:57:02 PM

Coronavirus Special Report

Friday, March 12, 2021

TOP NEWS

one year later

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COVID 1 Year In: What Employment Attys Still Don't Know

A growing number of Americans are getting vaccinated every day, and employers are thinking about what returning to workplaces may look like. Here, Law360 discusses what employment lawyers know and don't know about what's to come in the COVID-19 pandemic's second year.

The Defining Pandemic Moments For Health And Life Sci Attys

The coronavirus pandemic's first year tested America's health care and life sciences systems in unprecedented ways and set the stage for profound and lasting changes. Here, attorneys share the moments and lessons that stand out — and what they'll be watching as the pandemic enters its second year.

What COVID Taught Real Estate Attys About Force Majeure

When COVID-19 began rapidly spreading across the U.S., real estate lawyers scrambled to help clients figure out whether force majeure clauses could excuse them from certain obligations, and a year later, much has been learned about their efficacy. Here, Law360 looks at three things lawyers have discovered.

Why A Surge Of COVID Securities Suits Hasn't Happened

The first year of the worldwide reckoning with COVID-19 saw the biotech and pharmaceutical industries get hit hardest by investor actions tied to the pandemic, though the chances of the virus spawning a broader wave of securities litigation seem to be slimming.

COVID Inflamed Damaging Year For Data Breach Victims

Data breach responders are coming up for air after an onslaught of security episodes over the past year, as hackers' evolving tactics collided with unprecedented challenges for organizations responding to the COVID-19 pandemic, cybersecurity lawyers tell Law360.

WHAT IT MEANS FOR YOUR PRACTICE

How COVID Has Reshaped M&A Agreements

Nearly one year into the COVID-19 pandemic, it's clear that even merger and acquisition agreements are not immune to the novel disease, as dealmakers are negotiating more specific material adverse effect clauses and leaning more often on the use of earnouts as part of deal consideration.

Compliance Officers Stretched Thin As Remote Work Goes On

One year into the declaration of COVID-19 as a national emergency, the shift to remote work is stretching compliance officers as they struggle to keep tabs on employees and face steep learning curves with new technological tools, experts tell Law360.

Virus Vaccine Tracking To Keep Focus On Data Privacy

A year after the onset of the COVID-19 pandemic in the U.S., companies are still grappling with questions about how to handle and retain sensitive health information, and emerging efforts to monitor who's been vaccinated will only exacerbate these issues.

1 Year Into Pandemic, These Real Estate Questions Remain

Questions about the future of office space and the viability of hotels are among the unknowns for the real estate sector, one year after COVID-19 began its rapid spread across the U.S. Here, Law360 looks at three lingering questions for commercial real estate a year into the pandemic.

Key Takeaways From The Biggest COVID Real Estate Cases

Major real estate cases brought on by COVID-19 have shown courts are amenable to considering "material adverse change" clauses as means to call off M&A deals, while a pair of tenant-friendly rent dispute rulings also have landlords on high alert. Here, Law360 looks at what's been learned from four key disputes.

Locke Lord
Lowenstein Sandler
Manatt Phelps
Mark Migdal & Hayden
McCarter & English
Michael Best
Miller Canfield
Modus Law
Morgan Lewis
Morrison & Foerster
Munsch Hardt
O'Melveny & Myers
Ogletree Deakins
Ongaro PC
Paul Weiss
Perkins Coie
Quadrant Chambers
Quattlebaum Grooms
Quinn Emanuel
Reed Smith
Richards Layton
Robinson & Cole
Ropes & Gray
Schmidt Kramer
Seyfarth Shaw
Shernoff Bidart
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Cornerstone Research Inc.
Cresco Labs Inc.
Duquesne University
Early Warning Services LLC
Erie Insurance Inc.

For 'Essential' Cannabis Businesses, Pandemic Year A Boom

The pandemic marked a turning point for the cannabis industry, which was facing its first real downturn when state officials chose it as one of the businesses that could stay open amid the closure orders designed to curb COVID-19.

REGIONAL IMPACT

Texas Judges See Lasting Benefits From Pandemic Practices

Virtual hearings are largely what has allowed Texas courts to keep the administration of justice trudging along during a year of the global pandemic, and what started as the short-term necessity of remote proceedings will have lasting impacts on court operations.

How COVID Strengthened Texas As A Bankruptcy Hub

The Southern District of Texas saw a surge in commercial bankruptcy filings during 2020, drawing a caseload second only to Delaware's during the coronavirus pandemic, which attorneys attribute to the accessibility, ingenuity and predictability of a pair of Houston judges who have spent years giving the district a high profile.

5 Pennsylvania Cases That Shaped A Year Of COVID

Pennsylvania's 2020 docket related to the COVID-19 pandemic was a series of flashpoints that reflected the tensions throughout the nation as the courts dealt with emergency shutdown orders, mask mandates and the limits of state power to enforce them.

Ill. Courts Stare Down Backlog As Jury Trials Start To Resume

Navigating COVID-19 has left Illinois courts staring down a massive jury trial backlog of both civil and criminal cases, and when trials resume in the coming weeks, state and federal courts will have a tremendous amount of work to do to clear their dockets.

How Florida's Courts Have Been Forever Changed By COVID

The technological revolution in Florida's legal industry brought on by the COVID-19 pandemic has improved efficiency and saved clients money, but the necessary shift to online interactions has made mentoring young attorneys a challenge, and delays in jury trials are expected to clog up courts in the coming years.

Ga. Probate Judges Want Relief After Year Of COVID Havoc

Georgia probate court judges and clerks, hardest hit by the coronavirus pandemic of any group in the state's legal community, feel mounting frustration over the lack of protections they've gotten from the state in the last year.

'Sorry For The Disruption': A Year Of Remote Court In The UK

It was a lawyer's star turn in a London courtroom lost to a poor internet connection. Such is the world of remote hearings, forced out of courtrooms a year ago amid the pandemic. And while the experience has improved, lawyers say hitches remain.

Lawyers Predict UK's Virtual Hearings May Outlast Pandemic

When March rolled around last year, no one using the English civil courts would have guessed the judiciary was on the verge of going digital. But many practitioners now predict some of the drastic technological changes will be here to stay.

ONGOING CLOSINGS

Coronavirus: The Latest Court Closures And Restrictions

UPDATED March 11, 2021, 4:14 PM EST | As courts across the country take

Financial Industry Regulatory Authority Inc.
Friendly Ice Cream Corp.
GameStop Corp.
Giant Eagle Inc.
HIMSS
Hannaford Brothers Co.
Inovio Pharmaceuticals, Inc.
InterDigital Inc.
International Business Machines Corp.
J.C. Penney Co. Inc.
LVMH Group
LeafLink Inc.
Leafly Holdings Inc.
Lenovo Group Ltd.
LexisNexis Group
Marijuana Policy Project
Massachusetts Mutual Life Insurance Co.
Microsoft Corp.
Mirae Asset Financial Group
Moderna Inc.
NPC International Inc.
National Employment Law Project
Neiman Marcus Group
Panasonic Corp.
Pizza Hut Inc.
RELX PLC
Reddit Inc.
SRS Acquiom Inc.
Simon Property Group Inc.
Skype Technologies SA
Smarsh Inc.
Sorrento Therapeutics Inc.
Taubman Centers, Inc.
The Atlanta Journal-Constitution
The Florida Bar
Twitter Inc.
Tyson Foods Inc.
Valve Corp.
Volkswagen AG
Zoom Video Communications Inc.
iAnthus Capital Holdings Inc.

GOVERNMENT AGENCIES

Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services
Competition Appeal Tribunal
Congressional Budget Office
Council of Inspectors General on Integrity and Efficiency

measures to prevent the spread of the coronavirus, some are restricting access and altering their procedures. Click state or court to jump to section.

EXPERT ANALYSIS

1 Year Into Pandemic, It's Time To Rethink Law Firm Billing

The particular tasks for which a law firm client can expect to be billed have become unpredictable in the era of COVID-19, making flat fees and other alternative fee arrangements more attractive for both in-house and outside counsel, says Jessica Hodkinson at Panasonic.

What Companies Should Know About SIGPR Oversight

Brian Miller, the special inspector general for pandemic recovery, discusses what companies and attorneys can do to avoid CARES Act fraud, how his team approaches protecting taxpayer money, and some of the challenges and successes SIGPR faced building an agency from the ground up amid a pandemic.

Delaware Court of Chancery
Equal Employment Opportunity Commission
European Union
Executive Office of the President
Federal Bureau of Investigation
Federal Reserve System
Financial Crimes Enforcement Network
Florida Supreme Court
Food and Drug Administration
Georgia Supreme Court
Government Accountability Office
National Institutes of Health
National Labor Relations Board
Occupational Safety and Health Administration
Pennsylvania Supreme Court
Texas Supreme Court
U.S. Bankruptcy Court for the Northern District of Illinois
U.S. Court of Appeals for the Federal Circuit
U.S. Court of Appeals for the Ninth Circuit
U.S. Department of Defense
U.S. Department of Health and Human Services
U.S. Department of Justice
U.S. Department of Labor
U.S. Department of Veterans Affairs
U.S. Department of the Treasury
U.S. District Court for the Southern District of New York
U.S. Environmental Protection Agency
U.S. General Services Administration
U.S. Patent and Trademark Office
U.S. Postal Service
U.S. Securities and Exchange Commission
U.S. Senate
U.S. Supreme Court
World Health Organization

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Cc:	Griffin, Jenny; Peggie Lawrence; Patricia Vinson; Meredith Allen; Marcus Plescia; Andy Baker-White; Ericka McGowan; Grace Lee
Subject:	Agenda and materials for 2/15 IDPC call
Date:	Thursday, February 10, 2022 6:56:23 PM
Attachments:	image001.png IDPC Agenda February 2022.docx Preparing for the Next Pandemic White Paper_narrative draft_2_8_22.docx DRAFT - Public Health Authority Policy Statement.003.docx

Hello, IDPC members,

Attached please see the agenda and materials for the ASTHO IDPC call scheduled for next Tuesday, February 15.

We look forward to speaking with you then.

Best, Kate

Kate Heyer, MPH
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(Pronouns: she/her/hers)

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From: CDC IMS 2019 NCIV Response STLT Partner Engagement
To: CDC All STLT COVID19 (Update Call); Simone, Patricia (Pattie) (CDC/DDPHSS/CSELS/DSEPD); Sina Josef, Carissa (CDC/DDID/NCEH-STP/DTE); Hayes, Nikki (CDC/DDNID/NCCDPHP/DCPC); Davis, Mark A. (CDC/DDPHSIS/CPS/DSLR); Barton Behravesh, Casey (CDC/DDID/NCEZID/OD); Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED); Patel, Manisha (Mo) (CDC/DDNID/NCIPC/OD); Marshall, Katherine F. (CDC/DDID/NCEZID/DFWED); Barnes, Jennifer M. (CDC/DDPHSIS/CPS/OD); Posey, Drew (CDC/DDID/NCEZID/DGMQ); Olson, Victoria (CDC/DDID/NCEZID/DHCPP); Bower, William (CDC/DDID/NCEZID/DHQP); Smith, Rachel M. (CDC/DDID/NCEZID/DHQP); Chen, Jessica (CDC/DDID/NCEZID/DFWED); Angay, Melissa (CDC/DDID/NCEZID/DEB); Ballardo-Romero, Nadia F. (CDC/DDID/NCEZID/DQD); Belay, Ermias (CDC/DDID/NCEZID/DHCPP); Sunkavalli, Arjun (CDC/DDID/NCEZID/DHQP); McQuiston, Jennifer H. (CDC/DDID/NCEZID/DHCPP); Bean, Amy (CDC/DDID/NCIRD/DSD); Tansey, Cassandra (CDC/DDID/NCEZID/DSE); Young, Andrea (CDC/DDPHSIS/CSTLTS/OD); Tiller, Rebekah (CDC/DDID/NCEZID/DHCPP); Smith, Jacinta L. (CDC/DDPHSIS/CPS/DSAT); Williams, Holly G. (CDC/DDNID/NCCDPHP/DDT); Harrington, Allison (CDC/DDPHSIS/CSELS/DSEPD); Phoenix West, Ursula (CDC/DDNID/NCBDDD/OD); Lee, Kinzie (CDC/DDNID/NCIPC/OD); Kumar, Molly Regina (CDC/DDPHSIS/CSELS/DSEPD); Peacock, Joanne L. (CDC/DDPHSIS/CPS/DSLR); Joshi, Niamba (CDC/DDPHSIS/CSHD/DPDM); Oliver, Angela (CDC/OD/OCS); McLeod, Timothy (CDC/DDID/NCEZID/DHQP); Kadzik, Melissa (CDC/DDID/NCEZID/OD); Lutterloh, Joseph (CDC/DDID/NCEZID/DHQP); Bandolin, Jean (CDC/DDPHSIS/CPS/DSLR); Robertson, Angela C. (CDC/DDNID/NCBDDD/DBDID); Judd, Michael (CDC/DDPHSIS/OD); Kirloch, Ryan D. (CDC/DDNID/NCCDPHP/DOH); Erstvoye, Julia (CDC/DDPHSIS/CSHD/DFD); Leach, Caitlin (CDC/DDID/NCEH-STP/OD); Painter, Elizabeth (CDC/DDID/NCEH-STP/DFBSG); Chatham-Stephens, Kevin (CDC/DDNID/NCBDDD/DHDD); Samuel, Lee (CDC/DDPHSIS/CSHD/DPDM); Esquenazi, Erica (CDC/DDID/NCHHSTP/OD); McCulloch, Audrey (CDC/DDPHSIS/CSHD/OD); Meyers, Anne (CDC/DDNID/NCH-HD/DEHSP); Labar, Kristin A. (CDC/DDNID/NCEH-HD/DEHSP); Patrick, Mary E. (CDC/DDNID/NCBDDD/DHDD); Coleman, Erik W. (CDC/DDNID/NCEH-HD/DEHSP); Franz, Marissa (CDC/DDID/NCIRD/DBD); McMillan, Amy (CDC/DDID/NCEZID/OD); Kohr, Jennifer M. (CDC/DD/OADPS); Casillas, Shannon (CDC/DDNID/NCIPC/DOP); Cloonan, Kate (CDC/DDNID/NCIPC/DOP); Peacock, Nwkosmia (ATSDR/OAO/OCHHA); Miller, Kirk (CDC/OCOO/OFRA/OA); Shanoure, Radhika (CDC/OD/NCIRD/OVD); Walter-Garcia, Madison (CDC/DDID/NCIRD/OD); Brink, Adam C. (CDC/DDID/NCIRD/ISD); Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Bhatt, Achal (CDC/DDID/NCIRD/ISD)
Cc: CDC IMS 2019 NCIV Response; IM-POIN Special Asstv; CDC IMS 2019 NCIV Response STLT Policy and Public Health Partnerships; CDC IMS AV/Communications; CDC IMS Response Coordinator -2
Subject: CDC All-State, Tribal, Local, and Territorial (STLT) Update Call
Attachments: 10.26.2021 CDC All STLT Update Call Agenda.pdf
09.27.2021 All STLT Update Call Summary.pdf

Call Purpose: CDC's 2019 Novel Coronavirus (COVID-19) response team will continue to host a national call series every Monday from 2:00 p.m. to 2:45 p.m. EST to provide state, tribal, local, and territorial (STLT) partners with the latest information on the COVID-19 outbreak and U.S. preparedness efforts.

Invited call participants include STLT preparedness directors, epidemiologists, health officials, public health laboratory directors, and nongovernmental partners.

CDC will continue to share the agendas and call notes weekly.

Participant Information: The CDC All-STLT Update Call will now be held as a Zoom webinar and requires a one-time registration. After registering, you will receive a unique participant link via email. Please note that your unique participant link will be the same for all calls in the series, through December 2021; you do not need to register for each individual call. Click here to register: <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcdc.zoomgov.com%2Fwebinar%2Fregister%2FWN_hJfZ-YpdTHdOfOKIILDU0w&data=04%7C01%7CThomas.Dobbs%40month.ms.gov%7Cb4e8b6990de4a4e17d208d986b9cb6eb%7C5590426dc8bf94d8869c0bbf4e750cb7%7C0%7C0%7C637688826981243992%7CUnknown%7CTWFpbGZsb3dfeyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=eVdtdYMt2%2BACICv+%2Bb95nfzFLXvYynklgwojr%2BLw0%3D&reserved=0> for the call series. The link can also be found here: https://cdc.zoomgov.com/webinar/register/WN_hJfZ-YpdTHdOfOKIILDU0w <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcdc.zoomgov.com%2Fwebinar%2Fregister%2FWN_hJfZ-YpdTHdOfOKIILDU0w&data=04%7C01%7CThomas.Dobbs%40month.ms.gov%7Cb4e8b6990de4a4e17d208d986b9cb6eb%7C5590426dc8bf94d8869c0bbf4e750cb7%7C0%7C0%7C637688826981243992%7CUnknown%7CTWFpbGZsb3dfeyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=eVdtdYMt2%2BACICv+%2Bb95nfzFLXvYynklgwojr%2BLw0%3D&reserved=0>.

Please do not share your participant link. After registering, the link you receive is unique to you and should not be shared. If you would like to invite a colleague to this call series, please request they email eocevent424@cdc.gov <mailto:eocevent424@cdc.gov>.

Add the link to your calendar as a reoccurring weekly event: To add this link to your calendar, select the "Add to Calendar" link within the email you receive. This will download the .ics file. Open the file and save the event to your calendar. Please ensure that you set this invitation to reoccur weekly.

All-STLT Update Call Dates 2021

The All-STLT Update Call will be on Mondays from 2 to 2:45 PM EST except for the dates below where the call will be held on a Tuesday.

* Tuesday, June 1 (Memorial Day May 31)
* Tuesday, July 6 (Independence Day July 5)
* Tuesday, September 7 (Labor Day September 6)
* Tuesday, October 12 (Columbus Day October 11)

From:	Dunajcik, Alicia (CDC/DDID/NCEZID/DPEI)
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Cc:	Green, Jamilla (CDC/DDID/NCEZID/DPEI); CDC IMS 2019 NCOV Response HDTF 4/6 Regional Support TM
Subject:	CDC COVID-19 Weekly Digest of Resources: 1/23 - 1/29
Date:	Monday, February 1, 2021 8:05:41 AM
Attachments:	2021-01-29-Science-Update_Public_Final_v2.pdf CDC COVID-19 Vaccine Technical Key Points 1.25.21.pdf COVID Vaccine Social Listening Report 1_27_21.pdf CDC Resources for Case Investigations and Contact Tracing_01082021.pdf

Hi Mississippi colleagues-

Here is your weekly digest of CDC resources.

CDC COVID-19 Science Update: See the latest science update, released on 1/29/2021, attached to this email. Previous science updates can be viewed at ***https://www.cdc.gov/library/covid19*.**

MMWR Articles: Below are links to recent COVID MMWR articles

- **January 29, 2021** Impact of COVID-19 on Cervical Cancer Screening Rates Among Women Aged 21–65 Years in a Large Integrated Health Care System — Southern California, January 1–September 30, 2019 and January 1–September 30, 2020
- **January 29, 2021** Trends in Outbreak-Associated Cases of COVID-19 — Wisconsin, March–November 2020
- **January 29, 2021** Response to a COVID-19 Outbreak on a University Campus — Indiana, August 2020
- **January 29, 2021** COVID-19 Cases and Transmission in 17 K–12 Schools — Wood County, Wisconsin, August 31–November 29, 2020
- **January 29, 2021** SARS-CoV-2 Transmission Associated with High School Wrestling Tournaments — Florida, December 2020–January 2021
- **January 29, 2021** Implementation and Evolution of Mitigation Measures, Testing, and Contact Tracing in the National Football League, August 9–November 21, 2020
- **January 29, 2021** Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021

*Older MMWR COVID-19 Reports can be viewed at
https://www.cdc.gov/mmwr/Novel_Coronavirus_Reports.html

CDC Website Updates: Please find updated CDC website pages for 1/23-1/29

Response Website Updates (1/23/21-1/29/21)

- Cases in the U.S. Friday, January 29, 2021
- COVID-19 Vaccination for Communities Friday, January 29, 2021
- COVID-19 Vaccine Communication Toolkit for Essential Workers: Getting Started Friday, January 29, 2021
- COVID-19 Vaccine Communication Toolkit for Community-Based Organizations: Getting Started Friday, January 29, 2021
- Requirement for Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States Friday, January 29, 2021
- US COVID-19 Cases Caused by Variants Friday, January 29, 2021
- Wear Face Masks on Public Transportation Conveyances and at Transportation Hubs Friday, January 29, 2021
- Federal Register Notice: Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19 Friday, January 29, 2021

- How CDC Determines the Level of a Country's COVID-19 Travel Health Notice Friday, January 29, 2021
- Crew Disembarkations through Commercial Travel Friday, January 29, 2021
- COVID-19 Forecasts: Deaths Friday, January 29, 2021
- Staffing Resources Friday, January 29, 2021
- COVIDView Weekly Summary Friday, January 29, 2021
- Coronavirus Disease 2019 (COVID-19) Friday, January 29, 2021
- COVID-19 Travel Recommendations by Country Friday, January 29, 2021
- Travel Friday, January 29, 2021
- Large Gatherings Thursday, January 28, 2021
- Non-Hospital Settings and COVID-19 Thursday, January 28, 2021
- Small Gatherings Thursday, January 28, 2021
- Toolkit for Pregnant People and New Parents Thursday, January 28, 2021
- Emerging SARS-CoV-2 Variants Thursday, January 28, 2021
- New Variant of Virus that Causes COVID-19 Detected Thursday, January 28, 2021
- Workplaces and Businesses Thursday, January 28, 2021
- Guidance for SARS-CoV-2 Point-of-Care Testing Thursday, January 28, 2021
- Ensuring the Safety of COVID-19 Vaccines in the United States Thursday, January 28, 2021
- Holiday Celebrations Thursday, January 28, 2021
- COVID-19 One-Stop Shop Toolkits Thursday, January 28, 2021
- Information for Healthcare Professionals about Coronavirus (COVID-19) Thursday, January 28, 2021
- Workplace Vaccination Program Wednesday, January 27, 2021
- Essential Workers & Employees: When & How to Get Vaccinated Wednesday, January 27, 2021
- Importance of COVID-19 Vaccination for Essential Workers Wednesday, January 27, 2021
- Frequently Asked Questions about v-safe Wednesday, January 27, 2021
- Wastewater Surveillance Data Reporting & Analytics Wednesday, January 27, 2021
- Previous COVID-19 Forecasts: Cases Wednesday, January 27, 2021
- COVID-19 Forecasts: Cases Wednesday, January 27, 2021
- Donate Blood Plasma and Help Save Lives Wednesday, January 27, 2021
- Previous COVID-19 Forecasts: Hospitalizations Wednesday, January 27, 2021
- COVID-19 Forecasts: Hospitalizations Wednesday, January 27, 2021
- CDC Seroprevalence Survey Types Wednesday, January 27, 2021
- Previous Forecasts of Total Deaths Wednesday, January 27, 2021
- Correctional and Detention Facilities Wednesday, January 27, 2021
- Household Checklist Wednesday, January 27, 2021
- Health Departments Wednesday, January 27, 2021
- Building Confidence in COVID-19 Vaccines Tuesday, January 26, 2021
- COVID-19 Vaccinations Tuesday, January 26, 2021
- K-12 Schools COVID-19 Mitigation Toolkit Tuesday, January 26, 2021
- Construction COVID-19 Checklists for Employers and Employees Tuesday, January 26, 2021
- Testing and International Air Travel Tuesday, January 26, 2021
- Training Case Investigators and Contact Tracers Tuesday, January 26, 2021
- What Construction Workers Need to Know about COVID-19 Tuesday, January 26, 2021
- Publications about COVID-19 for Laboratories Tuesday, January 26, 2021
- Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories Tuesday, January 26, 2021
- How to Report COVID-19 Laboratory Data Tuesday, January 26, 2021

- COVID-19 Contact Tracing Training Tuesday, January 26, 2021
- Related Materials Tuesday, January 26, 2021
- FAQs for Correctional and Detention Facilities Tuesday, January 26, 2021
- Travelers Prohibited from Entry to the United States Tuesday, January 26, 2021
- Information about the Moderna COVID-19 Vaccine Monday, January 25, 2021
- Information about the Pfizer-BioNTech COVID-19 Vaccine Monday, January 25, 2021
- Frequently Asked Questions about COVID-19 Vaccination Monday, January 25, 2021
- Training for Healthcare Professionals Monday, January 25, 2021
- K-12 Schools and Childcare Programs Monday, January 25, 2021
- Clinical Questions about COVID-19: Questions and Answers Monday, January 25, 2021

*Daily website updates are now viewable at https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html

Federal Emergency Management Agency (FEMA) Vaccination Distribution Updates

In a recent press release, FEMA has now obligated more than $1.2 billion to governmental partners with vaccination sites, as the agency continues its increased support in the ongoing battle against COVID-19.

That number is expected to grow in the days ahead.

Federal Funding to Accelerate State Vaccine Efforts: FEMA will provide reimbursement to state, local, tribal and territorial governments and the District of Columbia for use of their National Guard to respond to COVID-19 and other assistance, which may include support for vaccination distribution and administration, at a 100% cost share until Sept. 30, 2021.

The agency is expediting reimbursement for eligible emergency work projects to ensure resources are available to support vaccine distribution and administration. Funding covers emergency protective measures, such as:

- Supplies and commodities needed to safely store and administer the vaccine
- Transportation support and reasonable, necessary security for refrigerated trucks and support for leasing space to store and/or administer vaccines, including utilities, maintenance and security.
- Medical and support staff, including onsite infection control measures, personal protective equipment for staff, cloth face coverings for patients, temperature scanners, physical barriers and disinfection of the facility in accordance with CDC guidance.
- Dissemination of public information and communication regarding vaccinations.

The Coronavirus Response and Relief Supplemental Appropriations Act of 2021 appropriates $2 billion to FEMA to provide financial assistance to individuals and households for COVID-19-related funeral expenses at a 100% federal cost. The appropriation covers eligible funeral expenses incurred through Dec. 31, 2020. FEMA is reviewing the legislation and evaluating potential options for implementation.

Federal Coordination to Identify and Fill Resource Gaps: FEMA released "FEMA COVID-19 Vaccination Planning FAQ," a document to help assist governments with their vaccine distribution efforts and reimbursements for associated costs. The agency will work with the U.S. Department of Health and Human Services and other federal agencies to ensure a coordinated approach to using Defense Production Act authorities wherever necessary so private sector companies can increase vaccine supply and spur vaccine manufacturing.

FEMA Supporting and Establishing Vaccine Sites: FEMA will provide support to established vaccination locations, establish new community vaccination centers, and support National Guard operations to expand access to vaccines. To reach underserved and rural communities, FEMA, in collaboration with federal partners, will coordinate efforts to establish and support fixed facilities and establishing pop-up or temporary vaccination sites and mobile vaccination clinics.

Massachusetts Department of Public Health: Communications and Community Engagement for COVID-19 Vaccines

Check out this interesting and informative presentation that the Massachusetts DPH gave to the Vaccine Task Force last week, all about what has worked best when it comes to targeted community engagement strategies to promote COVID-19 vaccination. By utilizing a variety of tools such as Jamboard exercises and community focus groups, they identified themes around barriers to vaccination, vaccine hesitancy, how to increase adherence and improve community trust.

Upcoming Trainings/Meetings

- Below is a link to a series of accredited education about COVID-19 vaccine in general, safety, and administration considerations. Please distribute this information with your next regular communication with states.
    - Vaccine Courses, Broadcasts, Webcasts and Self Study Training | CDC
- Tiberius users can access the training video on submitting transfer requests at the following link: https://protect-ows.hhs.gov/workspace/compass/view/ri.compass.main.folder.c95b290c-2561-4cd1-85f7-e31dac51d34b [protect-ows.hhs.gov
-

Upcoming NACCHO Webinar: Tuesday, February 9 at 12 pm ET: COVID-19 Action in the Biden Era: A Fireside Chat with Dr. Fauci

Upcoming CDC Foundation Webinar: February 24 at 1:00-2:00 pm EST - Updates and Resources from CDC and Ad Council

COVID-19 Resources

- COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex
    - Considerations for Increasing COVID-19 Vaccination: Reaching and Increasing Uptake in Priority Populations
- COVID-19 Vaccine Technical Key Points (attached)
- FEMA Social Listening Report (attached)
    - Includes highlights from each HHS Region concerning COVID-19 vaccine rumors, supply chain, vulnerable populations and more.
- COVID-19 Vaccination Communication Toolkits for Community- Based Organizations and Essential Workers
    - COVID-19 vaccines will be available to essential workers and other community members soon. CDC has designed two toolkits to help build confidence in this new vaccine. The toolkits will help community-based organizations (CBOs) and employers to educate community members and workers about COVID-19 vaccines, raise awareness about the benefits of vaccination, and address common questions and concerns.
- CDC Resources for Case Investigation and Contact Tracing (attached)

Alicia Dunajcik, MPH
Health Department Liaison (Region 4: GA, MS, NC)
STLT Support Task Force/Health Department Section
COVID-19 Emergency Response
Centers for Disease Control and Prevention
Phone: 678-427-1486
Functional Inbox: eocevent438@cdc.gov
Personal Inbox: ota8@cdc.gov

From:	Green, Jamilla (CDC/DDID/NCEZID/DPEI)
To:	Byers, Paul; Craig, Jim; Jefferson, Randy (CDC/DDID/NCHHSTP/DSTDP); Ware, Daphne; Vaughn, Wayne
Cc:	CDC IMS 2019 NCOV Response HDTF 4/6 Regional Support TM
Subject:	CDC COVID-19 Weekly Digest of Resources: 1/30 - 2/5
Date:	Monday, February 8, 2021 5:02:45 PM
Attachments:	2021-02-05-Science-Update_Final_Public.pdf ELC_EnhancingDetectionExpansion_FAQs_2Feb2021.pdf Fact Sheet_12-things-jurisdictions-need-to-know-about-vaers_Feb2021.pdf

Good afternoon Mississippi Colleagues,

Here is your weekly digest of CDC resources.

CDC COVID-19 Science Update: See the latest science update, released on 2/5/2021, attached to this email. Previous science updates can be viewed at ***https://www.cdc.gov/library/covid19*.**

MMWR Articles: Below are links to recent COVID MMWR articles

- **February 5, 2021 (Early Release)** Observed Face Mask Use at Six Universities — United States, September–November 2020
- **February 5, 2021 (Early Release)** Decline in COVID-19 Hospitalization Growth Rates Associated with Statewide Mask Mandates — 10 States, March–October 2020
- **February 5, 2021** Sexual Orientation Disparities in Risk Factors for Adverse COVID-19–Related Outcomes, by Race/Ethnicity — Behavioral Risk Factor Surveillance System, United States, 2017–2019
- **February 5, 2021** Decreases in Young Children Who Received Blood Lead Level Testing During COVID-19—34 Jurisdictions, January–May 2020
- **February 5, 2021** Racial and Ethnic Disparities in the Prevalence of Stress and Worry, Mental Health Conditions, and Increased Substance Use Among Adults During the COVID-19 Pandemic — United States, April and May 2020
- **February 5, 2021** Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program — United States, December 14, 2020–January 14, 2021
- **February 5, 2021** Early COVID-19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program — United States, December 2020–January 2021

*Older MMWR COVID-19 Reports can be viewed at
https://www.cdc.gov/mmwr/Novel_Coronavirus_Reports.html

CDC Website Updates: Please find updated CDC website pages for 1/30-2/5

Response Website Updates (1/30/21-2/5/21)
• Cases in the U.S. Friday, February 05, 2021 • Overall US COVID-19 Vaccine Distribution and Administration Update as of Fri, 05 Feb 2021 06:00:00 EST Friday, February 05, 2021 • COVID-19 Science Update released: February 5, 2021 Edition 75 Friday, February 05, 2021 • Vaccination Considerations for Persons with Disabilities Friday, February 05, 2021 • COVID-19 Vaccination for Communities Friday, February 05, 2021 • Requirement for Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States Friday, February 05, 2021

Information for School Nurses and Other Healthcare Personnel (HCP) Working in Schools and Child Care Settings Friday, February 05, 2021

- Guidance for SARS-CoV-2 Point-of-Care Testing Friday, February 05, 2021
- Toolkit for Correctional and Detention Facilities Friday, February 05, 2021
- eCR Now: COVID-19 Electronic Case Reporting Friday, February 05, 2021
- COVID-19 Questions and Answers: For People Who Use Drugs or Have Substance Use Disorder Friday, February 05, 2021
- More Resources about COVID-19 Friday, February 05, 2021
- Protecting Seafood Processing Workers from COVID-19 Friday, February 05, 2021
- Communication Toolkit Friday, February 05, 2021
- Manufacturing Workers and Employers Friday, February 05, 2021
- Meat and Poultry Processing Workers and Employers Friday, February 05, 2021
- COVIDView Weekly Summary Friday, February 05, 2021
- COVID-19 Travel Recommendations by Country Friday, February 05, 2021
- Cases, Data, and Surveillance Friday, February 05, 2021
- Community, Work, and School Friday, February 05, 2021
- CDC Readiness and Planning Tool: To Prevent the Spread of COVID-19 in Primary and Secondary Schools in Low Resource Non-U.S. Settings Thursday, February 04, 2021
- COVID-19 Vaccine Information for Specific Groups Thursday, February 04, 2021
- US COVID-19 Cases Caused by Variants Thursday, February 04, 2021
- Workplaces and Businesses Thursday, February 04, 2021
- Wear Face Masks on Public Transportation Conveyances and at Transportation Hubs Thursday, February 04, 2021
- Federal Register Notice: Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19 Thursday, February 04, 2021
- Investigating the Impact of COVID-19 during Pregnancy Thursday, February 04, 2021
- Toolkit for People with Disabilities Thursday, February 04, 2021
- Print Resources Thursday, February 04, 2021
- How to Protect Yourself & Others Thursday, February 04, 2021
- ACIP Live Meeting Archive - January 27, 2021 Wednesday, February 03, 2021
- Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination Wednesday, February 03, 2021
- Federal Retail Pharmacy Partnership Program for COVID-19 Vaccination FAQs Wednesday, February 03, 2021
- Pharmacies Participating in the Federal Retail Pharmacy Program Wednesday, February 03, 2021
- Global Clinical Mitigation Wednesday, February 03, 2021
- Science Briefs Wednesday, February 03, 2021
- When Vaccine is Limited, Who Gets Vaccinated First? Wednesday, February 03, 2021
- Vaccines Wednesday, February 03, 2021
- Previous COVID-19 Forecasts: Cases Wednesday, February 03, 2021
- COVID-19 Forecasts: Cases Wednesday, February 03, 2021
- COVID-19 One-Stop Shop Toolkits Wednesday, February 03, 2021
- People with Certain Medical Conditions Wednesday, February 03, 2021
- Considerations for Public Beaches Wednesday, February 03, 2021
- Crew Disembarkations through Commercial Travel Wednesday, February 03, 2021
- Previous COVID-19 Forecasts: Hospitalizations Wednesday, February 03, 2021
- COVID-19 Forecasts: Hospitalizations Wednesday, February 03, 2021
- Daily Activities and Going Out Wednesday, February 03, 2021

Operating schools during COVID-19: CDC's Considerations Wednesday, February 03, 2021

- Previous Forecasts of Total Deaths Wednesday, February 03, 2021
- COVID-19 Forecasts: Deaths Wednesday, February 03, 2021
- Community Mitigation Wednesday, February 03, 2021
- Staffing Resources Wednesday, February 03, 2021
- Coronavirus Disease 2019 (COVID-19) Wednesday, February 03, 2021
- What Aircraft Maintenance Workers Need to Know about COVID-19 Wednesday, February 03, 2021
- Information for Health Departments on Reporting Cases of COVID-19 Wednesday, February 03, 2021
- Interim Guidance for Health Departments: COVID-19 Vaccination Implementation for People Experiencing Homelessness Tuesday, February 02, 2021
- Global Community Mitigation Tuesday, February 02, 2021
- New Variant of Virus that Causes COVID-19 Detected Tuesday, February 02, 2021
- Testing and International Air Travel Tuesday, February 02, 2021
- Know Your Travel Risk Tuesday, February 02, 2021
- Know When to Delay your Travel to Avoid Spreading COVID-19 Tuesday, February 02, 2021
- Travel during the COVID-19 Pandemic Tuesday, February 02, 2021
- Returning to Work Tuesday, February 02, 2021
- Research Use Only CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay Real-Time RT-PCR Primers and Probes Tuesday, February 02, 2021
- CDC's Diagnostic Multiplex Assay for Flu *and* COVID-19 and Supplies Tuesday, February 02, 2021
- COVID-19 in Newly Resettled Refugee Populations Tuesday, February 02, 2021
- Agriculture Workers and Employers Tuesday, February 02, 2021
- Test for Past Infection Tuesday, February 02, 2021
- What Airline Catering Kitchen Workers Need to Know about COVID-19 Tuesday, February 02, 2021
- COVID-19 Employer Information for Transit Maintenance Workers Tuesday, February 02, 2021
- What Airline Customer Service Representatives and Gate Agents Need to Know about COVID-19 Tuesday, February 02, 2021
- Use of Masks to Help Slow the Spread of COVID-19 Tuesday, February 02, 2021
- K-12 Schools and Childcare Programs Tuesday, February 02, 2021
- Travelers Returning from Cruise Ship and River Cruise Voyages Tuesday, February 02, 2021
- After You Travel Tuesday, February 02, 2021
- Travel: Frequently Asked Questions and Answers Tuesday, February 02, 2021
- Frequently Asked Questions Tuesday, February 02, 2021
- Travel Tuesday, February 02, 2021
- COVID-19 Graphics and Buttons Monday, February 01, 2021
- Considerations for Public Pools, Hot Tubs, and Water Playgrounds During COVID-19 Monday, February 01, 2021
- Air Travel Toolkit for Airline Partners Monday, February 01, 2021
- Road Travel Toolkit for Transportation Partners Monday, February 01, 2021
- General Business Frequently Asked Questions Monday, February 01, 2021
- What to Know About HIV and COVID-19 Monday, February 01, 2021
- Information for Laboratories about Coronavirus (COVID-19) Monday, February 01, 2021
- Information for Healthcare Professionals about Coronavirus (COVID-19) Monday, February 01, 2021
- What Paratransit Operators Need to Know about COVID-19 Saturday, January 30, 2021
- What Transit Station Workers Need to Know about COVID-19 Saturday, January 30, 2021
- What Bus Transit Operators Need to Know about COVID-19 Saturday, January 30, 2021

What Rail Transit Operators Need to Know about COVID-19 Saturday, January 30, 2021

- Personal and Social Activities Saturday, January 30, 2021
- Protect Yourself When Using Transportation Saturday, January 30, 2021
- How to Select, Wear, and Clean Your Mask Saturday, January 30, 2021
- How to Wear Masks Saturday, January 30, 2021
- What Rideshare, Taxi, Limo, and other Passenger Drivers-for-Hire Need to Know about COVID-19 Saturday, January 30, 2021

*Daily website updates are now viewable at https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html

Updates on the Federal Retail Pharmacy Program for COVID-19 Vaccination

The initial phased implementation of the program will begin with select retail pharmacies administering COVID-19 vaccine across the country as early as Thursday, February 11. The program will be implemented incrementally, based on the available supply of COVID-19 vaccines. As the vaccine supply increases, the program aims to expand the number of participating pharmacy locations ultimately providing COVID-19 vaccines in all 40,000 retail pharmacy locations nationwide. Allocations to support the Federal Retail Pharmacy Program are separate from weekly allocations provided to jurisdictions. What jurisdictions see in their weekly allocation will remain stable.

Eligibility Criteria for Vaccination

The Federal pharmacy partners will administer vaccine to individuals according to state-selected eligibility criteria. Pharmacy partners have developed screening questionnaires specific to each jurisdiction's criteria and will finalize them based on the survey results to help ensure eligibility prior to vaccination. After launch, immunization program managers will be able to update eligibility criteria weekly using an application in Tiberius, the centralized system used by the federal government to support vaccine distribution efforts. Information about how to use this new Tiberius application will be sent to immunization programs this week.

Program Data and Monitoring

By Friday, CDC will provide a list of the retail locations that will be providing COVID-19 vaccine in each jurisdiction as part of the initial phased implementation of the program.

All pharmacy partners enrolled in the Federal Retail Pharmacy Program are required to report inventory daily to VaccineFinder and patient administration information to the jurisdiction's IIS as well as directly to CDC's Data Clearing House. Jurisdictions will have access to patient administration data submitted by all pharmacies in their jurisdiction. Jurisdictions will also have access to information in Tiberius-specific to pharmacy programs.

Information will include details on stores that will be receiving vaccine, store-level supply information, and administration/uptake information as it becomes available. Jurisdictions will also be provided points of contacts for pharmacy partners to facilitate coordination with partners.

Communications Support

CDC has developed a **toolkit of materials** to help jurisdictions and partners describe and

communicate about the implementation of the Federal Retail Pharmacy Program. We hope these materials will assist in providing clear and consistent information about the program goals and parameters.

The toolkit includes the attached materials for your use and reference:

- Frequently Asked Questions about the Program for Jurisdictions and Pharmacy Partners
- Key communication messages for jurisdictions and pharmacy partners
- A One-Page Fact Sheet on the Federal Retail Pharmacy Program (to share with partners or members of the community)

Upcoming Trainings/Webinars/Jurisdictional Calls

- Below is a link to a series of accredited education about COVID-19 vaccine in general, safety, and administration considerations.
  - Vaccine Courses, Broadcasts, Webcasts and Self Study Training | CDC
- Tiberius users can access the training video on submitting transfer requests at the following link: https://protect-ows.hhs.gov/workspace/compass/view/ri.compass.main.folder.c95b290c-2561-4cd1-85f7-e31dac51d34b [protect-ows.hhs.gov

Upcoming NACCHO Webinars:

Tuesday, February 9 at 12 pm ET: COVID-19 Action in the Biden Era: A Fireside Chat with Dr. Fauci

Upcoming CDC Foundation Webinar:

February 24 at 1:00-2:00 pm EST - Updates and Resources from CDC and Ad Council

During this session,

- Anne Schuchat, principal deputy director at the CDC, will provide an update on vaccine distribution.
- A representative from the Ad Council will present messaging content and guidance for local public health officials
- Judy Monroe, president, and CEO of the CDC Foundation, will moderate an audience Q&A.

Georgia Tech Center for Design and Inclusive Innovation Webinar:

February 10 at 2:00 pm EST

- Guidance for Businesses and Employers Considering the Needs of People with Disabilities during COVID-19

CDC COVID-19 Partner Update Webinar

- COVID-19 Information for Essential Workplaces
- February 8 at 3:00 PM ET

NEW Pharmacy/LTCF Office Hours

- Office Hours will now be held twice a week on Tuesdays and Fridays from 4 - 4:30 pm ET. Please find the call-in information below:

  Microsoft Teams meeting

  Join on your computer or mobile app

  Click here to join the meeting

  Or call in (audio only)

+1 404-718-3800,,561828018# United States, Atlanta
(888) 994-4478,,561828018# United States (Toll-free)
Phone Conference ID: 561 828 018#
Find a local number | Reset PIN
Learn More | Meeting options

Upcoming National Vaccine Advisory Committee (NVAC) Meeting

- February 4-5, 1:00-5:45 PM
- Live webcast link and agenda found here

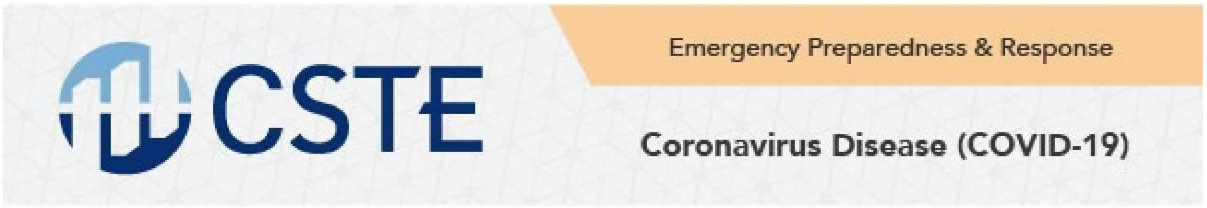
COVID-19 Resources

- Vaccine Confidence Consultations from Vaccine Task Force
  - This email serves as an entry point to many vaccine confidence consultation options offered by CDC. Vaccine confidence and communications experts will receive emails from providers and public health professionals and then set up brief calls to understand needs, tailor support, and provide further technical assistance in data collection, creation of communication products and more to promote community vaccine confidence for COVID-19 vaccines. They can be contacted at confidenceconsults@cdc.gov
- ELC Enhancing Detection Expansion FAQ (attached)
  - Developed by the ELC Team, this FAQ answers common questions about Enhancing Detection Expansion funding for jurisdictions. More information can be found on the ELC Website.
- Factsheet: 12 Things Jurisdictions Need to Know about VAERS (attached)
  - A factsheet developed by VTF on how to report adverse events following vaccination to the Vaccine Adverse Events Reporting System (VAERS)
- The COVID State-Profiles Report (aka Governors Report) is now posted publicly at COVID Data Tracker, and will be updated weekly. As a reminder, Community Profile Report has been posted publicly since December, and is updated daily. There is also a public facing version of the Therapeutics Distribution Location Tool.
- COVID-19 Vaccination Communication Toolkits for Community- Based Organizations and Essential Workers
  - COVID-19 vaccines will be available to essential workers and other community members soon. CDC has designed two toolkits to help build confidence in this new vaccine. The toolkits will help community-based organizations (CBOs) and employers to educate community members and workers about COVID-19 vaccines, raise awareness about the benefits of vaccination, and address common questions and concerns.

Thank you,

Jamilla Green, DrPH, MPH, CPH
Health Department Liaison (Region 4: KY, MS)
Health Department Section
State, Tribal, Local, and Territorial Support Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
qwq7@cdc.gov

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 1 (incl. ELC Reopening Schools Webinar, HHS Press Release, MMWR Early Releases, NIOSH Comms Resources, and more)
Date:	Thursday, April 1, 2021 1:04:09 PM
Attachments:	image001.png image002.png ELC Reopening Schools Guidance 26Mar2021-Final.pdf HHS COVID-19 Update - 329.msg HHS COVID-19 Update - 330.msg HHS COVID-19 Update - 331.msg MMWR ER - Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020 - March 31, 2021.pdf MMWR ER - Provisional Mortality Data — United States, 2020 - March 31, 2021.pdf Partner Key Update 331.msg safe-proper-sharps-disposal.pdf strategies-sharps-disposal-container.pdf



Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- TODAY: Webinar - ELC Reopening Schools [Link]
  - CDC's Epidemiology and Laboratory Capacity (ELC) Program will host a webinar **TODAY**, Thursday, **April 1** at **4:00 pm EDT** regarding funding to enable and expand school-based screening testing. Attendees can expect a review of the *Reopening Schools* guidance (*attached), subject matter expert perspectives, and a Q&A session. The webinar will be recorded and a link to download will be made available afterwards, in addition to a copy of slides.
  - Call information is below:
    - Weblink: https://www.mymeetings.com/nc/join/
      Conference Number: PWXW2102397
      Direct link: https://www.mymeetings.com/nc/join.php?i=PWXW2102397&p=9125099&t=c
    - Telephone: 1-415-228-4882 or 800-369-2098
      Passcode: 9125099

HHS Press Release: "HHS to Expand Access to COVID-19 Vaccines for Older Adults and People with Disabilities" [Link]

- On **Monday, March 29**, HHS announced a partnership between CDC and the Administration for Community Living (ACL) to provide nearly $100 million in funding to help increase vaccinations among older adults and people with disabilities. From the announcement: *"With funding from CDC, ACL will issue nearly $93 million in grants to the aging and disability networks in every state and territory. These funds will help provide critical services to overcome barriers that are preventing millions of those most at risk for serious illness and death from COVID-19 from receiving vaccines. This partnership also will provide an additional $5 million in funding for national hotlines to assist older adults and people with disabilities in registering for a vaccination and to connect them with local disability and aging agencies that can provide services and supports necessary to access them."*
- The full press release is available on HHS' website here.

- NIOSH Resources: "Safe and Proper Sharps Disposal During the COVID-19 Mass Vaccination Campaign" [Attachments, Link]
  - The National Institute for Occupational Safety and Health (NIOSH) recently released a new suite of communications products aimed at preventing needlesticks at mass vaccination sites, as well as promoting proper sharps disposal. Please see attached for two printouts that can be posted for staff and office use. An accompanying webpage is available on CDC's website here.
- MMWR Early Release: "Provisional Mortality Data — United States, 2020" [Attachment, Link]
  - From the summary: *"The age-adjusted death rate increased by 15.9% in 2020. Overall death rates were highest among non-Hispanic Black persons and non-Hispanic American Indian or Alaska Native persons. COVID-19 was the third leading cause of death, and the COVID-19 death rate was highest among Hispanics."*
- MMWR Early Release: "Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020" [Attachment, Link]
  - From the summary: *"Among 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both."*

Standing Updates

- CDC Partner Update – March 31 [Attachment]
  - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Updates – March 29, 30, & 31 [Attachments]
  - Please see attached for the latest COVID-19 updates from the HHS Office of

Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.

- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
  - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
  - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
  - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 14 (incl. COCA Call, MMWR Early Release, CDC Partner Update Call, AMCHP Scholarships, and more)
Date:	Wednesday, April 14, 2021 4:01:47 PM
Attachments:	image001.png image002.png TOMORROW CDC COCA Call Johnson JohnsonJanssen COVID-19 Vaccine and Cerebral Venous Sinus Thrombosis with Thrombocytopenia Update for Clinicians on Early Detection and Treatment.msg COVID-19 Partner Updates April 14th 2021.msg HHS COVID-19 Update - 413.msg MMWR ER - April 14, 2021.pdf CBO_Tribal Government Scholarship.pdf Healthcare Quality and Worker Safety (Apr 14).pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC COCA Call: Johnson & Johnson/Janssen COVID-19 Vaccine and Cerebral Venous Sinus Thrombosis with Thrombocytopenia – Update for Clinicians on Early Detection and Treatment [Attachment, Link]
    - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **tomorrow**, Thursday, **April 15** at **2:00 pm EDT** to present the latest evidence on cerebral venous sinus thrombosis (CVST) with thrombocytopenia associated with the administration of the Johnson & Johnson/Janssen COVID-19 vaccine. Speakers will discuss what is known about CVST, the importance of early detection, and updated vaccine recommendations. Call information is below:
        - Weblink: https://www.zoomgov.com/j/1614336614?pwd=ZVhQUHoyaG4zVFdua2czcE9EU20wUT09
          Telephone: (669) 254 5252 or (646) 828 7666
          Webinar ID: 161 433 6614
          Passcode: 160026
          Post-Event
          Recording: https://emergency.cdc.gov/coca/calls/2021/callinfo_041521.asp
- MMWR Early Release: "Laboratory Modeling of SARS-CoV-2 Exposure Reduction Through Physically Distanced Seating in Aircraft Cabins Using Bacteriophage Aerosol — November

2020" [Attachment, Link]
    - From the report: *"Based on laboratory modeling of exposure to SARS-CoV-2 on single-aisle and twin-aisle aircraft, exposures in scenarios in which the middle seat was vacant were reduced by 23% to 57%, compared with full aircraft occupancy, depending upon the model."*
- CDC Partner Update Call: "When to Clean, When to Disinfect, and What Science Says about SARS-CoV-2 on Surfaces" [Link]
    - CDC will host the next installment of its weekly partner call **Monday, April 19** at **3:00 pm EDT**. Dr. Cynthia Ogden will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Dr. Vincent Hill will discuss how SARS-CoV-2 impacts cleaning and disinfecting surfaces.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 4/19" in the subject line. The call will be recorded and posted to CDC's website here.
- AMCHP CBO and Tribal Government Conference Scholarships [Attachment, Link]
    - The Association of Maternal & Child Health Programs (AMCHP) is offering approximately 16 need-based scholarships to its annual conference taking place May 24–27, 2021. These scholarships are intended for community-based organizations or tribal governments. To apply, complete this survey by May 7. Questions may be sent to evidence@amchp.org.
- CDC COVID-19 Healthcare Quality and Worker Safety Information [Attachment]
    - Weekly summary, published April 13

Standing Updates

- CDC Partner Update – April 14 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Updates – April 13 [Attachment]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 21 (incl. ELC K-12 Deliverables, 4/23 ACIP Meeting, CDC Partner Call, MMWR Early Releases, and more)
Date:	Wednesday, April 21, 2021 3:35:30 PM
Attachments:	image001.png image002.png Partner Update April 212021.msg HHS COVID-19 Update - 419.msg HHS COVID-19 Update - 420.msg MMWR ER - April 21, 2021 - COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021.pdf MMWR ER - April 21, 2021 - Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021.pdf ELC K-12 Reopening Schools [Email].pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- ELC K-12 Reopening Schools Deliverables [Attachment]
  - Please see attached for a message from CDC's Epidemiology and Laboratory Capacity (ELC) Team. This message aims to clarify two deliverables due **Friday, April 23**:
    1. Validation/correction of the 'School District Weekly Reporting Template', pre-populated with school districts in your jurisdiction.
    2. A brief narrative of how you plan to partner and provide resources to the districts in your jurisdiction.
  - Full instructions are available in the attached PDF. From the message: *"We do not expect that every district in every jurisdiction will be ready to adopt screening testing immediately. During Phase 2/Activity 2, we will ask you to describe your plan for working with the jurisdictions in more specific terms. [...] We will be sharing FAQs in coming days to provide additional clarity; in the meantime, please don't hesitate to reach out to your ELC Project Officer or leadership with any questions or clarifications."*
- CDC ACIP Emergency Meeting [Link]
  - CDC's Advisory Committee on Immunization Practices (ACIP) will hold another virtual

emergency meeting **Friday, April 23** from **11:00 am–5:00 pm EDT** regarding safety in the use of the Johnson & Johnson (Janssen) vaccine.
    - Registration is *not* required. The meeting will be broadcast on uStream here.
- CDC Partner Update Call: Keeping Up with Critical Diabetes Care and Prevention During COVID-19 [Link]
    - CDC will host the next installment of its weekly partner call **Monday, April 26** at **3:00 pm EDT**. Dr. Kyle Bernstein will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Dr. Beth Bigman will discuss how to maintain critical diabetes care and prevention during the pandemic.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 4/26" in the subject line. The call will be recorded and posted to CDC's website here.
- MMWR Early Release: "Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021" [Attachment, Link]
    - From the summary: *"Twenty-two possible breakthrough SARS-CoV-2 infections occurred among fully vaccinated persons ≥14 days after their second dose of COVID-19 vaccine. Two thirds of persons were asymptomatic. A minority of persons with breakthrough infection experienced mild to moderate COVID-19–like symptoms; two COVID-19–related hospitalizations and one death occurred. No facility-associated secondary transmission was identified."*
- MMWR Early Release: "COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021" [Attachment, Link]
    - From the summary: *"In a COVID-19 outbreak at a Kentucky SNF involving a newly introduced variant to the region, unvaccinated residents and health care personnel (HCP) had 3.0 and 4.1 times the risk of infection as did vaccinated residents and HCP. Vaccine was 86.5% protective against symptomatic illness among residents and 87.1% protective among HCP."*

Standing Updates

- CDC Partner Update – April 21 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Updates – April 19 & 20 [Attachments]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]

- The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.

- CSTE COVID-19 Response Resource Repository [Link]
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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 6 (incl. Early MMWR, School-based Screening Webinar, COVID-19 Genomic Epidemiology Focus Group, and more)
Date:	Tuesday, April 6, 2021 2:52:48 PM
Attachments:	image001.png image002.png MMWR ER - Community Transmission of SARS-CoV-2 Associated with Local Bar - February, 2021.pdf ELC Reopening Schools webinar_2021 04 01.pdf COVID-19 Partner Updates April 5 2021.msg HHS COVID-19 Update - 45.msg

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- MMWR Early Release: "Community Transmission of SARS-CoV-2 Associated with a Local Bar Opening Event – Illinois, February 2021" [Attachment, Link]
    - From the summary: *"Forty-six cases of COVID-19 were linked to an indoor bar opening event that occurred during February 2021 in a rural Illinois county. Event patrons were linked to secondary cases among household, long-term care facility, and school contacts, resulting in one hospitalization and one school closure affecting 650 students."*
- Partner Alert: Community of Practice webinar "School-based Screening Testing" [Link]
    - This week's CDC Community of Practice call is on **Thursday**, **April 8** at **2:00 pm ET**. The webinar will focus on the importance of the partnership between public health and education in establishing COVID-19 K-12 screening testing programs and provide information on assistance being offered to support these programs. You may join the call here or dial in using the call-in line below:
        - Zoom Dial-in: 1 646-828-7666
          Meeting ID: 161 148 9877
          Passcode: 66625007
- ELC webinar slides and recording of "Reopening Schools" held Thursday, April 1* [Attachment, Link]

On **Thursday**, **April 1**, ELC hosted a webinar regarding its newest supplemental funding package "ELC Reopening Schools" to review Reopening Schools guidance, subject matter expert perspectives, and a Q&A session. The slides from the webinar are attached, and a link to the recording is available here. ***Please note: the recording is a large file download.**

- COVID-19 Genomic Epidemiology Toolkit Follow Up & Focus Group [Link]
    - Thanks to all who have tried the **COVID-19 Genomic Epidemiology Toolkit**! The Toolkit modules, created by CDC with state and local partners, provide easy-to-use training materials for applying genomic epidemiology to SARS-CoV-2 surveillance and outbreak investigations. Please visit the COVID-19 Genomic Epidemiology Toolkit page as we continue to add new videos and resource links. In an effort to improve the Toolkit, we plan to host a **focus group** to gather feedback. We are looking for volunteers and would appreciate your participation. The focus group will entail an hour-long zoom call with other participants. The only requirements are that you have used the toolkit and are willing to discuss your feedback. To volunteer or to ask any questions, please email GenEpiToolkit@cdc.gov.
- CDC Partner Update Call: "Contact Tracing for COVID-19: Do we still need it? (You bet we do!) Ask an Expert – Q&A with a CDC Expert on Current COVID-19 Guidance" [Link]
    - CDC will host the next installment of its weekly partner call **Monday, April 12** at **3:00 pm ET**. Dr. Kyle Bernstein will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Then, Dr. Melanie Taylor will discuss contact tracing and why it is still important during the COVID-19 Response.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 4/12" in the subject line. The call will be recorded and posted to CDC's website here.
- CDC Media Statement: "CDC Issues Next Phase of the Conditional Sail Order for Cruise Ship Operators" [Link]
    - On **Friday**, **April 2**, CDC issued the next phase of technical guidance under the Framework for Conditional Sailing Order (CSO). From the statement: *[this phase requires]* "cruise lines to establish agreements at ports where they intend to operate, implement routine testing of crew, and develop plans incorporating vaccination strategies to reduce the risk of introduction and spread of COVID-19 by crew and passengers. Read the full statement here.

Standing Updates

- Webinar: White House COVID-19 Response Team w/ State & Local Health Officials [Link]
    - The White House COVID-19 Team will host a webinar **TODAY**, Tuesday, **April 6** at **6:00 pm EST**. Advance registration is required. After registering, you will receive a confirmation email with full call info.

    - Registration link: https://pitc.zoomgov.com/webinar/register/WN_IJV5E1zNRL2QmyyXrpki6Q
- CDC Partner Update – April 5 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – April 5 [Attachment]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: CSTE Emergency Response
To: CSTE Emergency Response
Cc: CSTE Novel Coronavirus 2019
Subject: CSTE COVID-19 Response | Digest for Apr. 9 (incl. CDC Info on Vaccine Breakthrough Infections, MH Survey Extension, CDC Webinar on Public Use Data, MMWR Early Release, and more)
Date: Friday, April 9, 2021 3:03:33 PM
Attachments: image001.png
image002.png
COVID-19 Partner Updates April 7th 2021.msg
COVID-19 Partner Updates April 9th 2021.msg
HHS COVID-19 Update - 46.msg
HHS COVID-19 Update - 47.msg
HHS COVID-19 Update - 48.msg
MMWR ER - April 7, 2021.pdf
[redacted]
Webinar_ CDC COVID-19 Case Surveillance Public Use Data with Geography - Overview of Privacy Protections.ics

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Resources on COVID-19 Vaccine Breakthrough Infections [Attachment]
  - Please see below for a message from CDC's COVID-19 Vaccine Breakthrough Case Investigations Team. This information is for internal use only, and is **not for distribution**:

[redacted]

- [redacted]
- Extension: CDC Public Health Worker Mental Health Survey [Link]
    - CDC is conducting a survey intended for people who worked in STLT public health departments in 2020, in an effort to understand and address the mental health impacts and support needs of our crucial public health workforce on the frontlines of the COVID-19 response. All full-time and part-time employees, contractors, fellows and others who work at the health department are eligible to participate, and we encourage you to broadly disseminate the survey to relevant staff.
    - **The survey deadline has been extended to Friday, April 16.** The 10-15 minute anonymous survey is available here.
- Webinar: "COVID-19 Case Surveillance Public Use Data with Geography – Overview of Privacy Protections" [Attachment, Link]
    - CDC will host a webinar **Friday, April 16** at **2:00 pm EDT** to discuss privacy protections for the new COVID-19 Case Surveillance Public Use Data with Geography. Please email questions in advance to eocevent394@cdc.gov with "Question for 4/16 CDC webinar on new public use dataset" in the subject line. Call information is available below:
        - Weblink: https://cdc.zoomgov.com/j/1618567396?pwd=WE9RWitrS09pdk1KSnA5TnhNdEVjQT09
          Meeting ID: 161 856 7396
          Telephone: (669) 254-5252 or (646) 828-7666 or (551) 285-1373 or (669) 216-1590
          Passcode: 44193919
    - An .ICS calendar file is also attached for your convenience.
- MMWR Early Release: "Factors Associated with Participation in Elementary School–Based SARS-CoV-2 Testing — Salt Lake County, Utah, December 2020–January 2021" [Attachment, Link]
    - From the report: *"As schools consider reopening, in-school specimen collection for SARS-CoV-2 testing could help reach potentially underserved populations to reduce community transmission. Explaining testing procedures in a parent's or guardian's preferred language, as was done in this situation, might also be important for promoting participation."*

Standing Updates

- CDC Partner Updates – April 7 & 9 [Attachments]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Updates – April 6, 7, & 8 [Attachments]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
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- Request Form for CSTE COVID-19 Call Topics [Link]
  - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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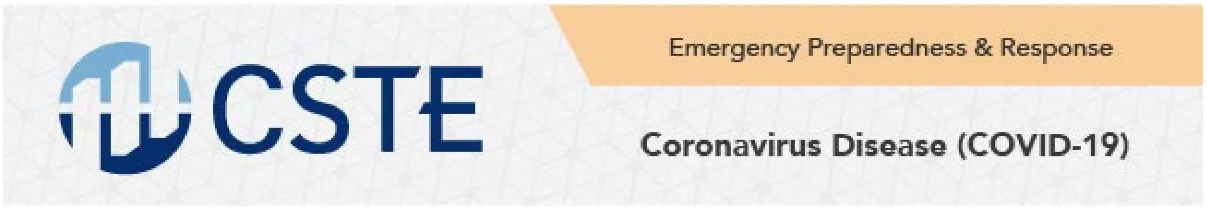
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Aug 6. (Early MMWRs, CDC Media Statement on Post-Vaccination COVID-19 Infection Rates, Updated Guidance for COVID-19 Prevention in K-12 Schools and more)
Date:	Friday, August 6, 2021 3:26:47 PM
Attachments:	image001.png image002.png mm7032e1-H.pdf mm7032e2-H.pdf mm7032e3-H.pdf Webinar_DOJ-ConfinementFacilities_Final.pdf Webinar_DOJ-ConfinementFacilities_QA-Summary.pdf Webinar_DOJ-ConfinementFacilities_Transcript.pdf ELC Enhancing Detection PM Guidance_8_5_2021_FINAL.pdf COVID-19 Partner Updates August 04 2021.msg HHS COVID-19 Update - 85.msg COVID-19 Partner Updates August 06 2021.msg



Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- Early MMWRs - Vol. 70, No. 31 [Attachments, Links]
  - The **August 6** edition of CDC's Morbidity and Mortality Weekly Report (MMWR) includes the following COVID-related articles:
    - Rapid Increase in Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — Mesa County, Colorado, April–June 2021COVID-19 Vaccine Administration, by Race and Ethnicity — North Carolina, December 14, 2020–April 6, 2021
    - Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021
    - Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥65 Years — 13 states, COVID-NET, February–April 2021
- New CDC Study: Vaccination Offers Higher Protection than Previous COVID-19 Infection [Link]
  - In response to today's MMWR on post-vaccination COVID-19 infection rates (linked here), CDC issued a media statement, announcing in part: "*In today's MMWR, a study of COVID-19 infections in Kentucky among people who were previously infected with SAR-CoV-2 shows that unvaccinated individuals are more than twice as likely to be reinfected with COVID-19 than those who were fully vaccinated after initially*

contracting the virus. These data further indicate that COVID-19 vaccines offer better protection than natural immunity alone and that vaccines, even after prior infection, help prevent reinfections."

- Read the CDC's full media statement here.

- Updated CDC Guidance for COVID-19 Prevention in K-12 Schools [Links]
  - On **August 5**, CDC updated its Guidance for COVID-19 Prevention in K-12 Schools to align with CDC's existing guidance for fully vaccinated people and assist K-12 schools in opening for in-person instruction and remaining open. Additionally, the Considerations for Case Investigation and Contact Tracing in K-12 Schools and Institutions of Higher Education (IHEs) has been updated to align with new CDC guidance.
  - The full updated Guidance is linked here.
- CDC COCA Call: Therapeutic Options to Prevent Severe COVID-19 in Immunocompromised People [Links]
  - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **Thursday, August 12** at **2:00 pm EDT** to discuss the FDA's role in issuing EUAs for certain monoclonal antibodies, options for compassionate use, the process for ordering and distributing monoclonal antibodies, and current data on using monoclonal antibodies for both non-hospitalized and immunocompromised patients. Presenters will also cover preventing, diagnosing, and treating COVID-19 in immunocompromised patients, including the role of monoclonal antibodies, serologic testing, and potential third dose of COVID-19 vaccinations.
    - Weblink: https://www.zoomgov.com/j/1612254638?pwd=SmNaNlJEUWt3YWdBMGtNRjhxRlZ1UT09
      Telephone: (646) 828-7666 or (669) 216-1590 or (551) 285-1373
      Webinar ID: 161 225 4638
      Passcode: 980771
      Access materials post-call:
      https://emergency.cdc.gov/coca/calls/2021/callinfo_081221.asp
- ELC & DOJ Webinar: Detection & Mitigation of COVID-19 in Confinement Facilities [Attachments, Link]
  - On **August 5**, CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) and the Department of Justice (DOJ) hosted a webinar, "Detection & Mitigation of COVID-19 in Confinement Facilities."
  - In case you missed it, you may watch/download the full webinar here. Also attached are a transcript and summary of the Q&A portion of the webinar.
- Updated ELC Enhancing Detection Performance Measures Guidance [Attachment]
  - Today, **August 6**, CDC released an updated ELC Enhancing Detection Performance Measures Guidance document (attached) for this new budget year that started August 1, 2021.
  - This guidance provides details for all ELC Enhancing Detection performance measures including all data elements, reporting frequency, and reporting timelines.
- Updated CDC Public Health Science Priority Questions [Link]
  - The CDC's *Public Health Science Agenda* for COVID-19 articulates key areas of scientific inquiry and opportunities to guide the development of actionable, evidence-based public health guidance to limit the spread and impact of SARS-CoV-2 and ultimately end

the COVID-19 pandemic. As the evidence base and public health response to the COVID-19 pandemic continues to evolve, this Public Health Science Agenda has helped promote efforts to fill critical, time-sensitive scientific gaps and to inform evidence-based decision making.

- On **August 4**, a second update to the Priority Public Health Science Questions was released (linked here) to help achieve the objectives outlined in the Public Health Science Agenda for COVID-19. The newest update includes 15 Priority Public Health Science Questions that were systematically developed to be relevant, actionable near-term, and reflective of the evolving needs of the ongoing public health response.

Standing Updates

- CDC Partner Updates – August 4 & August 6 [Attachments]
  - Please see attached for the latest update from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
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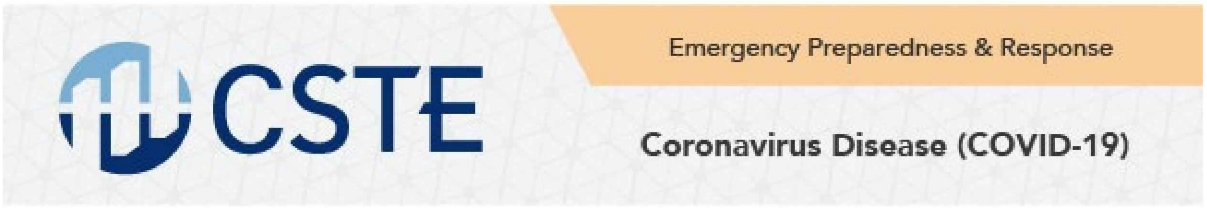
From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Dec. 30 (incl. MMWRs, HHS Therapeutics Update, CDC All STLT Call, and more)
Date:	Thursday, December 30, 2021 2:09:35 PM
Attachments:	image001.png image002.png UPDATE HHS Allocation of bam ete and REGEN-COV therapeutics.pdf MMWR Weekly - December 29 2021.pdf



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New Information

- MMWR – Vol. 70, No. 51-52 [Links, Attachment]
  - The **December 31** edition of CDC's Morbidity and Mortality Weekly Report (MMWR) includes the following COVID-related articles:
    - COVID-19 Vaccine Safety in Children Aged 5–11 Years — United States, November 3–December 19, 2021
    - Interim Estimate of Vaccine Effectiveness of BNT162b2 (Pfizer-BioNTech) Vaccine in Preventing SARS-CoV-2 Infection Among Adolescents Aged 12–17 Years — Arizona, July–December 2021
    - Characteristics and Clinical Outcomes of Children and Adolescents Aged <18 Years Hospitalized with COVID-19 — Six Hospitals, United States, July–August 2021
    - Evaluation of a Test-To-Stay Strategy in Transitional Kindergarten Through Grade 12 Schools — Los Angeles County, California, August 16–October 31, 2021
    - Evaluation of Test-To-Stay Strategy on Secondary and Tertiary Transmission of SARS-CoV-2 in K–12 Schools — Lake County, Illinois, August 9–October 29, 2021
    - Investigation of a SARS-CoV-2 B.1.1.529 (Omicron) Variant Cluster — Nebraska, November–December 2021
- HHS Update: Allocation of bam/ete and REGEN-COV therapeutics [Link, Attachment]
  - Yesterday, **December 29**, the U.S. Department of Health and Human Services (HHS) announced a pause in allocations of bamlanivimab/etesevimab and REGEN-COV COVID-

19 therapeutics to states or territories within regions of the country that have greater than 80% prevalence of the Omicron variant based on CDC NOWCAST data. The purpose of this pause is to ensure effective product is available in most sites.
    - Please see attached for the full update. You may email COVID19Therapeutics@HHS.gov with questions regarding the allocation of bam/ete and REGEN-COV.
- Reminder: CDC All-STLT Update Call Series – Register for 2022 Calls Before 1/3/22 [Link]
    - On **January 3, 2022**, CDC's weekly COVID-19 All-STLT Update call will be moving to a new Zoom link. Before that date, please register here to ensure your access to the 2022 call series. Please note that your unique participant link will be the same for all calls in the series through December 2022; you do not need to register for each individual call. Calls will be held on Mondays from 2:00–2:45 pm ET (unless otherwise notified).
    - Call registrants will also be added to CDC's partner update distribution list. Partner update emails are disseminated every Monday, Wednesday, and Friday afternoon, and are the same updates included below in our "Standing Updates" section.
- Lights, Camera, Action: The Future of Public Health Summit Series – Summit #2 [Link]
    - The CDC Foundation and other public health agencies are hosting a four-part virtual summit to advance recommendations for a modernized U.S. public health system. Registration is now open for the second summit, *Creating an Interoperable and Modern Data and Technology Infrastructure,* occurring on **January 25, 2022 at 11:00 am EST**. Speakers will include CDC's Deputy Director for Public Health Science and Surveillance, Dr. Daniel Jernigan, HHS's National Coordinator for Health Information Technology, Dr. Micky Tripathi and other prominent leaders in the field. Learn more and register for the Summit here.

Standing Updates

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Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: CSTE Emergency Response
To: CSTE Emergency Response
Cc: CSTE Novel Coronavirus 2019
Subject: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)
Date: Tuesday, January 11, 2022 4:19:27 PM
Attachments: image001.png
image002.png
N95 effectiveness as source control .pdf
PARTNER ALERT CDC Expands Booster Shot Eligibility.msg
COVID-19 Partner Updates January 10 2022.msg
HHS Therapeutics Projected Allocations_7 Jan 2022.pdf
HHS Update COVID-19 allocation projections for January .pdf
Lindsley-2021-A comparison of performance metr.pdf
Lindsley-2021-Efficacy of face masks, neck gai.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

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New Information

- CDC Partner Alert: N95 Effectiveness as Source Control [Attachments]
  - Today, **Tuesday, January 11**, CDC issued a partner update (attached) in response to numerous questions about N95 mask effectiveness as source control. The update shared two peer reviewed publications from National Institute for Occupational Safety and Health (NIOSH) researchers (both attached) on N95 mask effectiveness, including findings that a N95 respirator was 99% effective at blocking cough aerosols.
- HHS Update: COVID-19 Allocation Projections for January [Attachments]
  - On **Friday, January 7**, the U.S. Department of Health and Human Services (HHS) issued an update with a projected calendar of allocation amounts and cadence of COVID-19 therapeutics for the remainder of January (attached). Questions may be directed to us COVID19Therapetuics@hhs.gov.
- Partner Alert: CDC Expands Booster Shot Eligibility [Attachment, Link]
  - On **Saturday, January 6**, CDC issued a partner alert (attached) adjusting its recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months. CDC has extended this recommendation to recipients of a Moderna primary series. This means that people 12 years of age and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.

- CDC COCA Call: What Clinicians Need to Know About the New Oral Antiviral Medications for COVID-19 [Links]
    - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **tomorrow, Wednesday, January 12 at 2:00 pm EST** to discuss the recent emergency use authorizations (EUAs) for new oral antiviral medications intended to decrease hospitalizations, as well as prevent severe COVID-19 and death Call information is below:
        - Weblink: https://www.zoomgov.com/j/1612974214?pwd=VitYMEorako1YWhCaXpnaWdsc2Ixdz09
          Telephone: (660) 254-5252 or (646) 828-7666 or (669) 216-1590 or (551) 285-1373
          Webinar ID: 161 297 4214
          Passcode: 180866
          Post-Event Recording:
          https://emergency.cdc.gov/coca/calls/2021/callinfo_011222.asp
- Reminder: CDC Preventive Medicine Grand Rounds: "The Public Health System of the Future – Moving Ahead in Partnership with Health Care & Other Sectors" [Link]
    - CDC will host its monthly Preventive Medicine Grand Rounds **tomorrow, Wednesday, January 12** at **1:30 pm EST**. The session will focus on the public health system of the future and the speaker is John Auerbach, Director of Intergovernmental and Strategic Affairs for CDC. Continuing education (CE) is available at no cost. Registration information is available here.

Standing Updates

- CDC Partner Update – January 10 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – January 10 [Link]
    - Please click here for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am ET**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]

- CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Jan. 22 (incl. WH National Strategy on COVID-19 Materials, MMWRs, Call Reminders and more)
Date:	Friday, January 22, 2021 1:47:13 PM
Attachments:	image001.png image002.png National Strategy for the COVID-19 Response and Pandemic Preparedness.msg FACT SHEET President Biden Takes Aggressive and Immediate Action to Contain COVID-19 Crisis.msg MMWR ER - January 22, 2021.pdf CDC COCA Call Treating Long COVID Clinician Experience with Post-Acute COVID-19 Care.msg MMWR Weekly – January 22, 2021.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of recent Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

- White House National Strategy for the COVID-19 Response and Pandemic Preparedness and Executive Order on a Data-Driven Response [Attachment, Link]
  - Yesterday, the White House released its National Strategy for the COVID-19 Response and Pandemic Preparedness, providing a roadmap to guide America out of the worst public health crisis in a century. An executive summary of the new National Strategy is attached, while the complete plan is linked above. A fact sheet summarizing the new National Strategy to quickly contain the COVID-19 crisis has also been released. [Link]
  - The White House also issued an executive order yesterday to ensure a "Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats." [Link]
  - White House activities – Thursday, January 21, 2021 [Link] and Friday, January 22, 2021 [Link]
- MMWR Early Release: "Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021" [Attachment, Link]
  - From the summary: *"During December 21, 2020–January 10, 2021, monitoring by the Vaccine Adverse Event Reporting System detected 10 cases of anaphylaxis after administration of a reported 4,041,396 first doses of Moderna COVID-19 vaccine (2.5 cases per million doses administered). In nine cases, onset occurred within 15 minutes of vaccination. No anaphylaxis-related deaths were reported."*
- Reminder: CSTE Webinar: COVID-19 during Pregnancy [Link]

- CSTE will host its next COVID-19 Response Membership Webinar, "COVID-19 during Pregnancy," **Friday, January 29, 2021** at **3:00 pm EST**. CDC will present the current evidence on COVID-19 in pregnant women and their babies and provide an overview of current surveillance efforts, including successes and challenges. Massachusetts will provide a state perspective on efforts to improve identification of SARS-CoV-2 infection during pregnancy through data linkages to existing data sources.
- Call capacity is limited to 1,000 participants, and is first-come, first-served. Call information is below:
  - Weblink: https://webinar.ringcentral.com/j/1487195918
  - Telephone: (470) 860-2200 *[East]* | (773) 231-9226 *[North]* | (469) 445-0100 *[South]* | (623) 404-9000 *[West]* | (720) 902-7700 *[Central]*
  - Meeting ID: 148 719 5918
  - One-Tap Mobile: *+1(470)8692200,,1487195918# [East] |+1(773)2319226,,1487195918# [North] | +1(469)4450100,,1487195918# [US South] | +1(623)4049000,,1487195918# [US West] | +1(720)9027700,,1487195918# [US Central]*

- Reminder: CDC Partner Update Call: Engaging Faith Leaders to Advance Effective COVID-19 Response: Lessons Learned through Global-Domestic Collaborations [Link]
  - CDC will host a webinar **Monday, January 25, 2021** at **3:00 pm EST**. During the call, Dr. Cliff McDonald will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Dr. Jay Butler will give a brief status report on the pandemic and an overview of prevention with a specific emphasis on opportunities for faith-based organizations. Dr. Susan Hillis will describe successes from other countries through shared collaborative leadership between faith and government partners. Ms. Lauren Erickson-Mamane will also discuss COVID-19 resources developed for Global Faith Leaders by the International Task Force.
  - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 1/25" in the subject line. The call will be recorded and posted to CDC's website here.
- Reminder: COCA Call: Treating Long COVID: Clinician Experience with Post-Acute COVID-19 Care [Attachment]
  - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **Thursday, January 28, 2021** at **2:00 pm EST**. During this call, presenters will share their firsthand experiences with treating long COVID, focusing on the pulmonary, neurologic, and psychological aspects. They will also describe their experiences with establishing clinics that provide care for patients with these long-term effects.
    - Weblink: https://www.zoomgov.com/j/1606808037?pwd=NUx3a1hQd2tVWVZBU0JobFgxUDJ2Zz09
      Telephone: (669) 254 5252 or (646) 828 7666
      Webinar ID: 160 680 8037
      Passcode: 594536

Post-Event Recording:
https://emergency.cdc.gov/coca/calls/2021/callinfo_012821.asp

- CDC Media Statement: "Media Statement from CDC Director Rochelle P. Walensky, MD, MPH, on Extending the Eviction Moratorium" [Link]
  - From the statement: *"As a protective public health measure, I will extend the current order temporarily halting residential evictions until at least March 31, 2021. The COVID-19 pandemic has presented a historic threat to our nation's health. It has also triggered a housing affordability crisis that disproportionately affects some communities."*
- MMWR Release: "COVID-19 Case Investigation and Contact Tracing Efforts from Health Departments — United States, June 25–July 24, 2020" [Attachment, Link]
  - From the summary: *"An analysis of 56 health departments found wide variation in capacity and capability to conduct timely and effective case investigation and contact tracing. The study found that case interviews were less timely and fewer contacts were identified when caseloads were higher, implying that high numbers of cases compromised the prompt and complete identification of contacts."*
- Reminder: Request Form for CSTE COVID-19 Call Topics [Link]

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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Mar. 23 (incl. DOE Resources, CDC Lab Update, CSTE Webinar, CDC Call to Action, Priority Science Questions, and more)
Date:	Tuesday, March 23, 2021 4:14:59 PM
Attachments:	image001.png image002.png Laboratory Update CMS Posts FAQ for Reporting Sequencing Results for SARS-CoV-2 Variants.msg HHS COVID-19 Update - 322.msg COVID-19 Partner Updates March 22.msg CLIA SARS-CoV-2 Variant FAQ_updated 3.19.21.pdf Department of Education Resources for Reopening Schools.pdf Back to School Call to Action_Final.pdf Partner Update - Priority Science Questions.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- Department of Education Resources for Reopening Schools [Attachment]
    - Please see attached for information regarding:
        - The Department of Education's virtual National Safe School Reopening Summit occurring **tomorrow**, Wednesday, **March 24** (registration is available here)
        - Details on a "Safer Schools and Campuses Best Practices Clearinghouse," which includes a "Lessons from the Field" webinar series that will begin **Wednesday, March 31** (information is available here)
        - The upcoming release of Volume 2 of the K-12 COVID-19 Handbook for districts, schools, and educators
- CDC Lab Update: CMS Posts FAQ for Reporting Sequencing Results for SARS-CoV-2 Variants [Attachment, Link]
    - Please see the following message from CDC's Laboratory Outreach Communication System (LOCS):
        - *On March 19, 2021, the U.S. Centers for Medicare & Medicaid Services (CMS) posted the "CLIA SARS-CoV-2 Variant Testing Frequently Asked Question" document to provide information for facilities that perform sequencing to identify SARS- CoV-2 genetic variants. CMS will not cite CLIA-certified laboratories that perform SARS-CoV-2 genetic variant testing on identified specimens and report*

patient-specific variant results to state or local public health departments without establishing performance specifications as required by §493.1253(b)(2), provided that the laboratory only reports patient-specific results to a public health department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment. If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA-certified laboratory and in compliance with all applicable CLIA regulations."

- The FAQ document is available on CMS' website here.

- CSTE Webinar: "Unpacking the COVID-19 Genomic Epidemiology Toolkit" [Link]
  - The next installment of CSTE's membership webinar series will take place **Thursday, March 25** at **3:00 pm EDT**. The webinar, co-hosted by CSTE and CDC's Office of Advanced Molecular Detection (AMD), will cover the recently released COVID-19 Genomic Epidemiology Toolkit. This toolkit is designed to help epidemiologists use genomic data to track and investigate SARS-CoV-2 in their jurisdictions, and consists of brief, modular video presentations with audio transcripts. During the webinar, featured presenters will showcase toolkit features and answer questions.
  - Call capacity is limited to 1,000 participants, and is first-come, first-served. Call information is below:
    - Weblink: https://webinar.ringcentral.com/j/1466093845
      Telephone: (470) 860-2200 *[East]* | (773) 231-9226 *[North]* | (469) 445-0100 *[South]* | (623) 404-9000 *[West]* | (720) 902-7700 *[Central]*
      Meeting ID: 146 609 3845
      One-Tap Mobile: +1(470)8692200,,1466093845# *[East]* |
      +1(773)2319226,,1466093845# *[North]* |
      +1(469)4450100,,1466093845# *[South]* |
      +1(623)4049000,,1466093845# *[West]* |
      +1(720)9027700,,1466093845# *[Central]*

- CDC Call to Action: "Help Kids' Safe Return to School - Get Caught Up on Recommended Vaccines" [Attachment]
  - Please see below for a message from CDC's COVID-19 Vaccine Task Force Partnership Team:
    - *"COVID-19 disrupted both in-person learning and routine well-child visits for many children over the last year. As a result, too many children have fallen behind on receiving recommended vaccines. We all want our kids to be back in school safely, and that means getting caught up on vaccines that were missed over the last year. Please find attached a Call to Action, which outlines efforts needed to get children caught up on vaccinations. This letter will be posted on the CDC website soon and we will be hosting a partner webinar in the near future to discuss this important topic. Thank you for your continued partnership and attention to this critical issue."*
  - The referenced Call to Action is attached to this email.

- CDC Priority Science Questions [Attachment, Link]
  - Please see attached for a message from CDC's State, Tribal, Local and Territorial

Support Task Force, regarding the release of a new set of *Priority Science Questions* intended to guide prioritization of CDC's scientific research portfolio related to COVID-19, including articles published in *MMWR* and other scientific journals. These questions are in response to the objectives in CDC's *Science Agenda for COVID-19*.
    - The new set of Priority Science Questions is now available on CDC's website here.

Standing Updates

- CDC Partner Update Call: "Understanding the Role of Telehealth Usage During the COVID-19 Pandemic" [Link]
    - CDC will host the next installment of its weekly partner call **Monday, March 29** at **3:00 pm EDT**. Dr. Cynthia Ogden will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Drs Hanna B Demeke, Paramjit Sandhu, and Antoni Neri will discuss highlights on the usage of telehealth systems during the COVID-19 Response.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 3/29" in the subject line. The call will be recorded and posted to CDC's website here.
- CDC Partner Update – March 22 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – March 22 [Attachment]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
    - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Nov. 23 (incl. CDC Travel Planner Launch, CDC Recs and Guidance, WH STLT Call, COCA Call, MMWR Early Releases, and more)
Date:	Monday, November 23, 2020 2:02:37 PM
Attachments:	image001.png image002.png Travel Planner Live to Public.pdf MMWR ER - Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020.pdf MMWR ER - COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State — Minnesota, August–September 2020 - November 20, 2020.pdf MMWR ER - Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020 - November 20, 2020.pdf CDC Response Website Updates (Nov 13–20).docx 2020_11_17_Science-Update_Final-Public.pdf

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[PureMessage: Suspect .eml attachment quarantined.]

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of recent Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

- CDC Travel Planner Public Launch [Attachment]
  - Please see attached for a letter from CDC's Global Migration Task Force announcing the public-facing launch of **CDC Travel Planner**. This web portal serves as a centralized communication platform for COVID-19 travel restrictions and policies enacted by STLT governments. If you have not done so already, add your jurisdiction's information using the instructions listed in the attached letter. You can also promote the Travel Planner using marketing materials linked within.
- CDC Recommendations: "Prioritizing Case Investigations and Contact Tracing for COVID-19 in High Burden Jurisdictions" [Link]
  - Today, CDC released new recommendations for prioritizing case investigations and contact tracing to assist health departments experiencing escalating COVID-19 cases. These new recommendations further refine existing prioritization recommendations and presents new modeling data regarding timeframes to maximize the effectiveness of contact tracing activities.

CDC Guidance: "Considerations for Restaurant and Bar Operators" [Link]

- Released Wednesday, November 18

- White House National State, Local, Tribal COVID-19 Briefing Call [Link]
  - The White House Office of Intergovernmental Affairs (IGA) will host its next weekly briefing call for STLT leaders **Wednesday, December 2** at **1:00 pm EST**. RSVPs will be allocated in the order they are received. To register, click here.
- CDC COCA Call: The Impact of Telehealth on Health Equity from the Perspective of Large Healthcare Systems during the COVID-19 Pandemic [Attachment]
  - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **Tuesday, December 8** at **2:00 pm EST** to discuss how telehealth has affected health equity in their patient populations before and during the COVID-19 pandemic. Presenters from Kaiser Permanente and the Veteran's Health Administration will share strategies to expand access that can reduce disparities and improve culturally responsive care to help achieve health equity within each organization. Call information is below:
    - Weblink: https://www.zoomgov.com/j/1600369650
      Telephone: (669) 254 5252 or (646) 828 7666
      Webinar ID: 160 036 9650
      Post-Event
      Recording: https://emergency.cdc.gov/coca/calls/2020/callinfo_120820.asp
- MMWR Early Release: "The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020" [Attachment, Link]
  - From the summary: *"In addition to scientific data and implementation feasibility, four ethical principles will assist ACIP in formulating recommendations for the initial allocation of COVID-19 vaccine: 1) maximizing benefits and minimizing harms; 2) promoting justice; 3) mitigating health inequities; and 4) promoting transparency."*
- MMWR Early Release: "COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State — Minnesota, August–September 2020" [Attachment, Link]
  - From the summary: *"Following a 10-day motorcycle rally in South Dakota attended by approximately 460,000 persons, 51 confirmed primary event-associated cases, 21 secondary cases, and five tertiary cases were identified in Minnesota residents. An additional nine likely rally-associated secondary or tertiary cases occurred. Four patients were hospitalized, and one died. Genomic sequencing supported the associations with the motorcycle rally."*
- MMWR Early Release: "Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020" [Attachment, Link]
  - From the summary: *"The governor of Kansas issued an executive order requiring wearing masks in public spaces, effective July 3, 2020, which was subject to county authority to opt out. After July 3, COVID-19 incidence decreased in 24 counties with mask mandates but continued to increase in 81 counties without mask mandates."*
- Reminder: CDC Partner Update Call: Resilience and Mental Health for the Holidays [Link]
  - CDC will host a webinar **Monday, November 30** at **3:00 pm EST** focusing on the

upcoming holiday season. Dr. Cliff McDonald will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Additionally, Dr. Kathleen Ethier will discuss strategies for building resilience and mental health during the COVID-19 pandemic and the holiday season.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 11/30" in the subject line. The call will be recorded and posted to CDC's website here.
- CDC Response Website Updates [Attachment]
    - for November 13–20
- CDC COVID-19 Science Update [Attachment, Link]
    - Published November 17
- Reminder: Request Form for CSTE COVID-19 Call Topics [Link]

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
Business Hours Line: 770.458.3811
After-Hours Line: 678.256.3945
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Nov. 6 (incl. CDC Lab Alert and Advisory, MMWR Early Release, CDC Web Updates, CDC Science Update)
Date:	Friday, November 6, 2020 3:14:20 PM
Attachments:	image001.png image002.png MMWR ER - Declines in SARS-CoV-2 Transmission, Hospitalizations, and Mortality After Implementation of Mitigation Measures - November 6, 2020.pdf CDC Response Website Updates (Oct 31–Nov 6).docx 2020_11_03_Science-Update_FINAL-Public.pdf

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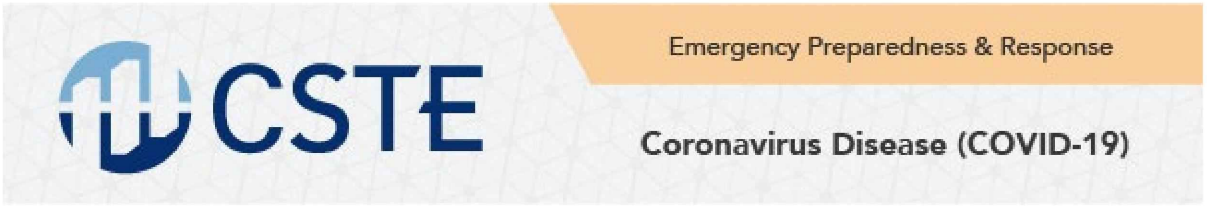
[PureMessage: Suspect .eml attachment quarantined.]



Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of recent Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

- CDC Lab Alert: FDA Issues Safety Letter about Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 [Attachment, Link]
  - Please see the following message from CDC's Laboratory Outreach Communication System (LOCS):
    "On November 3, 2020, the U.S. Food and Drug Administration (FDA) issued a Letter to Clinical Laboratory Staff and Health Care Providers to alert clinical laboratory staff and health care providers that false positive results can occur with antigen tests, including when users do not follow the instructions for use of antigen tests for the rapid detection of SARS-CoV-2. This letter includes important information about potential false positive results with antigen tests for rapid detection of SARS-CoV-2:
    - *Details on false positive results with antigen tests*
    - *Recommendations for health care providers and clinical laboratory staff*
    - *Actions FDA is taking*
    - *Instructions for reporting problems with a device*

    For questions about this letter, email COVID19DX@fda.hhs.gov."
- CDC Lab Advisory: CDC Updates Specimen Collection Guidelines for COVID-19 [Attachment, Link]
  - Please see the following message from CDC's Laboratory Outreach Communication

System (LOCS):
"On November 3, 2020, CDC updated the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19 web page. The updated guidelines provide more detailed recommendations for several methods of collecting specimens for SARS-CoV-2 testing:

- *Nasopharyngeal swabs*
- *Nasal mid-turbinate swabs*
- *Anterior nares specimen collection*
- *Saliva*

- MMWR Early Release: "Declines in SARS-CoV-2 Transmission, Hospitalizations, and Mortality After Implementation of Mitigation Measures— Delaware, March–June 2020" [Attachment, Link]
  - From the summary: *"State-mandated stay-at-home orders and public mask mandates coupled with case investigations with contact tracing contributed to an 82% reduction in COVID-19 incidence, 88% reduction in hospitalizations, and 100% reduction in mortality in Delaware during late April–June."*
- CDC Response Website Updates [Attachment]
  - for October 31–November 6
- CDC COVID-19 Science Update (November 3) [Attachment, Link]
  - The *COVID-19 Science Update* is a publication series from CDC that provides brief summaries of new COVID-19-related studies, intended for use by public health professionals responding to this pandemic. Summaries are released every Tuesday and Friday. All previous COVID-19 Science Updates are available on CDC's website here.
- Reminder: Request for CSTE COVID-19 Call Topics [Link]
  - To ensure timely and relevant information is provided to our members, CSTE has developed a topic submission form, available here. Please submit suggestions for topics (or speakers) to be discussed on future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations.

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Emergency Preparedness & Response Mailbox
Business Hours Line: 770.458.3811
After-Hours Line: 678.256.3945
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Oct. 5 (incl. CDC Lab Alert, MMWR Early Release, FDA Home Test Authorization, and more)
Date:	Tuesday, October 5, 2021 3:22:46 PM
Attachments:	image003.png image004.png MMWR ER - October 5, 2021.pdf Lab Alert Ellume Issues Voluntary Recall of Specific Lots of Ellume COVID-19 Home Tests.msg MasK-12-508.pdf COVID-19 Partner Updates October 4 2021.msg HHS COVID-19 Update - 104.msg FDA Authorizes COVID-19 Over-the-Counter Home Antigen Test.msg

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Lab Alert: Ellume Issues Voluntary Recall of Specific Lots of Ellume COVID-19 Home Tests [Attachment, Links]
    - Please see the following message from CDC's Laboratory Outreach Communication System (LOCS):
      *"On **October 1**, the digital diagnostics company Ellume announced a voluntary recall on specific lots of the Ellume COVID-19 Home Test, the company's rapid, self-administered COVID-19 antigen test, because there is an increased chance that tests from the affected lot numbers may give a false positive result. Ellume advises consumers to visit their website to check whether their product is part of the affected lots and, if affected, to receive further instructions."*
- MMWR Early Release: "National and State Trends in Anxiety and Depression Severity Scores Among Adults During the COVID-19 Pandemic — United States, 2020–2021" [Attachment, Link]
    - From the summary: *"Nationwide, average anxiety severity scores increased 13% from August to December 2020 and then decreased 26.8% from December 2020 to June 2021. Similar increases and decreases occurred in depression severity scores."*
- FDA Authorizes Additional OTC Home Test to Increase Access to Rapid Testing for Consumers [Attachment, Link]

On **October 4**, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the ACON Laboratories Flowflex COVID-19 Home Test, an over-the-counter (OTC) COVID-19 antigen test, which adds to the growing list of tests that can be used at home without a prescription. This action (linked here and attached) should significantly increase the availability of rapid, at-home tests and is expected to double rapid at-home testing capacity in the U.S. over the next several weeks. By years end, the manufacturer plans to produce more than 100 million tests per month, and this number will rise to 200 million per month by February 2022.

- CDC MasK-12 Project [Attachment]
    - CDC is partnering with schools and districts in states throughout the U.S. this fall to evaluate mask adherence in K-12 schools. CDC will train school-identified observers to collect data on mask adherence across participating schools. Observers may include high school students who are interested in science or public health, and the project offers a great opportunity for real-world public health experience. Schools can also use staff or volunteers to conduct observations.
    - Results from this investigation will be used to inform decision-making around masking in K-12 school settings, report findings to evaluate messaging and education around mask use, and to identify locations on school campuses where mask adherence can be improved. Enrollment for the MasK-12 project will occur in early October. If you are interested in participating or would like to learn more, email eocevent335@cdc.gov.

Standing Updates

- CDC Partner Update – October 4 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – October 4 [Attachment]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
    - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please

visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Oct. 6 (incl. Abbott BinaxNOW Training, MMWR Early Release, CDC Partner Call)
Date:	Tuesday, October 6, 2020 3:38:53 PM
Attachments:	image001.png image002.png MMWR ER COVID-19 Incidence After Mitigation Measures - October 6, 2020.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, Surveillance/Informatics Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of recent Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

- Webinars: Abbott BinaxNOW Training [Links]
  - This week, Abbott Laboratories will hold two educational webinars in support of their BinaxNOW COVID-19 tests. These webinars are designed to reinforce the Training Toolkit and highlight key points that should be kept in mind during BinaxNOW COVID-19 and NAVICA implementation. To register for either training, please use the links below:
    - **Wednesday, October 7** at **4:00 pm EDT**: [Link]
    - **Friday, October 9** at **4:00 pm EDT**: [Link]
  - For additional training videos and documents, visit Abbott's website here.
- MMWR Early Release: "Trends in COVID-19 Incidence After Implementation of Mitigation Measures — Arizona, January 22–August 7, 2020" [Attachment, Link]
  - From the summary: *"The number of COVID-19 cases in Arizona stabilized and then decreased after sustained implementation and enforcement of statewide and locally enhanced mitigation measures, beginning approximately 2 weeks after implementation and enforcement of mask mandates and enhanced sanitations practices began on June 17; further decreases were observed during July 13–August 7, after statewide limitations and closures of certain services and businesses."*
- CDC Partner Update Call: Campus Guidebook – Slowing the Spread at US Colleges and Universities [Link]
  - CDC will host a webinar **Monday, October 19** at **3:00 pm EDT**, focusing on COVID-19 at colleges and universities. Dr. Cliff McDonald will share updates on CDC's COVID-19 response, including the latest scientific information available. Additionally, Drs. Greta

Massetti and Lisa Barrios will review CDC COVID-19 guidance for institutes of higher education.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 10/19" in the subject line. The call will be recorded and posted to CDC's website here.
- Reminder: Request for CSTE COVID-19 Call Topics [Link]
    - To ensure timely and relevant information is provided to our members, CSTE has developed a topic submission form, available here. Please submit suggestions for topics (or speakers) to be discussed on future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations.

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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
Business Hours Line: 770.458.3811
After-Hours Line: 678.256.3945
preparedness.cste.org

From: CSTE Emergency Response
To: CSTE Emergency Response
Cc: CSTE Novel Coronavirus 2019
Subject: CSTE COVID-19 Response | Materials from Ad Hoc All State Epi Call (Oct. 19)
Date: Wednesday, October 21, 2020 5:52:38 PM
Attachments: image001.png
image002.png
image003.png
Science Agenda Development and Update.pdf
Mask Effectiveness References.zip
20201016_Science Update.pdf
20200925_Science Update.pdf
20200521_Science Update.pdf

Sent to State Epidemiologists, CLUE, and the CSTE Executive Board

Thank you for joining this week's CSTE COVID-19 Response Ad Hoc Weekly All State Epi Call. The following call materials have been gathered for your awareness:

- Slides: "Science Agenda Development and Update" [Attachment]
  - Presented by Dr. Chris Braden, CDC
- Resources: Effectiveness of Community Mask Use [Links, Attachments]
  - In response to a request for additional scientific evidence regarding effectiveness of community mask use to support local mandates, please find the attached articles shared with us by Dr. McDonald and Dr. John Brooks. Dr. Brooks also recommended the October 3–9 Weekly Science Review from *Resolve to Save Lives*, available here.
  - Additionally, Dr. McDonald recommended the new *CDC COVID-19 Science Update* publication series, available on CDC's website here. Three of these updates feature either summaries or informative briefs on articles related to masks, and are attached to this email for your convenience.
- Announcement 1: NIOSH Funding Opportunity Announcement for State Occupational Safety and Health Surveillance Programs [Links]
  - The National Institute for Occupational Safety and Health (NIOSH) recently published the funding announcement for the State Occupational Safety and Health Surveillance Program. NIOSH intends to commit $40 million in total costs (direct and indirect) over a five-year period to fund about 30 applications. The letter of intent deadline is **October 30**, and the deadline to apply for this cooperative agreement is **December 16**. Full funding details can be found at grants.gov; for more information, please contact NIOSH Scientific Program Official, CAPT Linda West, at lkw0@cdc.gov.
    - You can find more information about the State Occupational Safety and Health Surveillance Program on NIOSH's website here. For more information on the

grant process, visit the NIOSH Extramural Research and Training Programs website here.

- Announcement 2: NHSN Webinars - "Reporting Results of Point of Care Testing for COVID-19 – A New NHSN Pathway" [Links]
  - CDC's National Healthcare Safety Network (NHSN) team will host two webinars this week to train attendees on its new Long Term Care Facility COVID-19 Pathway laboratory data reporting option. This option will enable nursing homes to enter point of care (POC) SARS-CoV-2 laboratory test data into the NHSN application. NHSN, in turn, will report the nursing home POC laboratory test data electronically to the public health agency—state or local—that has jurisdictional authority and responsibility to receive and use the nursing home's data. Webinar information is below:
    - **Thursday, October 22** at **11:00 am EDT**
      Weblink: https://cdc.zoomgov.com/j/1613111399?pwd=NjNCR0svMFk3N1JtUWhZVUxOT3YxUT09
      Passcode: 6x+*.8bx
      - One-Tap Mobile:
        +16692545252,,1613111399#,,,,,,0#,,73848065# *or* +16468287666,,1613111399#,,,,,,0#,,73848065#
        Telephone: (669) 254-5252 *or* (646) 828-7666
        Meeting ID: 161 311 1399
        Passcode: 73848065
    - **Friday, October 23** at **2:00 pm EDT**
      Registration link: https://cdc.zoomgov.com/meeting/register/vJIsd-2orzooHuSyPRJ5icjmzTkwOlSrC1k
      - After registering, you will receive a confirmation email containing call information
      - This will be a rebroadcast of the 10/22 training, followed by a live Q&A session

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As a reminder, the next CSTE Ad Hoc Weekly All State Epi Call is **Monday, October 26** at 4:00 pm EDT.

Council of State and Territorial Epidemiologists · 2635 Century Parkway NE, Ste 700 · Atlanta, Georgia 30345 · 770.458.3811 · 770.458.8516

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CSTE

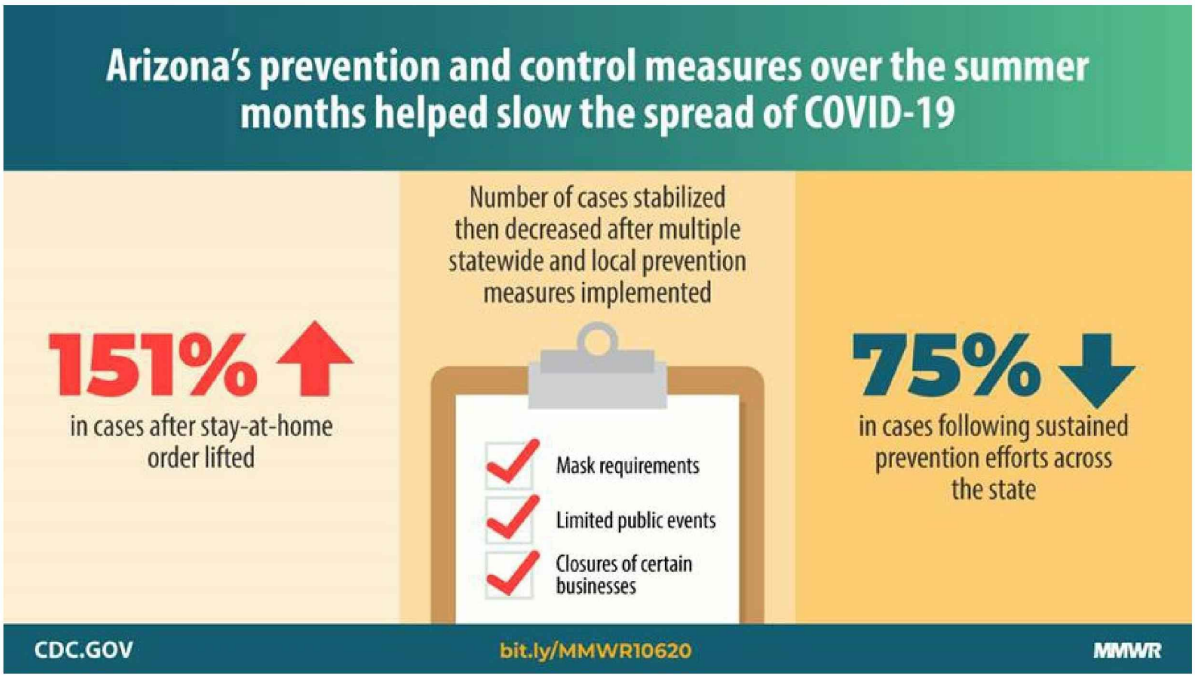
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
Business Hours Line: 770.458.3811

After-Hours Line: 678.256.3945
preparedness.cste.org

From: CDC Weekly Preview (CDC)
Subject: Embargoed: MMWR Early Release Preview for October 6, 2020
Date: Tuesday, October 6, 2020 10:01:01 AM
Attachments: image001.png
image006.png
MMWR ER COVID-19 Incidence After Mitigation Measures - October 6, 2020.pdf

All information in this email is embargoed. Please do not distribute or share this information through email, print, the Internet, or social media until after 1 pm (ET), Tuesday, October 6, 2020. Information and dates are subject to change.

MMWR
Morbidity and Mortality Weekly Report
The MMWR is embargoed until 1 PM ET Tuesday, October 6, 2020



Trends in COVID-19 Incidence After Implementation of Mitigation Measures — Arizona, January 22-August 7, 2020
Link when live: https://www.cdc.gov/mmwr/volumes/69/wr/mm6940e3.htm?s_cid=mm6940e3_w

Subscribe to the new *MMWR* podcast series
The *MMWR* Weekly COVID-19 Briefing is a weekly podcast to update readers on the latest scientific information from CDC's COVID-19 response. In each episode, *MMWR* Editor-in-Chief Dr. Charlotte Kent provides an overview of the latest scientific information published in *MMWR*. New episodes are posted every Monday. Subscribe on Apple Podcasts, Stitcher, Spotify, and Google Play.

This week, MMWR published a series of reports describing the role that young adults have played in the spread of COVID-19. This issue also looked at COVID-19 among school-aged children and CDC deployments to work with health agencies in state, tribal, local, and territorial areas.

For questions, please contact MMWRCommunications@cdc.gov
For media questions, please contact Media@cdc.gov
To subscribe to *MMWR*: Click here

From:	Craig, Jim
To:	Adcox-Green, Ashley; Boxx, Robert; Byers, Paul; Craft, Christy; Darnell, Tim; Hall, David; Horn, Marshall; Jennings, Twyla; Parker, Melissa; Sharlot, Liz; Taylor, Kathryn; William McLeod; Vaughn1, Wayne; Ware, Daphne; Williams, Alisa; Young, Dorthy
Subject:	FW: CDC COVID-19 Weekly Digest of Resources: 1/30 - 2/5
Date:	Monday, February 8, 2021 6:26:06 PM
Attachments:	2021-02-05-Science-Update_Final_Public.pdf ELC_EnhancingDetectionExpansion_FAQs_2Feb2021.pdf Fact Sheet_12-things-jurisdictions-need-to-know-about-vaers_Feb2021.pdf

FYSA

From: Green, Jamilla (CDC/DDID/NCEZID/DPEI) <qwq7@cdc.gov>
Sent: Monday, February 8, 2021 5:02 PM
To: Byers, Paul <Paul.Byers@msdh.ms.gov>; Craig, Jim <Jim.Craig@msdh.ms.gov>; Jefferson, Randy (CDC/DDID/NCHHSTP/DSTDP) <ryj8@cdc.gov>; Ware, Daphne <Daphne.Ware@msdh.ms.gov>; Vaughn, Wayne <Wayne.Vaughn@msdh.ms.gov>
Cc: CDC IMS 2019 NCOV Response HDTF 4/6 Regional Support TM <eocevent438@cdc.gov>
Subject: CDC COVID-19 Weekly Digest of Resources: 1/30 - 2/5

Good afternoon Mississippi Colleagues,

Here is your weekly digest of CDC resources.

CDC COVID-19 Science Update: See the latest science update, released on 2/5/2021, attached to this email. Previous science updates can be viewed at ***https://www.cdc.gov/library/covid19*.**

MMWR Articles: Below are links to recent COVID MMWR articles

- **February 5, 2021 (Early Release)** Observed Face Mask Use at Six Universities — United States, September–November 2020
- **February 5, 2021 (Early Release)** Decline in COVID-19 Hospitalization Growth Rates Associated with Statewide Mask Mandates — 10 States, March–October 2020
- **February 5, 2021** Sexual Orientation Disparities in Risk Factors for Adverse COVID-19–Related Outcomes, by Race/Ethnicity — Behavioral Risk Factor Surveillance System, United States, 2017–2019
- **February 5, 2021** Decreases in Young Children Who Received Blood Lead Level Testing During COVID-19—34 Jurisdictions, January–May 2020
- **February 5, 2021** Racial and Ethnic Disparities in the Prevalence of Stress and Worry, Mental Health Conditions, and Increased Substance Use Among Adults During the COVID-19 Pandemic — United States, April and May 2020
- **February 5, 2021** Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program — United States, December 14, 2020–January 14, 2021
- **February 5, 2021** Early COVID-19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program — United States, December 2020–January 2021

*Older MMWR COVID-19 Reports can be viewed at
https://www.cdc.gov/mmwr/Novel_Coronavirus_Reports.html

CDC Website Updates: Please find updated CDC website pages for 1/30-2/5

Response Website Updates (1/30/21-2/5/21)

- Cases in the U.S. Friday, February 05, 2021
- Overall US COVID-19 Vaccine Distribution and Administration Update as of Fri, 05 Feb 2021 06:00:00 EST Friday, February 05, 2021
- COVID-19 Science Update released: February 5, 2021 Edition 75 Friday, February 05, 2021
- Vaccination Considerations for Persons with Disabilities Friday, February 05, 2021
- COVID-19 Vaccination for Communities Friday, February 05, 2021
- Requirement for Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States Friday, February 05, 2021
- Information for School Nurses and Other Healthcare Personnel (HCP) Working in Schools and Child Care Settings Friday, February 05, 2021
- Guidance for SARS-CoV-2 Point-of-Care Testing Friday, February 05, 2021
- Toolkit for Correctional and Detention Facilities Friday, February 05, 2021
- eCR Now: COVID-19 Electronic Case Reporting Friday, February 05, 2021
- COVID-19 Questions and Answers: For People Who Use Drugs or Have Substance Use Disorder Friday, February 05, 2021
- More Resources about COVID-19 Friday, February 05, 2021
- Protecting Seafood Processing Workers from COVID-19 Friday, February 05, 2021
- Communication Toolkit Friday, February 05, 2021
- Manufacturing Workers and Employers Friday, February 05, 2021
- Meat and Poultry Processing Workers and Employers Friday, February 05, 2021
- COVIDView Weekly Summary Friday, February 05, 2021
- COVID-19 Travel Recommendations by Country Friday, February 05, 2021
- Cases, Data, and Surveillance Friday, February 05, 2021
- Community, Work, and School Friday, February 05, 2021
- CDC Readiness and Planning Tool: To Prevent the Spread of COVID-19 in Primary and Secondary Schools in Low Resource Non-U.S. Settings Thursday, February 04, 2021
- COVID-19 Vaccine Information for Specific Groups Thursday, February 04, 2021
- US COVID-19 Cases Caused by Variants Thursday, February 04, 2021
- Workplaces and Businesses Thursday, February 04, 2021
- Wear Face Masks on Public Transportation Conveyances and at Transportation Hubs Thursday, February 04, 2021
- Federal Register Notice: Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19 Thursday, February 04, 2021
- Investigating the Impact of COVID-19 during Pregnancy Thursday, February 04, 2021
- Toolkit for People with Disabilities Thursday, February 04, 2021
- Print Resources Thursday, February 04, 2021
- How to Protect Yourself & Others Thursday, February 04, 2021
- ACIP Live Meeting Archive - January 27, 2021 Wednesday, February 03, 2021
- Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination Wednesday, February 03, 2021
- Federal Retail Pharmacy Partnership Program for COVID-19 Vaccination FAQs Wednesday, February 03, 2021
- Pharmacies Participating in the Federal Retail Pharmacy Program Wednesday, February 03, 2021
- Global Clinical Mitigation Wednesday, February 03, 2021
- Science Briefs Wednesday, February 03, 2021
- When Vaccine is Limited, Who Gets Vaccinated First? Wednesday, February 03, 2021

- Vaccines Wednesday, February 03, 2021
- Previous COVID-19 Forecasts: Cases Wednesday, February 03, 2021
- COVID-19 Forecasts: Cases Wednesday, February 03, 2021
- COVID-19 One-Stop Shop Toolkits Wednesday, February 03, 2021
- People with Certain Medical Conditions Wednesday, February 03, 2021
- Considerations for Public Beaches Wednesday, February 03, 2021
- Crew Disembarkations through Commercial Travel Wednesday, February 03, 2021
- Previous COVID-19 Forecasts: Hospitalizations Wednesday, February 03, 2021
- COVID-19 Forecasts: Hospitalizations Wednesday, February 03, 2021
- Daily Activities and Going Out Wednesday, February 03, 2021
- Operating schools during COVID-19: CDC's Considerations Wednesday, February 03, 2021
- Previous Forecasts of Total Deaths Wednesday, February 03, 2021
- COVID-19 Forecasts: Deaths Wednesday, February 03, 2021
- Community Mitigation Wednesday, February 03, 2021
- Staffing Resources Wednesday, February 03, 2021
- Coronavirus Disease 2019 (COVID-19) Wednesday, February 03, 2021
- What Aircraft Maintenance Workers Need to Know about COVID-19 Wednesday, February 03, 2021
- Information for Health Departments on Reporting Cases of COVID-19 Wednesday, February 03, 2021
- Interim Guidance for Health Departments: COVID-19 Vaccination Implementation for People Experiencing Homelessness Tuesday, February 02, 2021
- Global Community Mitigation Tuesday, February 02, 2021
- New Variant of Virus that Causes COVID-19 Detected Tuesday, February 02, 2021
- Testing and International Air Travel Tuesday, February 02, 2021
- Know Your Travel Risk Tuesday, February 02, 2021
- Know When to Delay your Travel to Avoid Spreading COVID-19 Tuesday, February 02, 2021
- Travel during the COVID-19 Pandemic Tuesday, February 02, 2021
- Returning to Work Tuesday, February 02, 2021
- Research Use Only CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay Real-Time RT-PCR Primers and Probes Tuesday, February 02, 2021
- CDC's Diagnostic Multiplex Assay for Flu *and* COVID-19 and Supplies Tuesday, February 02, 2021
- COVID-19 in Newly Resettled Refugee Populations Tuesday, February 02, 2021
- Agriculture Workers and Employers Tuesday, February 02, 2021
- Test for Past Infection Tuesday, February 02, 2021
- What Airline Catering Kitchen Workers Need to Know about COVID-19 Tuesday, February 02, 2021
- COVID-19 Employer Information for Transit Maintenance Workers Tuesday, February 02, 2021
- What Airline Customer Service Representatives and Gate Agents Need to Know about COVID-19 Tuesday, February 02, 2021
- Use of Masks to Help Slow the Spread of COVID-19 Tuesday, February 02, 2021
- K-12 Schools and Childcare Programs Tuesday, February 02, 2021
- Travelers Returning from Cruise Ship and River Cruise Voyages Tuesday, February 02, 2021
- After You Travel Tuesday, February 02, 2021
- Travel: Frequently Asked Questions and Answers Tuesday, February 02, 2021
- Frequently Asked Questions Tuesday, February 02, 2021
- Travel Tuesday, February 02, 2021
- COVID-19 Graphics and Buttons Monday, February 01, 2021

Considerations for Public Pools, Hot Tubs, and Water Playgrounds During COVID-19 Monday, February 01, 2021

- Air Travel Toolkit for Airline Partners Monday, February 01, 2021
- Road Travel Toolkit for Transportation Partners Monday, February 01, 2021
- General Business Frequently Asked Questions Monday, February 01, 2021
- What to Know About HIV and COVID-19 Monday, February 01, 2021
- Information for Laboratories about Coronavirus (COVID-19) Monday, February 01, 2021
- Information for Healthcare Professionals about Coronavirus (COVID-19) Monday, February 01, 2021
- What Paratransit Operators Need to Know about COVID-19 Saturday, January 30, 2021
- What Transit Station Workers Need to Know about COVID-19 Saturday, January 30, 2021
- What Bus Transit Operators Need to Know about COVID-19 Saturday, January 30, 2021
- What Rail Transit Operators Need to Know about COVID-19 Saturday, January 30, 2021
- Personal and Social Activities Saturday, January 30, 2021
- Protect Yourself When Using Transportation Saturday, January 30, 2021
- How to Select, Wear, and Clean Your Mask Saturday, January 30, 2021
- How to Wear Masks Saturday, January 30, 2021
- What Rideshare, Taxi, Limo, and other Passenger Drivers-for-Hire Need to Know about COVID-19 Saturday, January 30, 2021

*Daily website updates are now viewable at https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html

Updates on the Federal Retail Pharmacy Program for COVID-19 Vaccination

The initial phased implementation of the program will begin with select retail pharmacies administering COVID-19 vaccine across the country as early as Thursday, February 11. The program will be implemented incrementally, based on the available supply of COVID-19 vaccines. As the vaccine supply increases, the program aims to expand the number of participating pharmacy locations ultimately providing COVID-19 vaccines in all 40,000 retail pharmacy locations nationwide. Allocations to support the Federal Retail Pharmacy Program are separate from weekly allocations provided to jurisdictions. What jurisdictions see in their weekly allocation will remain stable.

Eligibility Criteria for Vaccination

The Federal pharmacy partners will administer vaccine to individuals according to state-selected eligibility criteria. Pharmacy partners have developed screening questionnaires specific to each jurisdiction's criteria and will finalize them based on the survey results to help ensure eligibility prior to vaccination. After launch, immunization program managers will be able to update eligibility criteria weekly using an application in Tiberius, the centralized system used by the federal government to support vaccine distribution efforts. Information about how to use this new Tiberius application will be sent to immunization programs this week.

Program Data and Monitoring

By Friday, CDC will provide a list of the retail locations that will be providing COVID-19 vaccine in each jurisdiction as part of the initial phased implementation of the program.

All pharmacy partners enrolled in the Federal Retail Pharmacy Program are required to report inventory daily to VaccineFinder and patient administration information to the jurisdiction's IIS as

well as directly to CDC's Data Clearing House. Jurisdictions will have access to patient administration data submitted by all pharmacies in their jurisdiction. Jurisdictions will also have access to information in Tiberius-specific to pharmacy programs.

Information will include details on stores that will be receiving vaccine, store-level supply information, and administration/uptake information as it becomes available. Jurisdictions will also be provided points of contacts for pharmacy partners to facilitate coordination with partners.

Communications Support

CDC has developed a **toolkit of materials** to help jurisdictions and partners describe and communicate about the implementation of the Federal Retail Pharmacy Program. We hope these materials will assist in providing clear and consistent information about the program goals and parameters.

The toolkit includes the attached materials for your use and reference:

- Frequently Asked Questions about the Program for Jurisdictions and Pharmacy Partners
- Key communication messages for jurisdictions and pharmacy partners
- A One-Page Fact Sheet on the Federal Retail Pharmacy Program (to share with partners or members of the community)

Upcoming Trainings/Webinars/Jurisdictional Calls

- Below is a link to a series of accredited education about COVID-19 vaccine in general, safety, and administration considerations.
    - Vaccine Courses, Broadcasts, Webcasts and Self Study Training | CDC
- Tiberius users can access the training video on submitting transfer requests at the following link: https://protect-ows.hhs.gov/workspace/compass/view/ri.compass.main.folder.c95b290c-2561-4cd1-85f7-e31dac51d34b [protect-ows.hhs.gov

Upcoming NACCHO Webinars:

Tuesday, February 9 at 12 pm ET: COVID-19 Action in the Biden Era: A Fireside Chat with Dr. Fauci

Upcoming CDC Foundation Webinar:

February 24 at 1:00-2:00 pm EST - Updates and Resources from CDC and Ad Council

During this session,

- Anne Schuchat, principal deputy director at the CDC, will provide an update on vaccine distribution.
- A representative from the Ad Council will present messaging content and guidance for local public health officials
- Judy Monroe, president, and CEO of the CDC Foundation, will moderate an audience Q&A.

Georgia Tech Center for Design and Inclusive Innovation Webinar:

February 10 at 2:00 pm EST

- Guidance for Businesses and Employers Considering the Needs of People with Disabilities during COVID-19

CDC COVID-19 Partner Update Webinar

- COVID-19 Information for Essential Workplaces
- February 8 at 3:00 PM ET

NEW Pharmacy/LTCF Office Hours

- Office Hours will now be held twice a week on Tuesdays and Fridays from 4 - 4:30 pm ET. Please find the call-in information below:

Microsoft Teams meeting

Join on your computer or mobile app

Click here to join the meeting

Or call in (audio only)

+1 404-718-3800,,561828018# United States, Atlanta

(888) 994-4478,,561828018# United States (Toll-free)

Phone Conference ID: 561 828 018#

Find a local number | Reset PIN

Learn More | Meeting options

Upcoming National Vaccine Advisory Committee (NVAC) Meeting

- February 4-5, 1:00-5:45 PM
- Live webcast link and agenda found here

COVID-19 Resources

- Vaccine Confidence Consultations from Vaccine Task Force
  - This email serves as an entry point to many vaccine confidence consultation options offered by CDC. Vaccine confidence and communications experts will receive emails from providers and public health professionals and then set up brief calls to understand needs, tailor support, and provide further technical assistance in data collection, creation of communication products and more to promote community vaccine confidence for COVID-19 vaccines. They can be contacted at confidenceconsults@cdc.gov
- ELC Enhancing Detection Expansion FAQ (attached)
  - Developed by the ELC Team, this FAQ answers common questions about Enhancing Detection Expansion funding for jurisdictions. More information can be found on the ELC Website.
- Factsheet: 12 Things Jurisdictions Need to Know about VAERS (attached)
  - A factsheet developed by VTF on how to report adverse events following vaccination to the Vaccine Adverse Events Reporting System (VAERS)
- The COVID State-Profiles Report (aka Governors Report) is now posted publicly at COVID Data Tracker, and will be updated weekly. As a reminder, Community Profile Report has been posted publicly since December, and is updated daily. There is also a public facing version of the **T**herapeutics Distribution Location Tool**.**
- COVID-19 Vaccination Communication Toolkits for Community- Based Organizations and Essential Workers
  - COVID-19 vaccines will be available to essential workers and other community members soon. CDC has designed two toolkits to help build confidence in this new vaccine. The toolkits will help community-based organizations (CBOs) and employers to educate community members and workers about COVID-19 vaccines, raise awareness about the benefits of vaccination, and address common questions and concerns.

Thank you,

Jamilla Green, DrPH, MPH, CPH

Health Department Liaison (Region 4: KY, MS)
Health Department Section
State, Tribal, Local, and Territorial Support Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
qwq7@cdc.gov

From:	Byers, Paul
To:	Dobbs, Thomas E; Central Office Epi COVID Team; Craig, Jim; Broom, Sarah; Pearson, Meg; Smith, Elisabeth
Subject:	FW: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)
Date:	Tuesday, January 11, 2022 4:27:00 PM
Attachments:	image001.png image002.png N95 effectiveness as source control .pdf PARTNER ALERT CDC Expands Booster Shot Eligibility.msg COVID-19 Partner Updates January 10 2022.msg HHS Therapeutics Projected Allocations_7 Jan 2022.pdf HHS Update COVID-19 allocation projections for January .pdf Lindsley-2021-A comparison of performance metr.pdf Lindsley-2021-Efficacy of face masks, neck gai.pdf

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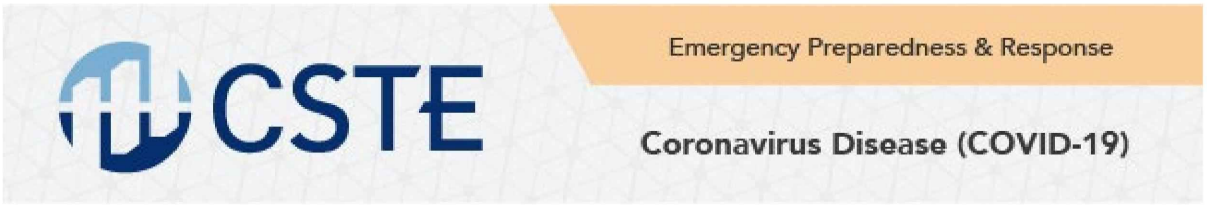
Please see updates.

Paul Byers, MD
State Epidemiologist

From: CSTE Emergency Response <Preparedness@cste.org>
Sent: Tuesday, January 11, 2022 4:17 PM
To: CSTE Emergency Response <Preparedness@cste.org>
Cc: CSTE Novel Coronavirus 2019 <CSTEncov2019@cste.org>
Subject: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)



Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Partner Alert: N95 Effectiveness as Source Control [Attachments]
    - Today, **Tuesday, January 11**, CDC issued a partner update (attached) in response to numerous questions about N95 mask effectiveness as source control. The update shared two peer reviewed publications from National Institute for Occupational Safety and Health (NIOSH) researchers (both attached) on N95 mask effectiveness, including findings that a N95 respirator was 99% effective at blocking cough aerosols.

HHS Update: COVID-19 Allocation Projections for January [Attachments]

- On **Friday, January 7**, the U.S. Department of Health and Human Services (HHS) issued an update with a projected calendar of allocation amounts and cadence of COVID-19 therapeutics for the remainder of January (attached). Questions may be directed to us COVID19Therapetuics@hhs.gov.

- Partner Alert: CDC Expands Booster Shot Eligibility [Attachment, Link]
  - On **Saturday, January 6**, CDC issued a partner alert (attached) adjusting its recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months. CDC has extended this recommendation to recipients of a Moderna primary series. This means that people 12 years of age and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.
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From:	Craig, Jim
To:	Adcox-Green, Ashley; Boxx, Robert; Byers, Paul; Craft, Christy; Darnell, Tim; Hall, David; Horn, Marshall; Jennings, Twyla; Parker, Melissa; Sharlot, Liz; Taylor, Kathryn; William McLeod; Ware, Daphne; Williams, Alisa; Young, Dorthy
Subject:	FW: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)
Date:	Wednesday, January 12, 2022 8:45:26 AM
Attachments:	image001.png image002.png N95 effectiveness as source control .pdf PARTNER ALERT CDC Expands Booster Shot Eligibility.msg COVID-19 Partner Updates January 10 2022.msg HHS Therapeutics Projected Allocations_7 Jan 2022.pdf HHS Update COVID-19 allocation projections for January .pdf Lindsley-2021-A comparison of performance metr.pdf Lindsley-2021-Efficacy of face masks, neck gai.pdf

Interesting studies on mask efficacy. Spoiler alert – while there is variability and more study needed, they work.

Jim

From: Byers, Paul <Paul.Byers@msdh.ms.gov>
Sent: Tuesday, January 11, 2022 4:27 PM
To: Dobbs, Thomas E <Thomas.Dobbs@msdh.ms.gov>; Central Office Epi COVID Team <CentralOfficeEpiCOVIDTeam@msdh.ms.gov>; Craig, Jim <Jim.Craig@msdh.ms.gov>; Broom, Sarah <Sarah.Broom@msdh.ms.gov>; Pearson, Meg <Meg.Pearson@msdh.ms.gov>; Smith, Elisabeth <elisabeth.smith@msdh.ms.gov>
Subject: FW: CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)

Please see updates.

Paul Byers, MD
State Epidemiologist

From: CSTE Emergency Response <Preparedness@cste.org>
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To: CSTE Emergency Response <Preparedness@cste.org>
Cc: CSTE Novel Coronavirus 2019 <CSTEncov2019@cste.org>
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To:	Dobbs, Thomas E; Central Office Epi COVID Team; Craig, Jim; Broom, Sarah; Pearson, Meg; Smith, Elisabeth
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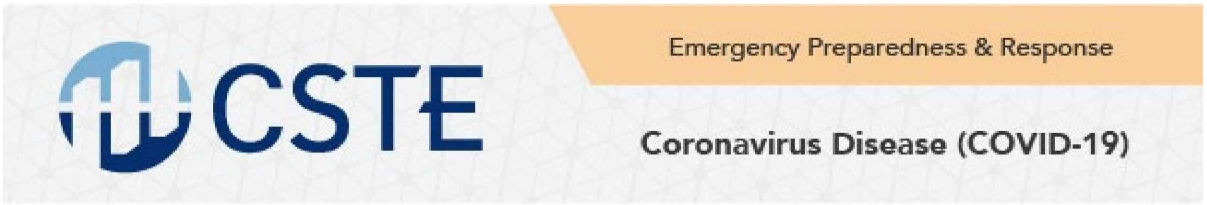

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To:	Adcox-Green, Ashley; Boxx, Robert; Byers, Paul; Craft, Christy; Darnell, Tim; Hall, David; Horn, Marshall; Jennings, Twyla; Parker, Melissa; Sharlot, Liz; Taylor, Kathryn; William McLeod; Ware, Daphne; Williams, Alisa; Young, Dorthy
Subject:	FW: HHS COVID-19 Update - 3/31
Date:	Friday, April 2, 2021 6:03:48 AM

Good morning!

From: Polk, Jennifer (OS/ASPR/SIIM) <Jennifer.Polk@hhs.gov>
Sent: Thursday, April 1, 2021 7:53 AM
Subject: HHS COVID-19 Update - 3/31

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Wednesday, March 31, 2021 8:26 PM
Subject: HHS COVID-19 Update - 3/31

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 31, 2021:

Highlights from the White House COVID-19 Response Team briefing:

Andy Slavitt:

- **Increasing Vaccination Sites:** The President committed to opening at least 12 more federally run mass vaccination sites, adding to the existing total of 25 sites. Three new sites will open next week in Memphis, Tennessee, Milwaukee, Wisconsin, and Greenbelt, Maryland, in addition to the two we announced on Monday in St. Louis, Missouri, and Gary, Indiana. Each of these sites is the first federally run mass vaccination site in its respective state, and each can administer 3,000 vaccinations a day.
- **Mask Mandates:** We need every governor, mayor, and local leader to maintain or reinstate mask mandates. And we need every American to do their part so that we can win this race and save lives.

Dr. Walensky:

- **Case Update:** CDC's most recent data show that the seven-day average of new cases is slightly less than 62,000 cases per day. We continue to see an increase, and this is almost a 12 percent increase from the seven-day period prior. Hospitalizations also continue to increase. The most recent seven-day average — about 4,900 admissions per day — is up from 4,600 admissions per day in the prior seven-day period. The seven-day average of deaths remains slightly above 900 deaths per day.
- **Inequities in COVID-19 Deaths:** COVID-19 deaths were highest for older adults and males, and were higher, as we previously saw, among American Indian and Alaska Natives, Hispanics, non-Hispanic Blacks, and non-Hispanic Native Hawaiian and Pacific Islander persons compared

to non-Hispanic whites. In fact, among nearly all these ethnic and racial minority groups, the COVID-19-related deaths were more than double the death rate of non-Hispanic white persons. Based on the current state of the pandemic, these impacts have remained in 2021, where we continue to see that communities of color account for an outsize portion of these deaths.

- **Number of People Vaccinated:** This week, we will reach 100 million people who have received at least one dose of the COVID-19 vaccine in the United States — a remarkable feat in such a short period of time. Further, over 70 percent of people over age 65, our most vulnerable group, have received at least one vaccine dose. In addition to increasing the number of mass vaccination sites across the country with FEMA, expanding the Federal Retail Pharmacy Program, and ensuring that all Americans have a vaccine site within five miles of their home, we are also activating mobile vaccination units and clinics. CDC is also excited to partner with the Administration for Community Living to support their efforts to get older, at-risk adults and those with disabilities vaccinated.
- **Guidance for Adult Day Service Centers:** CDC updated COVID-19 guidance for adult day service centers. These populations are at high risk for severe COVID-19 disease, and this guidance will help center administrators and staff protect themselves and adults receiving their services by promoting and engaging in preventive behaviors that reduce COVID-19 spread and help maintain healthy operations and environments of these facilities.
- **B.1.1.7 Variant:** We now have B.1.1.7 (U.K. variant) as 26 percent of the circulating variant across the United states, and it is the predominant strain in at least five regions of the United States. The variant is more transmissible – somewhere between 50 and 70 percent more transmissible than the wild-type strain. Therefore, to the extent that people are not practicing those standard mitigation strategies, we do think that more infections will result because of B.1.1.7. We believe that the current mitigation strategies of masking and distancing would work just as well against the current, the wild-type strain, as they do the B.1.1.7 strain.

Dr. Fauci:

- **Importance of Getting Vaccinated:** We are seeing now immune protection against COVID-19 variants when individuals are vaccinated against the wild-type strain, namely the common virus in society, on two mechanisms: the antibody response that has a spillover effect and the cross-reactivity. Vaccination is not only going to protect us against the common COVID-19 virus in society, but it has the potential, to a greater or lesser degree, to also protect against a range of variants. So, when vaccination becomes available, get vaccinated.

Vaccine Updates

Federal Retail Pharmacy Program: CDC updated their general information on the Federal Retail Pharmacy Program for COVID-19 Vaccination. As the program expands and supply becomes more readily available, the allocation may be adjusted to reflect partner size (number of store locations nationwide), reach (percent of the total US population living within 5 miles of a store location), and ability to vaccinate (throughput). The program, which will scale up to eventually include COVID-19 vaccination at all 40,000+ retail locations, will make it easier for individuals to access free COVID-19 vaccine at a pharmacy in their community, and improve vaccine uptake while decreasing the

logistical and operations burden on state, local, and territorial health departments.

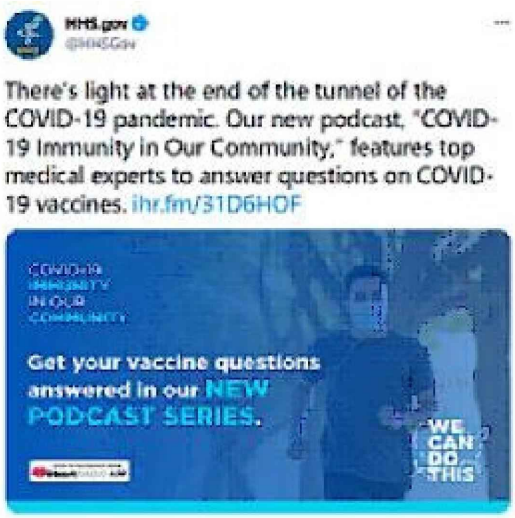
Johnson & Johnson Janssen Vaccine: CDC updated their general information on the Johnson & Johnson Vaccine. The J&J/Janssen vaccine is recommended for people aged 18 years and older. Learn more about how CDC is making COVID-19 vaccine recommendations and CDC's vaccine rollout recommendations.

FEMA Vaccination Sites: FEMA announced that it will open a COVID-19 vaccination site in Greenbelt, Maryland on April 7th. The center's capacity is expected to be up to 3,000 shots per day. President Biden also committed to opening sites in Memphis, TN and Milwaukee, WI. These sites join many new FEMA vaccination sites recently announced, including in Boston, Massachusetts; Essex, New Jersey; Norfolk, Virginia; and Yakima, Washington, all of which open today. In the next week, federal communication vaccination center pilot sites in Gary, Indiana and St. Louis, Missouri are scheduled to open, as well. The agency has provided more than $4.47 billion for expenses related to COVID-19 vaccination at 100% federal cost share.

Peace Corps Assistance in COVID-19 Response: FEMA and the Peace Corps announced a historic partnership to combat the COVID-19 pandemic, marking only the second time in the Peace Corp's history where volunteers will serve a domestic deployment. The Peace Corps will soon begin recruiting for the special domestic deployment through Peace Corps Response, a program that sends in individuals with specialized experienced to short-term service assignment of up to 12 months. Assignments will focus on urgent needs as identified by FEMA and on communities that have been traditionally under-served.

Evaluating Moderna COVID-19 Variant Vaccine: An investigational vaccine designed to protect against the B.1.351 SARS-CoV-2 variant has been administered as part of a new Phase 1 clinical trial evaluating the vaccine candidate's safety and immunogenicity in adult volunteers. The vaccine, known as mRNA-1273.351, was developed by the biotechnology company ModernaTX, Inc., based in Cambridge, Massachusetts. The trial is led and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The trial will enroll approximately 210 healthy adult volunteers at four clinical research sites in the United States that are part of the NIAID-funded Infectious Diseases Clinical Research Consortium (IDCRC).

HHS Podcast: HHS's new podcast, *COVID-19 Immunity in Our Community*, features top medical experts to answer questions on COVID-19 vaccines. Today's episode, "Building Vaccine Trust Within the Black Community," discusses how we can start to rebuild the Black community's trust in the vaccines, in order to achieve herd immunity and, hopefully, regain some sense of normalcy in our everyday lives.



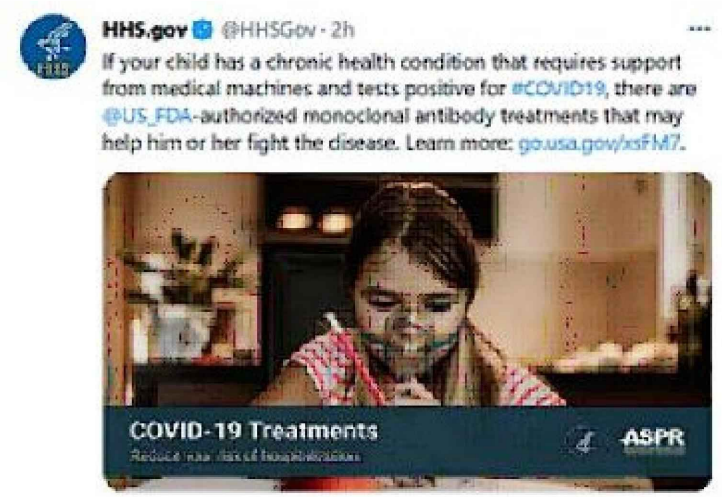
Testing and Treatment

Covid-19 Precautions: CDC updated their COVID-19 page, reiterating that it is critical to keep taking precautions to prevent COVID-19. Learn more about how to protect yourself and others from CDC's recommendations.

COVID-19 Self Testing: CDC and NIH launched an innovative community health initiative called "Say Yes! COVID Test" starting in two locales, Pitt County, North Carolina, and coming soon to Chattanooga/Hamilton County, Tennessee. As many as 160,000 residents across the two communities will have access to free, rapid antigen tests that they can administer themselves to use three times a week for one month. NIH will provide the tests (also called a home-test or at-home test) and evaluate the effectiveness of the initiative, which aims to determine if frequent self-administered COVID-19 testing helps residents reduce community transmission of SARS-CoV-2, the virus that causes COVID-19 disease.

$147 Million to Expand Production of Swabs: DOD and HHS awarded $146.7 million to Puritan Medical Products on March 26 for renovations in the company's Orlinda, Tenn. facility to increase production capacity of foam tip swabs used in COVID-19 diagnostic tests. Funded through HCEA, the award will help the company boost total production capacity of the swabs to 250 million per month by February 2022.

Monoclonal Antibody Treatments: 3 EUAs for monoclonal antibody (mAb) treatments for mild-to-moderate COVID-19 in at-risk patients: bamlanivimab, casirivimab/imdevimab, and bamlanivimab/etesevimab. Learn more about FDA-authorized monoclonal treatments that can help at-risk patients fight the disease.



HHS Innovative Challenge for Masks: The U.S. Department of Health and Human Services launches $500,000 innovation challenge competition today encouraging American inventors to aid the nation's COVID-19 response by designing effective, comfortable face masks for personal use that resolve the common complaints people have about wearing masks. The contest taps into the nation's creativity and entrepreneurial spirit to help curb the spread of SARS-CoV-2, the virus that causes COVID-19.

Information for Specific Populations

Healthcare Workers: CDC updated their guidance for managing patients with COVID-19, including clinical guidance, home and hospital care, care for special populations, disease severity, and more.

Guidance for Adult Day Services Centers: CDC released guidance for administrators and staff to prevent the spread of COVID-19. Adult Day Services Centers (ADSCs) provide social or health services to community-dwelling adults aged 65 and over and adults of any age living with disability. Older adults and persons with disabilities are at highest risk for severe illness from COVID-19 including hospitalization, intensive care, and death. ADSC administrators and staff can help protect themselves and program participants (that is, adults attending ADSCs) from COVID-19 by promoting and engaging in preventive behaviors that reduce spread and maintain healthy operations and environments at ADSC facilities. This guidance is meant to supplement — not replace — any Federal, state, tribal, local, or territorial public health and safety laws, rules, and regulations with which adult day services center programs must comply. CDC has also developed recommendations for participants at ADSCs and their caregivers.

Suggestions for Youth and Summer Camps: CDC offers suggestions for ways in which camp administrators can help protect campers, staff, and communication, and prevent the spread of COVID-19. Camp administrators can determine, in collaboration with state and local health officials, whether and how to implement these considerations, making adjustments to meet the unique needs and circumstances of the local community. Implementation should be guided by what is feasible, practical, acceptable, and tailored to the needs of each community. These suggestions are meant to supplement— not replace —any state, local, territorial, or tribal health and safety laws, rules, and regulations with which camps must comply.

Essential Services for Malaria: CDC updated their key considerations for continuing essential

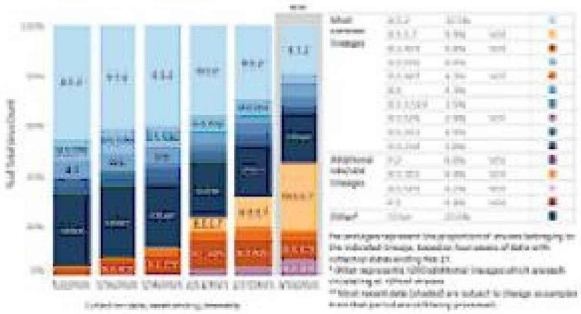
malaria prevention and control activities safely and effectively. These considerations should supplement country Ministry of Health guidance.

CMS Updates

Medicare Fee-for-Service Billing: CMS updated their COVID-19 Frequently Asked Questions on Medicare Fee-for-Service (FFS) Billing. The policies set out in this FAQ are effective for the duration of the public health emergency unless superseded by future legislation. The FAQs in this document supplement the previously released FAQs, 1135 Waiver FAQs.

Research

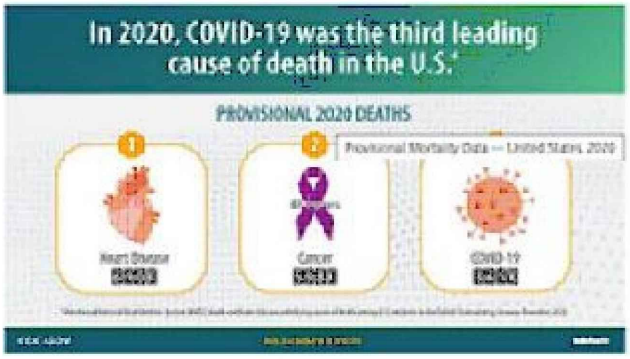
Variant Proportions in the U.S: CDC's national genomic surveillance program identifies new and emerging SARS-CoV-2 variants to determine implications for COVID-19 diagnostics, treatments, or vaccines authorized for use in the United States. Monitoring the spread of emerging variants in the United States relies on widespread, rapid sequencing. To accelerate sequencing in the United States, CDC has contracted with commercial diagnostic laboratories, and, in partnership with the Association of Public Health Laboratories (APHL), has implemented the National SARS-CoV-2 Strain Surveillance (NS3) program to provide a comprehensive and population-based US surveillance system. This data, along with data from many other sources, are used to inform national and state public health actions related to variants.



COVID-19 2020 Mortality Surveillance: The Morbidity and Mortality Weekly Report (*MMWR*) on death certificate-based ICD-10 diagnosis codes for COVID-19 mortality surveillance addresses that among the 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both. These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of death certificate diagnoses is essential for an authoritative public record.

Provisional 2020 Mortality Data: The Morbidity and Mortality Weekly Report (*MMWR*) on provisional mortality data in the United States in 2020 addresses that the age-adjusted death rate increased by 15.9% in 2020. Overall death rates were highest among non-Hispanic Black persons and non-Hispanic American Indian or Alaska Native persons. COVID-19 was the third leading cause of death, and the COVID-19 death rate was highest among Hispanics. Provisional death estimates

provide an early indication of shifts in mortality trends. Timely and actionable data can guide public health policies and interventions for populations experiencing higher numbers of deaths that are directly or indirectly associated with the COVID-19 pandemic.



Case Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 cases will remain stable or have an uncertain trend over the next 4 weeks, with 223,000 to 723,000 new cases likely reported in the week ending April 24, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of new reported cases per week will likely decrease in 4 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported cases are uncertain or predicted to remain stable in the other states and territories. View previous case forecasts.

Hospitalization Forecasts: This week's national ensemble predicts that the number of new daily confirmed COVID-19 hospital admissions will remain stable or have an uncertain trend over the next 4 weeks, with 2,300 to 8,700 new confirmed COVID-19 hospital admissions likely reported on April 26, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of daily confirmed COVID-19 hospital admissions will likely increase in 6 jurisdictions and decrease in 12 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported hospital admissions are uncertain or predicted to remain stable in the other states and territories. View previous hospitalization forecasts.

Death Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 deaths will remain stable or have an uncertain trend over the next 4 weeks, with 3,100 to 10,200 new deaths likely reported in the week ending April 24, 2021. The national ensemble predicts that a total of 565,000 to 585,000 COVID-19 deaths will be reported by this date. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of newly reported deaths per week will likely decrease in 8 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported deaths are uncertain or predicted to remain stable in the other states and territories. View previous death forecasts.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

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From:	Craig, Jim
To:	Sharlot, Liz; Byers, Paul
Cc:	Dobbs, Thomas E
Subject:	FW: TIME SENSITIVE and EMBARGOED: TFAH"s Ready or Not 2022 report on public health emergency preparedness
Date:	Wednesday, March 9, 2022 12:27:15 PM
Attachments:	image001.png Report Measures States" Preparedness for Public Health Emergencies.docx 2022-ReadyOrNot-FINAL Embargo.pdf

FYSA

From: Meredith Allen <mallen@astho.org>
Sent: Tuesday, March 8, 2022 4:27 PM
To: Meredith Allen <mallen@astho.org>
Subject: TIME SENSITIVE and EMBARGOED: TFAH's Ready or Not 2022 report on public health emergency preparedness

Dear Directors of Public Health Preparedness,

Attached is the embargoed copy, with supporting information, of the Trust for America's 2022 Health Ready or Not Preparedness Report which is **EMBARGOED UNTIL 12:01 AM, MARCH 10, 2022**.

We anticipate that this release will generate some level of national, regional, and local media coverage as well as possibly inquiries from state legislatures and/or your governors' offices, especially given ongoing response to the COVID-19 pandemic. As such, we recommend that states be prepared to share specific examples of progress, accomplishments and, yes, unmet needs, associated with all-hazards readiness, including specific recent high profile incident responses.

ASTHO has also shared this embargoed report with State and Territorial Health Officials and Senior Deputies.

Thank you,
Meredith

Meredith Allen, DrPH, MS
Vice President, Health Security
Association of State and Territorial Health Officials
2231 Crystal Drive, Suite 450, Arlington, VA 22202
Tel: (571) 318-5407 | astho.org
Twitter | Facebook | Blog

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From: Centers for Disease Control and Prevention
To: Young, Dorthy
Subject: Field Notes: King County Monitors the Ongoing Economic, Social, and Health Effects of COVID-19
Date: Tuesday, March 2, 2021 7:44:35 AM

Field Notes

King County Monitors the Ongoing Economic, Social, and Health Effects of COVID-19

Community mitigation strategies used to slow pandemics—such as physical distancing policies, mask mandates, avoiding crowds, hand washing or using hand sanitizers, business and school closures, and travel restrictions—can reduce the spread of disease but have other effects on individual health and community well-being. As the local health jurisdiction tasked with protecting the health of its residents, Public Health—Seattle & King County (PHSKC) needed to quickly develop ways to monitor and evaluate the ongoing social and economic impacts of the COVID-19 mitigation response. The first COVID-19 case diagnosed in the United States came through the international airport in King County, Washington, in January 2020, with additional community-acquired cases

diagnosed among King County residents in February 2020. As cases began to increase, state and local governments enacted strategies designed to prevent person-to-person spread of the novel coronavirus.

In population health assessments, King County often performs better than the US average but continues to face stark health disparities by race/ethnicity, location, and income. COVID-19 is no exception. With support from CDC, PHSKC incorporated aspects of CDC's approach to evaluating COVID-19 community mitigation strategies to track various social, emotional, and economic impacts on the King County community since April 2020.

For more information about this story and to read other highlights from the field, visit Field Notes on CDC's Public Health Professionals Gateway.

Learn More

Have a story?

Does your health department have an example of success or innovation you'd like to share? Contact us at CSTLTSfeedback@cdc.gov to submit your idea, and it might be featured in a future Field Notes.

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Field Notes is a feature from the Center for State, Tribal, Local, and Territorial Support that spotlights success and innovation in state, tribal, local, and territorial health agencies.

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Email

Centers for Disease Control and Prevention

1600 Clifton Rd Atlanta, GA 30329 1-800-CDC-INFO (800-232-4636) TTY: 888-232-6348

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From:	Kate Heyer
To:	Dobbs, Thomas E; David Lakey, MD; ScottHarris; Joe Mclaughlin; jose.romero@arkansas.gov; kristen.ehresmann@state.mn.us; Randall Mayer; Jeff Stover; Terry Dwelle; Shah, Nirav
Cc:	Griffin, Jenny; Peggie Lawrence; Patricia Vinson
Subject:	Follow Up from August ASTHO IDPC call
Date:	Friday, September 10, 2021 8:27:12 AM
Attachments:	image001.png IDPC meeting notes August 2021.docx

Hello, IDPC members,

Attached are the notes and suggested action items from the August IDPC call. I ask that you please not distribute the notes outside of this group.

I will send a draft of the *Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease* policy statement when it is ready.

Given the preference for a quarterly meeting, we will plan to hold the next call on **November 16 at 12PM ET**. An Outlook invitation is forthcoming.

Thank you again and please do not hesitate to reach out with any questions or discussion items for the next call.

Kate

Kate Heyer, MPH
Senior Director, Infectious Disease Infrastructure and Policy
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From:	Kate Heyer
To:	McLaughlin, Joseph B (HSS); David Lakey, MD; Shah, Nirav; Dobbs, Thomas E; ScottHarris; jose.romero@arkansas.gov; kristen.ehresmann@state.mn.us; Randall Mayer; Jeff Stover; Terry Dwelle; manisha.juthani@ct.gov
Cc:	Griffin, Jenny; Patricia Vinson; Grace Lee; Marcus Plescia; Meredith Allen; Andy Baker-White; Ericka McGowan; Carolyn McCoy
Subject:	Follow up from 11/16 ASTHO IDPC call
Date:	Tuesday, November 23, 2021 3:24:10 PM
Attachments:	image001.png IDPC Meeting Notes_11.22.2021.docx DRAFT - Public Health Authority Policy Statement.002.docx

Good afternoon,

Thank you for participation in last week's IDPC call. Attached please see notes from the call and an updated draft of the *Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease* policy statement.

- Since we met last week, we have been fortunate to gain a new IDPC member! **Dr. Manisha Juthani (SHO-CT)** has agreed to serve on the IDPC and plans to join us on our next call. Please join me in welcoming her to our group.
- *Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease* policy statement: Andy incorporated edits from our call in the attached draft. **If you are interested in meeting with Andy as a small group to wordsmith the draft, please let me know and I'll work to propose a few dates and times for that conversation.**
- As I mentioned during the call, Alyssa Boyea from our staff will be also be sending a request for your feedback to the questionnaire to assess public opinion on rebuilding trust and confidence in public health after the Thanksgiving holiday.
- Additionally, CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) will soon be updating its Data Security and Confidentiality Guidelines. The purpose of the document is to recommend standards for all NCHHSTP programs that, when adopted, will facilitate the secure collection, storage, and use of data while maintaining confidentiality. NCHHSTP has requested that ASTHO provide concrete examples and feedback on what needs to be updated in these guidelines. Please share anything you think should be added, removed, or reframed within these guidelines with me by **December 15.**

Lastly, the next IDPC call is scheduled for **February 15, 2022 at 12PM ET**. An agenda and call-in information will be sent closer to the call. Please send any suggested agenda topics to me.

Thank you all for your continued support of the IDPC and have a wonderful Thanksgiving.

Kate

Kate Heyer, MPH
Senior Director, Infectious Disease Infrastructure and Policy
Association of State and Territorial Health Officials
(571) 318-5490

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From: Kate Heyer
To: Dobbs, Thomas E
Cc: Griffin, Jenny
Subject: Follow up from the August ASTHO IDPC meeting
Date: Wednesday, September 8, 2021 3:17:05 PM
Attachments: image001.png
IDPC_meeting_notes_August_2021.docx

Hi Dr. Dobbs,

Attached please see the high-level notes and proposed action items from the August IDPC call. I have 2 comments in the document that I would appreciate your thoughts on before I distribute to the committee. Please let me know if you approve of the notes and any thoughts about the proposed action items.

Also, would you like to plan for the next IDPC call to be held on November 16 at 11AM CT/12PM ET? That would fit the quarterly cadence the members requested and is in the same time block as our August call. If that does not work, I will send a Doodle poll for scheduling.

Best, Kate

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From: Dobbs, Thomas E
Subject: Fw: Follow up from 11/16 ASTHO IDPC call
Date: Friday, December 10, 2021 2:24:59 PM
Attachments: image001.png
IDPC Meeting Notes_11.22.2021.docx
DRAFT - Public Health Authority Policy Statement.002.docx

From: Kate Heyer <kheyer@astho.org>
Sent: Tuesday, November 23, 2021 3:22 PM
To: McLaughlin, Joseph B (HSS) <joseph.mclaughlin@alaska.gov>; David Lakey, MD <dlakey@utsystem.edu>; Shah, Nirav <nirav.shah@maine.gov>; Dobbs, Thomas E <Thomas.Dobbs@msdh.ms.gov>; ScottHarris <Scott.Harris@adph.state.al.us>; jose.romero@arkansas.gov <jose.romero@arkansas.gov>; kristen.ehresmann@state.mn.us <kristen.ehresmann@state.mn.us>; Randall Mayer <randall.mayer@idph.iowa.gov>; Jeff Stover <jeff.stover@vdh.virginia.gov>; Terry Dwelle <tldwelle1692t@gmail.com>; manisha.juthani@ct.gov <manisha.juthani@ct.gov>
Cc: Griffin, Jenny <Jenny.Griffin@msdh.ms.gov>; Patricia Vinson <Patricia.Vinson@adph.state.al.us>; Grace Lee <glee@astho.org>; Marcus Plescia <mplescia@astho.org>; Meredith Allen <mallen@astho.org>; Andy Baker-White <abaker-white@astho.org>; Ericka McGowan <emcGowan@astho.org>; Carolyn McCoy <cmccoy@astho.org>
Subject: Follow up from 11/16 ASTHO IDPC call

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From:	Dobbs, Thomas E
To:	Craig, Jim
Subject:	Fw: TFAH"s Ready or Not report releasing this Wednesday - (Sent by Tim Hughes on behalf of Rhea Farberman)
Date:	Monday, March 8, 2021 5:44:47 PM
Attachments:	New Report Measures States" Health Emergency Preparedness[1].pdf TFAH-2021-ReadyOrNot-FnlEmb.pdf

Top Tier

From: Tim Hughes <thughes@tfah.org>
Sent: Monday, March 8, 2021 3:02 PM
To: Tim Hughes <thughes@tfah.org>
Subject: TFAH's Ready or Not report releasing this Wednesday - (Sent by Tim Hughes on behalf of Rhea Farberman)

Dear State Health Official,

TFAH will release its annual report *Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism* measuring states' health emergencies preparedness on Wednesday, March 10. Not surprisingly, this year the report has a special focus on the impact of COVID-19, highlighting the need to increase resources for emergency preparedness. We clarify that our report measures all-hazards preparedness and is not a measure of any state's COVID-19 response.

As we have done in past years, we measure 10 health security indicators in each state and discuss the relationship of each to all-hazard preparedness. We placed states into one of three performance tiers (high, middle and low) based on these indicators. Twenty states and the District of Columbia placed in the high-performance tier, 15 states placed in the middle performance tier and 15 states placed in the low performance tier.

Particularly significant in this year's report is our emphasis on how the pandemic demonstrated the importance of the federal government's role in a health emergency on the scale of a pandemic, the impact of structural racism on a community's resilience during a health emergency, and, the critical need for core public health funding including workforce and infrastructure support.

The report is being shared with news media ahead of the Wednesday morning lift of the embargo. It is likely to be covered in news markets across the country. I recommend you share these materials with your communications staff today so they can prepare for any media requests.

I'd be happy to answer any questions.

Thank you,
Rhea

Rhea K. Farberman, Director
Strategic Communications and Policy Research
Trust for America's Health
rfarberman@tfah.org

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From: NASHP News
To: Dobbs, Thomas E
Subject: Gov. Lujan Grisham will Provide Keynote Address at #NASHPCONF21
Date: Tuesday, August 3, 2021 10:45:53 AM

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News | August 3, 2021

Top Headlines

- Gov. Lujan Grisham will Provide Keynote Address at #NASHPCONF21
- ARPA Provides States with Funds to Address Mental Health in Schools
- New State Option for Funding Mobile Crisis Intervention Services
- 2021 State Leg. Session Recap on States' Efforts to Lower Drug Costs

Governor Lujan Grisham will Provide Keynote Address

• Sept. 21, 2021, Governor Lujan Grisham will kick off #NASHPCONF21: State Health Policy Unmuted with remarks on lessons learned during COVID-19, continued challenges and how to think about recovery in New Mexico.

• A panel of state health leaders will follow to discuss their efforts to control the spread of COVID-19 and how they are preparing for recovery including the use of federal funds for strengthening the public health system, promoting health equity, and responding to trauma and behavioral health crises. This is a must-attend event that you don't want to miss. Learn more and register today!

REGISTER NOW

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ARPA Gives States Opportunities to Support Behavioral Health for Children and Youth

ARPA Provides States with Funds to Address Mental Health in Schools

• The American Rescue Plan Act (ARPA) allocates $122.8 billion to state and local education agencies to support students returning to school, including school mental health systems.

New State Option for Funding Mobile Crisis Intervention Services

• ARPA creates a new state option for funding MCIS through Medicaid. States can leverage this opportunity and design their policies to support MCIS for children and youth, whose behavioral health needs have increased during the pandemic.
State Grant Applications Due August 13, 2021.

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2021 State Legislative Session Recap on States' Efforts to Lower Drug Costs

• During the 2021 legislative session, 20 states enacted 43 laws to address rising drug costs.

• Enacted state laws include establishing a prescription drug affordability board (PDAB), limiting patients' out-of-pocket insulin costs, regulating pharmacy benefit managers (PBMs), and requiring prescription drug price transparency. Read more.

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A Case Study of the Virginia COVID-19 Equity Leadership Task Force and Health Equity Working Group

• This new case study is part of a learning network hosted by the National Governors Association, Duke-Margolis Center for Health Policy, and NASHP that convenes governor-appointed health equity COVID-19 task force leaders throughout the nation.

• The case study highlights efforts from the Virginia COVID-19 Equity Leadership Task Force and Health Equity Working Group. The Commonwealth of Virginia integrated principles of equity and inclusion into the infrastructure of state government; an approach that has been instrumental in the state's response to COVID-19 and beyond.

• The learning network hosted a summit last week on reimagining the collection, reporting, and use of race and ethnicity data across states which will result in a publication later this summer.

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States' COVID-19 Public Health Emergency Declarations, Mask Requirements and Travel Advisories

• On July 27, the CDC released new guidance recommending that all individuals, regardless of vaccination status, wear masks indoors in places with high COVID transmission rates.

• At least seven states have aligned with these recommendations, while Nevada and DC have reinstated indoor mask mandates for vaccinated individuals.

• NASHP is tracking the status of each state's mask requirements, as well as COVID-19 emergency orders and actions to reopen, here.

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Resource of the Month

A Case Study of Building Strong Brains Tennessee, an Approach to ACEs Mitigation

• This month, NASHP features A Case Study of Building Strong Brains Tennessee (BSBTN): An Initiative to Address Adverse Childhood Experiences (ACEs) and Become a Trauma-Informed State. The case study highlights BSBTN, a

public/private partnership established to prevent and mitigate the impacts of ACEs to promote statewide economic development and prosperity.

• In this case study, the National Governors Association Center for Best Practices, Duke-Margolis Center for Health Policy, and a former Tennessee leader highlight BSBTN and its key successful elements.

• View other state resources at the Healthy Child Development State Resource Center. Submit new resources to Elinor Higgins.

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Announcements

States-Only Roundtable Discussion on Increasing immunization in Advance of Back-to-School

Registration Open for NAHDO's 36th Annual Conference

Respite Workforce Pilot: Deadline for Interested Applicants is August 6

State Tracking

Costs
State Legislative Action to Lower Pharmaceutical Costs

State Drug Pricing Laws: 2017-2021

State Legislative Action to Lower Health System Costs

COVID-19
Vaccine Mandates Legislative Tracker

COVID-19 Federal Funding Earmarked for Hospitals, Providers, and States

States' COVID-19 Public Health Emergency Declarations, Mask Requirements and Travel Advisories

State Approaches to Contact Tracing during the COVID-19 Pandemic

How States Collect, Report, and Act on COVID-19 Race and Ethnicity Data

States Use Appendix K Waivers to Support Home- and Community-Based Services in Response to COVID-19

State Medicaid and CHIP Strategies to Protect Coverage during COVID-19

Coverage
States' Efforts to Extend Medicaid Coverage to Postpartum Women

State Actions that Support and Expand Palliative Care

Where States Stand on Exchanges

Careers

Policy Associate — Chronic and Vulnerable Populations Team

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From: Polk, Jennifer (OS/ASPR/SIIM)
Subject: HHS COVID-19 Update - 3/31
Date: Thursday, April 1, 2021 7:53:48 AM

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Wednesday, March 31, 2021 8:26 PM
Subject: HHS COVID-19 Update - 3/31

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 31, 2021:

Highlights from the White House COVID-19 Response Team briefing:

Andy Slavitt:

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- **Mask Mandates:** We need every governor, mayor, and local leader to maintain or reinstate mask mandates. And we need every American to do their part so that we can win this race and save lives.

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- **Case Update:** CDC's most recent data show that the seven-day average of new cases is slightly less than 62,000 cases per day. We continue to see an increase, and this is almost a 12 percent increase from the seven-day period prior. Hospitalizations also continue to increase. The most recent seven-day average — about 4,900 admissions per day — is up from 4,600 admissions per day in the prior seven-day period. The seven-day average of deaths remains slightly above 900 deaths per day.
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- **Number of People Vaccinated:** This week, we will reach 100 million people who have received at least one dose of the COVID-19 vaccine in the United States — a remarkable feat in such a short period of time. Further, over 70 percent of people over age 65, our most vulnerable group, have received at least one vaccine dose. In addition to increasing the number of mass vaccination sites across the country with FEMA, expanding the Federal

Retail Pharmacy Program, and ensuring that all Americans have a vaccine site within five miles of their home, we are also activating mobile vaccination units and clinics. CDC is also excited to partner with the Administration for Community Living to support their efforts to get older, at-risk adults and those with disabilities vaccinated.

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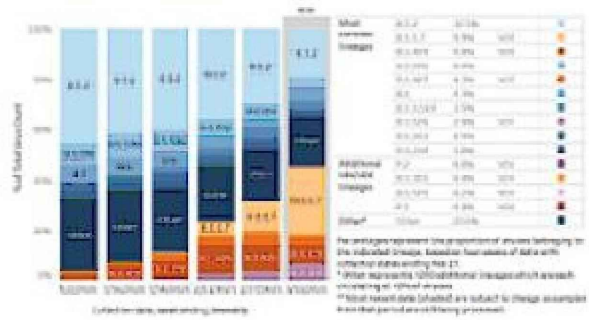

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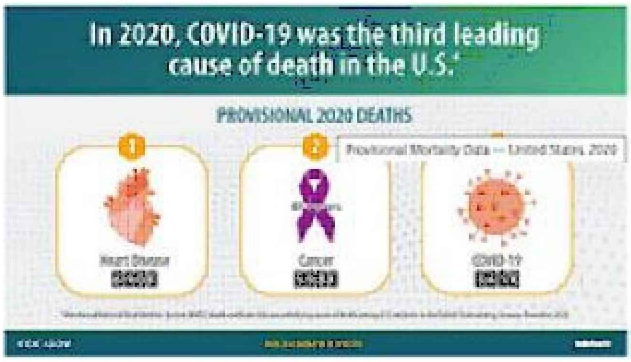

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Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA)
Subject: HHS COVID-19 Update - 3/31
Date: Wednesday, March 31, 2021 7:24:43 PM

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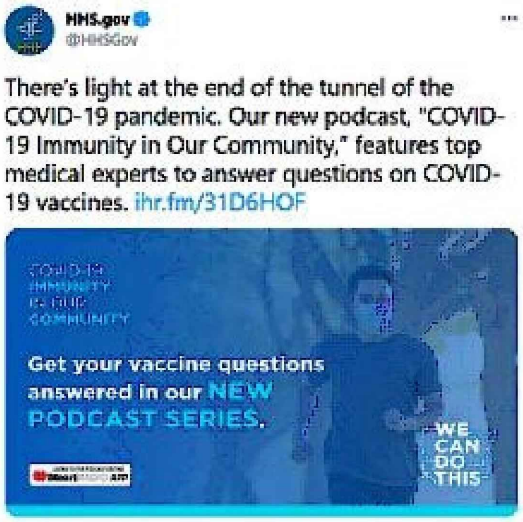

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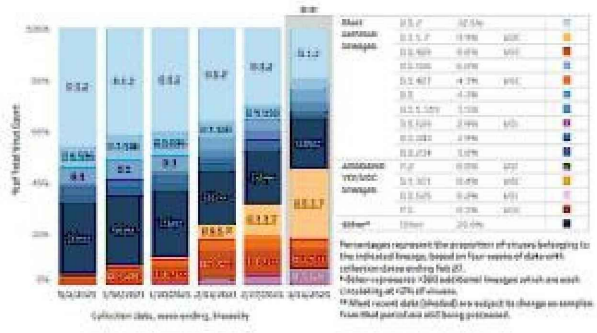

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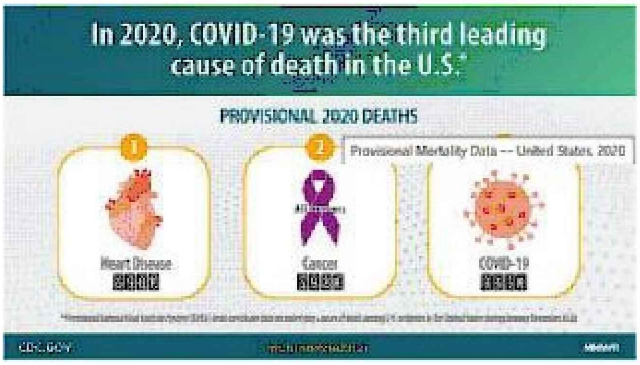

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U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA)
To: Baker, Michael (OS/IEA)
Subject: HHS COVID-19 Update - 4/19
Date: Monday, April 19, 2021 6:23:24 PM

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 19, 2021:

Renewal of Determination That a Public Health Emergency Exists: As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date (April 15, 2021) and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective April 21, 2021, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, that a public health emergency exists and has existed since January 27, 2020, nationwide.

Highlights from Friday and Monday's White House COVID-19 Response Team Briefing

Andy Slavitt

- **Vaccine Availability:** Over 80 percent of seniors have had at least their first shot. Fifty percent of adults in the U.S. have had at least one shot. We now have one thing on our mind: making sure that the other 50 percent know how easy it is to get a shot. If you still think it's too difficult your vaccine, here's what you need to know: the lack of supply, the shortage of locations, the confusing rules are all in the past. That cannot be said enough. There are thousands of more people ready to help you get vaccinated. There are now millions more vaccine doses available and waiting. There are now more than 60,000 safe and convenient places for you to get your shot.
- **Expanded Vaccine Eligibility:** If you are 16 or over, it is your turn to get vaccinated no matter where you live. There's a nine out of ten chance that you are located within five miles of your vaccine shot. For those of you who can't get to a vaccine site, we're helping community-based organizations connect vulnerable Americans with shots. And now, to get resources to healthcare providers serving at-risk populations and to promote equitable distribution of vaccines, today HHS is making $150 million available to community-based healthcare providers to strengthen their efforts to get shots in arms and care for patients with COVID-19.
- **Get Vaccinated:** Join the more than 130 million Americans who have already gotten at least one shot, that's half of all adults. Here's my direct plea to everyone listening: If you haven't already made an appointment to get vaccinated, make one right now. You are eligible. Then, reach out to your family, friends, and neighbors to make sure they can make an appointment too. See what help you can offer them to help those who might need extra assistance.
- **American Rescue Plan:** We are announcing a $1.7 billion investment to bolster the ability of the CDC and state and local public health departments to monitor, track, and defeat emerging threats — whether it's COVID-19 variants today or other viruses in the future — through a process known as genomic sequencing. This significant investment, which is made

possible due to the American Rescue Plan President Biden signed into law last month, is critical in our fight against the new and potentially dangerous variants of COVID-19. Right now, these variants account for nearly half of all COVID-19 cases in the United States, and we need more capacity in our public health system to identify and track these mutations. This funding will enable CDC and states to do more genomic sequencing as we activate the nation's great research capabilities to detect variants earlier and increase our visibility into emerging threats. This investment will give public health officials the chance to react more quickly to prevent and stop the spread. Today's investment also builds on the major investments in testing and genomic sequencing that we made earlier this year. That includes $10 billion of American Rescue Plan funding to support COVID-19 testing in schools, another $2.5 billion to help state and local public health agencies increase testing capacity in underserved and high-risk communities, and nearly $200 million to begin to increase genomic sequencing capacity that this investment comes on top of.

Dr. Walensky

- **Case Update:** Yesterday, CDC reported nearly 60,950 cases of COVID-19. Our seven-day average is up to over 67,440 per day. For context, one month ago, our seven-day average of cases was just over 53,000 per day. The seven-day average of hospital admissions is about 5,460. Sadly, the seven-day average of daily deaths are now increasing, with six consecutive days of increases, to about 695 deaths per day. Sunday, we again saw almost 700 deaths in a single day.
- **Vaccination Update:** So far, we have administered 209 million vaccine doses, with an average daily administration of more than 3 million doses. This brings us to 192.8 million doses in the first 100 days — 96 percent of our goal in 88 days. This means that almost 40 percent of the total population has received at least one dose of a COVID-19 vaccine, and one out of every four people is fully vaccinated. More than 65 percent of people age 65 and older and more than 25 percent of people are fully vaccinated.
- **Vaccine Effectiveness:** First, among nearly 4,000 healthcare personnel, first responders, and essential workers who received the Pfizer and Moderna vaccines, the risk of any infection, asymptomatic and symptomatic, was reduced by 90 percent after receiving the two recommended doses of the vaccine. This study was yet additional evidence that these vaccines are working. The efficacy we saw in clinical trials is now being shown in the real world. Second, last week, we released data on the number of so-called "breakthrough infections," of people who, despite being vaccinated, still tested positive for COVID-19 more than 14 days after they're getting their second vaccine dose. With any vaccine, we expect such rare cases. But so far, out of more than 84 million people who are fully vaccinated, we have only received reports of less than 6,000 breakthrough cases. Although this number is from 43 states and territories and likely an underestimate, it still makes a really important point: These vaccines are working. Of the nearly 6,000 cases, approximately 30 percent had no symptoms at all. Based on these data, here's the bottom line: Getting a vaccine will help protect you, it will help protect others, and it will help us end this pandemic.
- **Rising Cases and Variants:** Some of these increases are as a result of relaxed prevention efforts in states across the country, such as relaxed mask mandates or loosened restrictions on indoor restaurant seating. Another reason for these increases is the continued spread of highly transmissible variants — more than 50 to 70 percent more transmissible — which

makes the race to stop the transmission even more challenging and threatens to overwhelm our healthcare system again in parts of this country. CDC data show that the B117 variant — the variant originally identified in the United Kingdom — represents 44 percent of the virus circulating during the week of March 27th.

- **Johnson & Johnson Update:** After the press briefing on Wednesday (4/14), the Advisory Committee on Immunization Practices — or ACIP — met to discuss the six cases and provide recommendations. I want to thank the ACIP for their thoughtful discussion and their commitment to the science. The recommendation from this group of independent experts for a continued pause will allow additional time to review any additional cases that might come in, and for them to conduct a complete risk assessment and to evaluate the emerging science. ACIP will meet again this Friday, April 23rd, from 11:00 to 5:00 to provide further recommendations.

Dr. Fauci

- **Vaccine Efficacy in Clinical Trials:** This is work that has been done in tens of thousands of people in clinical trials, has been peer reviewed independently, and published in scientific journals. Pfizer and Moderna's efficacy are shown in the New England Journal of Medicine papers. The same holds true for J&J. All three are highly efficacious in clinical trials.
- **Vaccine Efficacy in Real-World Settings:** In over 23,000 employees at the University of Texas, the infection rate was miniscule among vaccinated employees: 0.05 percent. The CDC — looking, again, at the real-world effectiveness — showed that in almost 80,000 person-days with full immunization, 0.04 per 1,000 person-days.
- **Vaccine Safety:** We have an extraordinary capability to monitor safety, as an extremely rare adverse event of 6 individuals among 7,000 was picked up by the surveillance system. Those surveillance systems include ones that follow up on clinical trials, monitoring systems by the CDC, by the FDA, and other monitoring systems. When we say a vaccine is safe, you're talking about an exquisitely sensitive monitoring system.
- **NIH-sponsored Coronavirus Disease 2019 Treatment Guidelines Panel:** This is a panel of individuals co-chaired by Dr. Cliff Lane, who is the Deputy Director of NIAID, but also the Clinical Director of the Institute; Henry Masur, who is the Director of the Critical Care Medicine Unit at NIH; and Roy "Trip" Gulik, who is the Chief of Infectious Diseases at Weill Cornell Medicine in New York City. This panel was established to be able to work, literally in real time, updating guidelines for clinicians and healthcare providers throughout the country and the world on the latest information.

Dr. Murthy

- **American Indians and Alaska Natives:** According to a recent CDC report, American Indians and Alaska Natives were 3.5 times more likely to get COVID than a non-Hispanic, white population. Native people are also more than four times likely to be hospitalized as a result of COVID-19. Despite these challenges, our colleagues working in the Indian health system have heroically administered more than 1 million doses of COVID-19 vaccines. That is a remarkable achievement and a testament to their dedication. Today, the Biden administration is doubling down on this critical work with a — with a $4 billion investment from the American Rescue Plan to the Indian Health Service Tribal and urban Indian health programs. Specifically, these funds will support the following: expanded COVID-19

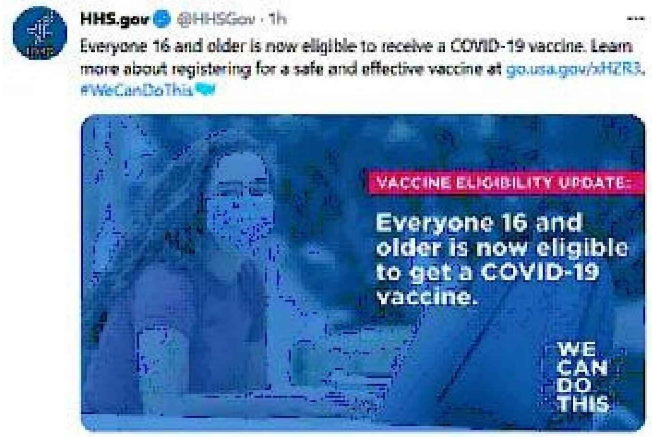
vaccinations, including mobile efforts, large-scale vaccination events, and public education and outreach campaigns; expanded testing, contact tracing, PPE access, and treatment; increased preventive health services for those at higher risk for COVID-19; and increased support for telehealth, the healthcare workforce, and the broader Indian healthcare system, which has been a hard hit during the pandemic due to lost reimbursements for care for both public and private insurance.

- **Increasing Access and Increasing Confidence:** The more people see those around and get vaccinated, particularly family and friends, the more comfortable they become with getting vaccinated themselves. The easier we make it to get vaccinated, the more people will get vaccinated, and that means more people around them would feel comfortable with getting vaccine themselves. That's why access and confidence go hand in hand, and so does safety. This brings me to the second topic. This week you've heard a lot from us about the pause with administering the Johnson & Johnson COVID-19 vaccine. These decisions are never simple, and this one was taken after a very careful assessment of the risks and benefits of calling for such a pause. However, the actions taken by CDC and the FDA this week should give Americans confidence that our safety system is working for them. For some members of the public, uncertainty about getting vaccinated stems from questions about how safe the vaccines are. This week is a reminder that safety is our top priority. Even when an extremely rare safety occurs, our scientific agencies will act with thoroughness and transparency so people can remain confident in the vaccines that are recommended to them.

Vaccine Updates

Vaccine Eligibility: CDC updated the following COVID-19 information pages to include that everyone 16 years of age and older is now eligible to get a COVID-19 vaccine: Vaccine FAQs, How Vaccines Get to You, Key Things to Know, and Vaccine Rollout Recommendations. CDC also updated the following information pages for specific communities to include the expanded eligibility of the COVID-19

vaccine: persons with disabilities, essential workers, healthcare personnel, older adults, and those high risk for severe illness. Get a COVID-19 vaccine as soon as you can. Moreover, CDC updated their general vaccination resources, including information on preparing for your vaccine.



Moderna Vaccine Update: The FDA updated their Moderna COVID-19 Vaccine Frequently Asked Questions page. On December 18, 2020, the U.S. Food and Drug Administration issued an emergency use authorization for the second vaccine for the prevention of coronavirus disease 2019 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows Moderna COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

Johnson & Johnson Update: On April 13, 2021, CDC and FDA recommended a pause in the use of Johnson & Johnson's Janssen COVID-19 Vaccine. Of the nearly 7 million doses administered so far in the United States, a small number of reports of a rare and severe type of blood clot have been reported in people after receiving the J&J/Janssen COVID-19 Vaccine. All reports occurred among women between the ages of 18 and 48, and symptoms occurred six to 13 days after vaccination. As of April 13, 2021, of the more than 180 million doses administered so far of the Pfizer-BioNTech or Moderna vaccines, no reports matching those associated with the J&J/Janssen vaccine have been received.

FEMA's J&J Update: In alignment with the recommendation from the CDC and FDA to pause the use of the Johnson & Johnson vaccine, FEMA immediately ceased administration of these doses at our federal community vaccination center pilot sites and mobile vaccine units. This pause will continue until further guidance is received from CDC and FDA. We are working with our state partners to determine the path forward and find alternative vaccine options for these sites.

FEMA Vaccination Sites: There are 31 active or temporarily closed federal community vaccination center pilot sites and 20 mobile pop-up sites in 22 states. Additionally, there are 10 mobile vaccination units deployed to eight states. These centers and units have administered more than 3.4 million vaccinations. Working with state governments FEMA will open additional federal community vaccination center pilot sites, which include federal support and supplemental vaccine allocation: this week, federal community vaccination center pilot sites are scheduled to open in Bessemer, Alabama; Tulsa, Oklahoma; and Central Point, Oregon. Last week, FEMA transitioned management

of the federal community vaccination center pilot sites in Los Angeles and Oakland to the state. FEMA continues to support both sites with federal personnel. Additionally, FEMA has obligated more than $936 million to support the state's vaccination efforts. These sites administered more than 671,000 shots since they opened on Feb. 16. FEMA mobile vaccination units have begun operations. These vehicles can bring vaccinations to hard-to-reach and high-risk populations who cannot access services from fixed sites. Ten mobile vaccination units are currently deployed to Connecticut, Maine, Maryland, Nebraska, Nevada, New Mexico, Oregon and South Dakota.

DoD Response to J&J Pause: In a press briefing on Friday, Pentagon Press Secretary John F. Kirby stated that while the DoD intended to use the Johnson & Johnson vaccine to support overseas personnel and their families, the vaccine distribution planners on our COVID task force developed a plan to reallocate doses of the Moderna vaccine to our overseas commands. Each service will now direct a total of approximately 30,000 additional doses of Moderna throughout the month of May. That's around roughly 10,000 per week, beginning May 10th, to overseas locations in European Command, Indo-Pacific Command and Central Command. This will help keep the vaccination efforts right on pace to provide initial doses to over 70 percent of our overseas personnel and their families by the end of May.

COVID-19 Illness After Vaccination: CDC released information regarding what you should know about the possibility of COVID-19 illness after vaccination. COVID-19 vaccines are effective. However, a small percentage of people who are fully vaccinated will still get COVID-19 if they are exposed to the virus that causes it. These are called "vaccine breakthrough cases." This means that while people who have been vaccinated are much less likely to get sick, it may still happen. Experts continue to study how common these cases are.

CDC Weekly Review: On Friday, CDC released their weekly review on the COVID-19 pandemic, including updated numbers of reported cases, SARA-CoV-2 variants, testing, vaccinations, hospitalizations, and deaths. Nationally, COVID-19-related emergency department visits as well as both hospital admissions and current hospitalizations have risen among patients ages 18 to 64 years in recent weeks. The good news is that emergency department visits and hospitalizations among people ages 65 years and older have decreased, likely demonstrating the important role vaccination plays in protecting against COVID-19. As access to vaccines for all Americans increases, we have reason to be hopeful. However, until more of the U.S. population is fully vaccinated, consistent use of prevention strategies, such as universal and correct use of masks, social distancing, and hand washing, will help to limit the spread of SARS-CoV-2, the virus that causes COVID-19. Even if you have been fully vaccinated against COVID-19, you should keep taking these everyday precautions in public places. For more information, view the CDC's data on vaccinations, vaccination demographics, and vaccination trends.

Operational Considerations for Jurisdictions Planning to Operate COVID-19 Vaccination Clinics: CDC released guidance for jurisdictions planning to operate COVID-19 vaccinations clinics. Safe and effective COVID-19 vaccines have been developed and authorized and are being manufactured. Jurisdictions are presently vaccinating people in their target populations. Currently, vaccine is available in growing quantities, with even more vaccine slated to become available soon. Most jurisdictions can provide access to vaccination using a combination of usual vaccination providers

(pharmacies and medical providers/community health centers) and a limited number of public health clinics. Many jurisdictions are planning for and operating multiple, temporary, large- and small-scale vaccination sites, both fixed location and mobile, as strategies to vaccinate more of the population rapidly. The Federal Emergency Management Agency (FEMA) is working with jurisdictions to establish Community Vaccination Centers (CVCs). These CVCs can be established as fixed facilities, drive-through facilities, or as mobile vaccination clinics based on a jurisdiction's needs.

ACIP Jurisdictions Estimated Worker Population: CDC updated their information from the Advisory Committee on Immunization Practices (ACIP) regarding vaccination data among different worker populations.

Testing and Treatment

FDA Revokes EUA for Monoclonal Antibody Bamlanivimab: On Friday, the FDA revoked the emergency use authorization (EUA) that allowed for the investigational monoclonal antibody therapy bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. Based on its ongoing analysis of emerging scientific data, specifically the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone resulting in the increased risk for treatment failure, the FDA has determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. Therefore, the agency determined that the criteria for issuance of an authorization are no longer met and has revoked the EUA. Instead of administering Bamlanivimab alone, health care providers should consider using the other authorized monoclonal antibody therapies expected to retain activity against the viral variants: Casirivimab and imdevimab, administered together, and Bamlanivimab and etesevimab, administered together.

FDA Testing Update: As of Friday, 363 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 266 molecular tests and sample collection devices, 75 antibody and other immune response tests, and 22 antigen tests. There are 46 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home tests, four over-the-counter (OTC) at-home antigen tests, and two OTC molecular tests. The FDA has authorized 7 antigen tests and 2 molecular tests for serial screening programs. The FDA has also authorized 457 revisions to EUA authorizations.

Funding

$150 Million from ARP to Support Community-Based Health Care Providers: HHS announced the availability of nearly $150 million to community-based health care providers to aid their response to COVID-19. These funds will support approximately 100 Health Center Program look-alikes to respond to and mitigate the spread of COVID-19, strengthen vaccination efforts, and enhance health care services and infrastructure in communities across the country. Health center look-alikes (LALs) are community-based health care providers that provide essential primary care services to underserved communities and vulnerable populations but are not Health Center Program grantees. This funding

will be made available through the Health Resources and Services Administration (HRSA) and is part of President Biden's commitment to ensuring equity in the nation's COVID-19 response and vaccination efforts.

Biden Administration Announces $1.7 Billion Investment to Fight COVID-19 Variants: In order to improve the detection, monitoring, and mitigation of COVID-19 variants, the Biden Administration is rapidly investing $1.7 billion from the American Rescue Plan to help states and other jurisdictions more effectively fight these mutations. An essential component of the response to the emerging COVID-19 variants is increasing the country's genomic sequencing — the process by which COVID DNA is decoded and potentially deadly mutations in the virus are detected. With this funding, allocated through the Centers for Disease Control and Prevention (CDC), will help the CDC, states, and other jurisdictions more effectively detect and track variants by scaling genomic sequencing efforts. With the information from sequencing, the CDC and state and local public health leaders can implement known prevention measures to stop the spread.

Biden Administration Invests $4 Billion in ARP Funding to Combat COVID-19 in Indian Country: As part of President Biden's continued efforts to ensure the pandemic response reaches all people and all communities, the Biden Administration is announcing it will invest more than $4 billion to combat COVID-19 in Indian Country. The funding, from the American Rescue Plan, will expand COVID-19 vaccinations, testing, and treatment; increase preventive health services to American Indians and Alaska Natives at higher risk for COVID-19; expand hospitals' and health clinics' ability to serve their communities during the pandemic and beyond; and provide the Indian Health Service (IHS), tribal health programs, and urban Indian health programs with needed funding to make up for lost reimbursements experienced during the pandemic.

FEMA Funeral Assistance Funding: As of today, FEMA has received more than 101,000 funeral assistance applications. Applicants may apply by calling 844-684-6333 (TTY: 800-462-7585) from 9 a.m. to 9 p.m. ET, Monday through Friday. Multilingual services are available. Callers who use a relay

service, videophone or captioned telephones should provide their specific number assigned to that service. It is important that FEMA is able to contact applicants. Please note, phone calls from FEMA may come from an unidentified number. FEMA will not contact anyone until they have called FEMA or have applied for assistance.

Reopening Guidance

Personal and Social Activities: CDC updated their information on engaging in personal and social activities. COVID-19 cases, hospitalizations, and deaths are extremely high across the United States. To decrease your chance of getting and spreading COVID-19, CDC recommends that you do not gather with people who do not live with you at this time. Attending events and gatherings increases your risk of getting and spreading COVID-19. Stay home to protect yourself and others from COVID-19.

Travel Health Notices: CDC updated their travel health notices to provide current risk assessment levels for COVID-19 in different countries.

Considerations for Casinos and Gaming Operations: As some casinos and gaming operations resume in some areas of the United States, CDC offers the following considerations for ways in which casino and gaming operators can help protect staff and customers and slow the spread of COVID-19. Casinos and gaming operations can determine, in collaboration with local, state, territorial, federal, or tribal health officials, whether and how to implement these considerations, making adjustments to meet the needs and circumstances of the local community. Implementation should be guided by what is feasible, practical, acceptable, and tailored to the needs of each community. For more information on bars and restaurants within casinos, please see CDC's Considerations for Restaurants and Bars. These considerations are meant to supplement—not replace—any local, state, territorial, federal, or tribal safety laws, rules, or regulations with which businesses must comply.

Community-Based Organizations: CDC updated their guidance for community-based organizations (CBOs). As some CBOs begin to resume or increase their level of activities, CDC offers considerations for ways these organizations can help protect individuals and communities and slow the spread of coronavirus disease 2019 (COVID-19). COVID-19 cases, hospitalizations, and deaths are extremely high across the United States. To decrease your chance of getting and spreading COVID-19, CDC recommends that you do not gather with people who do not live with you at this time. Attending events and gatherings increases your risk of getting and spreading COVID-19. Stay home to protect yourself and others from COVID-19.

Considerations for Institutions of Higher Education: CDC updated their guidance for institutions of higher education (IHEs). As some IHEs prepare to re-open or keep open in-person learning in the United States, IHEs are faced with the challenge of keeping students, faculty, staff, and volunteers safe due to the coronavirus disease 2019 (COVID-19) pandemic. CDC offers the following considerations for ways that IHEs can help protect students and employees (e.g., faculty, staff, and administrators) and slow the spread of COVID-19. This document refers only to risks related to COVID-19. IHEs may consider implementing several strategies to maintain healthy environments.

Information for Specific Populations

USDA Activities to Contain the COVID-19 Pandemic: The United States Department of Agriculture (USDA) updated their fact sheet on activities to contain the COVID-19 pandemic. USDA has deployed 1,064 disaster, public health specialists to assist with federal response.

Guidance for Large or Extended Families Living in the Same Home: CDC released guidance for large or extended families living in the same home. If you or someone in your household is at increased risk for severe illness from COVID-19, then all family members should act as if they are at increased risk. This can be difficult if space is limited for large or extended families living together. While avoiding close contact with others and isolating someone who is sick can feel lonely, these actions are necessary to reduce the spread of COVID-19 and protect yourself and your household.

DoD Force Health Protection Guidance: On Friday, the Department of Defense released the memorandum for Force Health Protection Guidance (Supplement 20) – Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic. This memorandum applies to official and unofficial travel and proves updated pre- and post-travel guidance for purposes of force health protection (FHP) for Service members, DoD family members, DoD civilian employees, and DoD contractor personnel, as well as fully vaccinated individuals.

Staffing Resources: CDC updated their staffing resources and guidance to strengthen the public health workforce. CDC updated their information regarding the number of CDC COVID-19 response staff deployed across America.

Cleaning, Disinfecting, and Ventilation: CDC updated their resources for cleaning, disinfecting, and ventilation, including an updated toolkit for school administrators on cleaning, disinfection, and hand hygiene. Reducing the risk of exposure to SARS-CoV-2, the virus that causes COVID-19, by cleaning and disinfection is an integral part of opening schools that will require careful planning.

Childhood Vaccination Toolkit for Clinicians: CDC released a toolkit for clinicians on getting children caught up on receiving recommended vaccinations. COVID-19 disrupted both in-person learning and routine well-child visits for many children over the last year. As a result, too many children have fallen behind on receiving recommended vaccines. Children need to get caught up now so that they are protected as they go back to in-person learning and summer camps. Healthcare providers can identify families whose children have missed doses and contact them to schedule appointments. Providers can also let families know what precautions are in place for safe delivery of in-person services.

Health Departments and Public Safety Partners: CDC updated their information for health departments and public health partners to help educate communities and promote COVID-19 vaccination.

Manufacturing Workers & Employers: CDC and the Occupational Safety and Health Administration (OSHA) updated their guidance for manufacturing workers and employers.

Acute Care Delivery at Home Tip Sheet: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released a tip sheet providing an overview of characteristics of various types of acute care delivery at home programs to help healthcare providers better understand this care model. Some healthcare providers and systems have been providing hospital-level care in patient's homes for years; others have implemented acute care delivery at home models in response to overcrowding at hospitals due to COVID-19.

COVID-19 and Healthcare Professional Stress and Resilience: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released Issue 12 of The Exchange, which examines the impact of COVID-19 on healthcare professionals. The issue focuses on three categories: understanding acute and chronic stressors in the healthcare worker population, identifying at-risk employees, and promising practices in building resilience.

COVID-19 Healthcare Delivery Impacts: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) updated their tip sheet to help healthcare system planners prepare to mitigate potential healthcare delivery impacts.

Strategies to Help Combat the Coronavirus Blues: The COVID-19 Schools Task Force, FEMA Region VII, and HHS Region 7 released a document summarizing the contents of the Mind Over Matter Resource Guide. This guide can be used to support messaging for college and university campus communities to help combat COVID-19 fatigue and promote general wellness, both during and after the pandemic.

Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19: On April 2, 2021, the CDC released a declaration determining that the eviction of tenants could be detrimental to public health control measures to slow the spread of COVID-19. View the posted order, as well as eviction protection declaration forms in English and Spanish. Please visit HUD's COVID-19 Emergency Information for Housing Counselors for additional resources and information.

United States Coast Guard Vaccine FAQs: The United States Coast Guard updated their Frequently Asked Questions page about the vaccine, and specific questions related to Coast Guard administered vaccines.

Older Adults: CDC updated their information for older adults, who are at a greater risk of hospitalization or dying if diagnosed with COVID-19. The risk for severe illness with COVID-19 increases with age, with older adults at highest risk. If you have a family member or friend who lives in a nursing home, assisted living facility, or other type of senior living or retirement community, you may be concerned about COVID-19. To protect friends and family members who live in these communities, CDC has issued updated recommendations for visitations at post-acute facilities. These recommendations align with the Centers for Medicare and Medicaid Services (CMS) guidance for visitations under various circumstances.

Caring for Someone Sick: CDC updated their guidance for caregivers in non-healthcare settings. Cleaning with a household cleaner that contains soap or detergent reduces the amount of germs on

surfaces and objects and decreases risk of infection from surfaces. In most situations, cleaning alone removes most virus particles on surfaces.

People at Increased Risk: CDC updated their resources available for people at increased risk, and for other people who need to take extra precautions.

Non-Emergency Transportation for Tribal Communities: CDC updated their guidance on non-emergency transportation for tribal communities. Tribal community members may need to regularly share personal vehicles with members outside of their own households. They may also need to use personal vehicles to transport people who are visibly sick. In addition, tribal organizations may provide medical transportation to their community members using non-emergency vehicles (cars or vans, for example). CDC outlines precautions that can be considered to minimize risk of spreading COVID-19 when sharing personal vehicles.

Implementing Screening and Treatment of Unhealthy Alcohol Use During COVID-19: The Agency for Healthcare Research and Quality (AHRQ) posted an article on implementing screening and treatment of unhealthy alcohol use during COVID-19. Since the onset of the COVID-19 pandemic in March 2020, alcohol sales have increased dramatically in many States across the country and rates of unhealthy alcohol use are rising in parallel. Unhealthy alcohol use, which refers to the full spectrum of alcohol misuse from risky or hazardous drinking to alcohol use disorder, is associated with adverse consequences, including poorer physical and mental health outcomes as well as negative socioeconomic effects. AHRQ's EvidenceNow: Managing Unhealthy Alcohol Use Initiative represents an important opportunity to help clinicians support many patients receive the appropriate diagnosis, counseling, and treatment for unhealthy alcohol use by implementing the best patient-centered outcomes research findings available to improve health.

Sprayers Safety Precautions: CDC updated their information regarding how to select cleaners, disinfectants, and application methods for use in facilities, businesses, and public indoor spaces to ensure that you can clean and disinfect safely and effectively. In most situations, cleaning surfaces (using soap or detergent) is enough to reduce SAR-CoV-2, the virus that causes COVID-19. Clean surfaces before disinfecting.

CMS Updates

Encouraging Latino Consumers to Enroll in Health Insurance Coverage: Today, HHS Secretary Xavier Becerra announced commitments from national organizations to support Latino outreach and enrollment efforts during the current Special Enrollment Period (SEP) made available on HealthCare.gov by President Biden due to the COVID-19 Public Health Emergency (English | Spanish). As part of the Latino Week of Action April 18 - 24, these organizations and HHS will share information with Latino consumers and use social media to encourage them to enroll in affordable, quality health plans through HealthCare.gov. Access to affordable health coverage and care is particularly important for Latinos in the US because 22% of non-elderly Latinos are uninsured, a rate almost 2.5 times that of White Americans. During this week and beyond, HHS and many organizations will send targeted messages, participate in earned media opportunities, and amplify the SEP through social media channels to raise awareness about the coverage options available

through HealthCare.gov for the Latino community. The Centers for Medicare & Medicaid Services (CMS) has also launched an outreach and an educational campaign, which includes broadcast and digital advertising and educates through email and text messages in both Spanish and English.

PPE

Guidance for Wearing Masks: CDC updated their guidance for wearing masks. Masks are a simple barrier to help prevent your respiratory droplets from reaching others. Studies show that masks reduce the spray of droplets when worn over the nose and mouth. CDC also updated their information on the different types of masks. CDC recommends that N95 respirators should be prioritized for protection against COVID-19 in healthcare settings. Essential workers and workers who routinely wore respirators before the pandemic should continue wearing N95 respirators. As N95s become available they can be worn in non-healthcare settings.

Research

Large Clinical Trial to Study Repurposed Drugs to Treat COVID-19 Symptoms: The NIH will fund a large, randomized, placebo-controlled Phase 3 clinical trial to test several existing prescription and over-the-counter medications for people to self-administer to treat symptoms of COVID-19. Part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public–private partnership, the ACTIV-6 trial aims to provide evidence-based treatment options for the majority of adult patients with COVID-19 who have mild-to-moderate symptoms and are not sick enough to be hospitalized. NIH will provide an initial investment of $155 million in funding for the trial.

Experimental Antiviral for COVID-19 Effective in Hamster Study: The experimental antiviral drug MK-4482 significantly decreased levels of virus and disease damage in the lungs of hamsters treated for SARS-CoV-2 infection, according to a new study from NIH scientists. SARS-CoV-2 is the virus that causes COVID-19. MK-4482, delivered orally, is now in human clinical trials. Remdesivir, an antiviral drug already approved by the U.S. Food and Drug Administration for use against COVID-19, must be provided intravenously, making its use primarily limited to clinical settings. In their study, published in the journal *Nature Communications*, the scientists found MK-4482 treatment effective when provided up to 12 hours before or 12 hours after infecting the hamsters with SARS-CoV-2. These data suggest that MK-4482 treatment potentially could mitigate high-risk exposures to SARS-CoV-2 and might be used to treat established SARS-CoV-2 infection alone or possibly in combination with other agents.

Public Health Investigations of COVID-19 Vaccine Breakthrough Cases: CDC released a case investigation protocol on public health investigations of COVID-19 vaccine breakthrough cases. The U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for three COVID-19 vaccines. In large, randomized controlled trials, each vaccine was safe and efficacious for preventing symptomatic, laboratory-confirmed COVID-19 disease. There were no statistically significant differences in efficacy by age, gender, race, or comorbidities. Despite the high level of efficacy, a small number of breakthrough cases occurred. The phase 3 studies have not yet identified risk factors for vaccine breakthrough cases; however, approximately 44,000 people received the FDA-authorized vaccines during the clinical trials and follow-up is ongoing. This protocol can be used

to guide public health investigations of COVID-19 vaccine breakthrough cases. We aim to capture both symptomatic and asymptomatic infections. Characterization of vaccine breakthrough cases could provide the first indication that a vaccine is less effective in certain demographic groups or that vaccine-induced immunity is waning, and booster doses may be needed. Clustering of cases among vaccinated persons by time, geographic area, or lot could help identify an issue in manufacturing, shipping, handling, or administration. Evaluating SARS-CoV-2 strains that cause vaccine breakthrough cases provides one way to monitor for variant strains that could result in lower vaccine efficacy.

COVID-19 and the Changing Healthcare Delivery Landscape: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released a study highlighting the impact of COVID-19 on healthcare delivery. The study examines supply chain, patients delaying emergency care, the delay of elective procedures, and financial impacts to the healthcare system.

COVID-19 Science Update: CDC released their weekly COVID-19 Science Update. This week's issue includes, but is not limited to, research on the following: the association of sociodemographic factors and blood group type with risk of COVID-19, increased household secondary attack rates with variants of concern**,** and the epidemiologic evidence for airborne transmission of SARS-CoV-2 during church singing.

Hospitalization and Death by Race/Ethnicity: CDC updated their information on hospitalization and death rates by race/ethnicity. Race and ethnicity are risk markers for other underlying conditions that affect health including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: HHS IEA (OS/IEA)
To: HHS IEA (OS/IEA)
Subject: HHS COVID-19 Update - 8/5
Date: Thursday, August 5, 2021 9:08:37 PM

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for August 5, 2021:

Highlights from President Biden's August 3rd Remarks on Fighting the COVID-19 Pandemic

- **Delta Variant and Transmissibility:** President Biden stated that because the Delta variant is highly transmissible, it is causing a new wave of cases, accounting for over 80% of cases in the United States today, with a likelihood of an increase in cases in the future. Biden states that the predicted increase is "a largely preventable tragedy that will get worse before it gets better."
- **COVID-19 and Vaccines:** Biden stated that the best way to protect yourself from COVID-19 is to get vaccinated; if vaccinated, it is highly unlikely to get COVID-19 and, if you contract the virus, you will likely experience mild symptoms if any. The data shows that the vast majority of cases, hospitalizations, and deaths due to COVID-19 are from the unvaccinated population. Biden commented, "The best line of defense against the virus is the vaccine… We have a pandemic of the unvaccinated."
- **Data of Increased Vaccination:** Biden reported a 55 percent increase in the average number of new people getting vaccinated every day in the past two weeks, and the highest seven-day total in a month. The eight states with the highest current case rates have seen a doubling of the number of people newly vaccinated each day. Biden declared that "we have to continue our aggressive efforts to vaccinate the unvaccinated."
- **Federal Steps to Incentivize Vaccination:** Biden outlined steps taken by his administration and other government-affiliated organizations to increase vaccinations. Places that have offered $100 to get vaccinated have seen an uptick of 25 percent of daily vaccination rates. Biden reiterated his plan to reimburse small- and medium-sized businesses who give paid time off to their employees to get vaccinated, to work with the Pentagon on adding COVID-19 to required vaccines for troops, and to require healthcare workers in the Department of Veterans Affairs to be vaccinated. Biden stated that these restrictions are "tough, unpopular steps to keep people safe and our economy strong."
- **States' Lack of Action on COVID:** President Biden stated that many states' harmful laws on mask mandates is disappointing and harmful; seven states have both banned mask mandates statewide and in schools while many students are not yet eligible to be vaccinated. The president cited these measures and accompanying low vaccination rates as the cause of the rise of cases, citing Florida and Texas as accounting for a third of all new cases. Biden declared that "COVID-19 is a national challenge, and we must come together — we have to come together — all of us together, as a country, to solve it."
- **Vaccination Abroad:** Biden stated that a global attack on the virus is in the United States' national interest. New, potentially more dangerous variants (such as the Delta variant) can mutate outside of the United States and threaten the country if a global approach is not taken. Biden highlighted American action in global vaccination, announcing that he will

purchase and donate 500 million doses from Pfizer; he also stated that the U.S. has domestically manufactured 110 million doses for global vaccination. Biden reiterated that he's "been very clear-eyed that we need to attack this virus globally, not just at home, because it's in America's self-interest to do so."

Highlights from the White House COVID-19 Response Team Briefing

Jeff Zients

- **Update on Progress in the Fight Against COVID:** Mr. Zients highlighted how, driven by the Delta variant, cases are continuing to rise, especially among the unvaccinated. Zients states that over the past seven days, seven states — among the leaders in unvaccinated percentage — accounted for half of the new cases and hospitalizations despite holding less than a quarter of US population; vaccines are the best way to protect against COVID. Vaccinations are on the rise; the past 24 hours served as the greatest number of vaccinations in a single day since July 3 and the daily average of vaccinations has increased for the fourth week in a row. Zients said that "clearly Americans are seeing the impact of being unvaccinated and unprotected and they respond by doing their part, rolling up their sleeve, and getting vaccinated."
- **Action on Vaccination Requirements:** Mr. Zients reiterated President Biden's call for federal workers and contractors to get vaccinated and notes the further requests for similar requirements in the private sector. Zients stated that over 650 colleges and universities are requiring students and staff on campus to be vaccinated and nationwide, over 100 hospitals and healthcare systems are requiring healthcare professionals to be vaccinated. "America's businesses, large and small, universities and medical schools, and many other institutions are stepping up on vaccination requirements and our message is quite simple: we support these vaccination requirements to protect workers, communities, and the country," Zients said.
- **COVID-19 Surge Response Teams:** Mr. Zients stated that the COVID-19 Surge Response Teams are in 16 states and addressing each state's specific needs, whether that is increased testing, mobile vaccination clinics, or hospital capacity. Zients noted the hundreds of federal employees deployed to the states that are assisting in combatting COVID. "Our whole of government response," Zients said, "will continue its relentless efforts to end this pandemic and deliver progress each and every day."

Dr. Walensky

- **COVID-19 Case Update:** Dr. Walensky stated that on August 3, the CDC reported 103,455 new cases of COVID with a 7-day average of about 89,463 cases per day, representing an increase of 43.3% from last week. Hospitalizations and deaths from this week compared to the last increased significantly; deaths rose 39.3 percent. Walensky stated that 83% of counties within the United States are experiencing moderate or high transmission. Those at high risk remain people who have not yet been vaccinated. Walensky said that "now is the time to get vaccinated. We know these vaccines are working and we know that they save lives."

Dr. Fauci

- **Vaccine Hesitancy and Concern Over Development Speed:** In response to Americans

worried about the speed of the development of the vaccine, Dr. Fauci outlined the various ways in which the vaccine is safe and not rushed: the investment of logistics and resources, the decades of prior research (both in platform technology and immunogen), the non-sequential investment in vaccine development, and the reuse of clinical trial sites originally built for HIV and influenza further sped the development. Fauci said that the vaccine "did not go too fast; it was a major investment both in the logistics, the resources, and the clinical and basic research."

Dr. Murthy

- **Vaccine Efficacy:** Dr. Murthy stated that the COVID-19 vaccines protect against the Delta variant, both at reducing the risk of infection and the severity if infected. Murthy said that "breakthrough infections of vaccinated people are the exception, not the rule."
- **Meeting of Living Surgeons General:** Yesterday, Dr. Murthy met with the living former surgeons general to discuss the vaccination effort with equity being at the forefront. The meeting covered health misinformation, ensuring that communities of color and rural areas are not left behind, and engaging with trusted community messengers. Murthy stated that "this gathering of surgeons general reflected the diversity of our nation, and it was emblematic of what we have to do together to defeat the virus."

Testing and Treatment

FDA Testing Updates: As of August 3, 398 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 279 molecular tests and sample collection devices, 87 antibody and other immune response tests and 32 antigen tests. There are 53 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, six antigen over-the-counter (OTC) at-home tests and two molecular OTC at-home tests. The FDA has authorized 13 antigen tests and eight molecular tests for serial screening programs. The FDA has also authorized 595 revisions to EUA authorizations.

Funding

FEMA COVID-19 Funeral Assistance Tops $888 Million: FEMA announced that COVID-19 funeral assistance has now increased to over $888 million to more than 135,000 people to assist with COVID-19-related funeral costs for deaths occurring on or after Jan. 20, 2020. The assistance, easing financial stress, comes from the Coronavirus Response and Relief Supplemental Appropriations Act of 2021 and the American Rescue Plan Act of 2021. Eligibility determinations are not driven by state/location; instead, they are based on when the applicant submits all required documentation.

Information for Specific Populations

CDC Issues Eviction Order in Areas of Substantial and High Transmission: CDC announced that Director Dr. Rochelle Walensky signed an order on August 3rd determining the evictions of tenants for failure to make rent or housing payments could be detrimental to public health control measures to slow the spread of SARS-CoV-2, the virus that causes COVID-19. This order will expire on October 3, 2021 and applies in United States counties experiencing substantial and high levels of community

transmission levels of SARS-CoV-2: This temporary protection from eviction in counties with heightened levels of community transmission exists in order to respond to recent, unexpected developments in the trajectory of the COVID-19 pandemic, including the rise of the Delta variant. It is intended to target specific areas of the country where cases are rapidly increasing, which likely would be exacerbated by mass evictions.

CDC Extends Order at the Southern and Northern Land Borders: The Centers for Disease Control and Prevention (CDC) has issued an order under Sections 362 and 365 of the Public Health Service Act, and associated implementing regulations, that temporarily suspends the introduction of certain noncitizens. The order is based on the Director's determination that introduction of such noncitizens, regardless of their country of origin, migrating through Canada and Mexico into the United States creates a serious danger of the introduction of COVID-19 into the United States, and the danger is so increased by the introduction of such noncitizens that a temporary suspension is necessary to protect the public health. Unaccompanied noncitizen children already excepted under a July 16, 2021, order, remain excepted from the order's coverage.

Readout of the Sixth Covid-19 Health Equity Task Force Meeting: HHS released a readout on Friday, July 30's, sixth COVID-19 Health Equity Task Force meeting to consider interim recommendations addressing future pandemic preparedness. Task Force Members discussed and voted favorably on interim recommendations, including but not limited to exploring strategies that meet local and regional staffing needs during pandemic response, expanding adequate and evidence-based healthcare access and funding infrastructure to treat patients in congregate settings, establishing and adjusting national standards as well as strategically target funding for water, sewage, and air quality to where it's needed, based on data from reliable equity indicators.

What to Consider When Planning to Operate a COVID-19 Vaccine Clinic: CDC released information regarding what to consider when planning to operate a COVID-19 vaccine clinic. The informational sheet provides guidance to conduct a gap analysis to determine specific geographic areas and specific populations that may benefit from additional sites to improve access to vaccination, work with community leaders and trusted members of the community to help with the success of vaccination clinics, and assess the optimal time to activate a vaccination site and consider the benefits of focused vaccination efforts. The page also page also provides a checklist of best practices for vaccination clinics held at satellite, temporary, or off-site locations.

Know What to Expect at Your Child's K- 12 School or Child Care Program: CDC released information for parents on what to expect for K-12 school or childcare programs. The page provides information for factors that a child's school or care program may consider, prevention strategies for these programs, and vaccination and masking.

CMS Updates

Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Rates Final Rule (CMS-1752-F): CMS announced that, on August 2, 2021, it issued the final rule for fiscal year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS). The final rule

updates Medicare payment policies and rates for operating and capital-related costs of acute care hospitals and for certain hospitals and hospital units excluded from the IPPS for FY 2022. The policies in this IPPS and LTCH PPS final rule build on key priorities to close health care equity gaps and support greater access to life-saving diagnostics and therapies during the COVID-19 public health emergency (PHE) and beyond. To continue to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments and to minimize any potential payment disruption immediately following the end of the PHE, CMS is extending the New COVID-19 Treatment Add-on Payment for eligible COVID-19 products through the end of the fiscal year in which the PHE ends.

Research

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings: CDC released an *MMWR* on the outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings in Barnstable County, Massachusetts in July, 2021. This report was released as an *MMWR* Early Release on July 30. Variants of SARS-CoV-2 continue to emerge. The B.1.617.2 (Delta) variant is highly transmissible. In July 2021, following multiple large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; 346 (74%) occurred in fully vaccinated persons. Testing identified the Delta variant in 90% of specimens from 133 patients. Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not. Jurisdictions might consider expanded prevention strategies, including universal masking in indoor public settings, particularly for large public gatherings that include travelers from many areas with differing levels of SARS-CoV-2 transmission. CDC Director Rachelle Walensky, MD, MPH, released an accompanying statement on the MMWR.

COVID-19 Vaccine Safety in Adolescents Aged 12–17: CDC released an *MMWR* on COVID-19 vaccine safety in adolescents aged 12–17 in the United States from December 14, 2020 - July 16, 2021. This report was released as an *MMWR* Early Release on July 30. In preauthorization trials of the Pfizer-BioNTech COVID-19 vaccine, adolescents aged 12–17 years reported local and systemic mild and moderate reactions. Myocarditis has been observed after vaccination with mRNA vaccines in post authorization monitoring. Local and systemic reactions after vaccination with Pfizer-BioNTech vaccine were commonly reported by adolescents aged 12–17 years to U.S. vaccine safety monitoring systems, especially after dose 2. A small proportion of these reactions are consistent with myocarditis. Mild local and systemic reactions are common among adolescents following Pfizer-BioNTech vaccine, and serious adverse events are rare. The Advisory Committee on Immunization Practices conducted a risk-benefit assessment and continues to recommend the Pfizer-BioNTech COVID-19 vaccine for all persons aged ≥12 years.

Full-dose Blood Thinners Reduce the Need for Organ Support in Moderately Ill COVID-19 Patients, but Not in Critically Ill Patients: NIH released a report on full-dose blood thinners reducing the need for organ support in moderately ill COVID-19 patients, but not critically ill patients. In April 2020, hospitalized COVID-19 patients received either a low or full dose of heparin, a blood thinner, for up to 14 days after enrollment. By December 2020, interim results indicated that full-dose anticoagulation did not reduce the need for organ support and may even cause harm in critically ill

patients. However, one month later, interim results indicated that full doses of heparin likely benefited moderately ill patients. The full study can be viewed here.

Long-Term Study of Brain Development Records Pandemic Life: NIH released a report on the analysis of adolescent brains to examine the long-term health impacts caused by the COVID-19 pandemic and shutdowns. Through surveys and tests, the study, from Adolescent Brain Cognitive Development (ABCD) Study and funded by NIH, is capturing the impact of the COVID-19 pandemic on children using an MRI.

Case Forecasts: This week's national ensemble predicts that 350,000 to 1,800,000 new cases will likely be reported in the week ending August 28, 2021. Over the last several weeks, more reported cases have fallen outside of the forecasted prediction intervals than expected. This suggests that current forecast prediction intervals may not capture the full range of uncertainty. Because of this, case forecasts for the coming weeks should be interpreted with caution. View previous case forecasts.

Hospitalization Forecasts: This week's national ensemble predicts that the number of new daily confirmed COVID-19 hospital admissions will likely increase over the next 4 weeks, with 6,700 to 24,000 new confirmed COVID-19 hospital admissions likely reported on August 30, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of daily confirmed COVID-19 hospital admissions will likely increase in 38 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported hospital admissions are uncertain or predicted to remain stable in the other states and territories. View previous hospitalization forecasts.

Death Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 deaths will likely increase over the next 4 weeks, with 2,300 to 9,100 new deaths likely reported in the week ending August 28, 2021. The national ensemble predicts that a total of 624,000 to 642,000 COVID-19 deaths will be reported by this date. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of newly reported deaths per week will likely increase in 17 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported deaths are uncertain or predicted to remain stable in the other states and territories. View previous death forecasts.

Top Military Medical Doctor Predicts Coronavirus Longevity: DoD released a report on the analysis of COVID-19 longevity according to director of Defense Health Agency, Army Lt. Gen. Ronald J. Place. Place stated his belief that COVID-19 and other such coronaviruses likely will stay in the environment and continue to mutate. Vaccines serve as the way to protect oneself from this lingering threat.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: CDC IMS 2019 NCOV Response STLT TF HDS Comms Section
Subject: Health Department Weekly 07.16.21
Date: Friday, July 16, 2021 2:43:47 PM
Attachments: image003.emz
image004.png
image005.png
CDC Strategic Public Health Science AJPH early release.pdf
Evidence_Experience_Expertise.pdf.pdf

Dear Health Department Colleagues,

Please see this week's highlights below. We have several items of note.

Additionally, get inspired! COVID-19 responder stories tell more about these public health heroes just like you!

Is there anything specific that you would like to see featured? Please do not hesitate to email any questions and suggestions to our Health Department Section Communications Team: eocevent501@cdc.gov

Thank you for all your continuing dedication to your communities,
STLT Support Task Force, Health Department Section

New + Notable

SARS-COV-2 Variants

Multiple variants of the virus that causes COVID-19 are circulating globally and within the United States. To date, four variants have been classified as a variant of concern (VOC). The variant of the virus that caused the first U.S. COVID-19 cases in January 2020 no longer circulates in the country. As new variants of the virus emerge and others fade away, the proportion of variants circulating in the United States will continue to rise and fall. Nationally, the proportion of cases attributed to the new VOCs are:

- B.1.617.2 (Delta) is predicted to increase to 51.7%, becoming the predominant lineage in the U.S.
- B.1.1.7 (Alpha) proportion is predicted to decrease to 28.7%.
- P.1 (Gamma) proportion is predicted to decrease to 8.9%.
- B.1.351 (Beta) is predicted to decrease slightly to 0.2%.
- B.1.617.2 (Delta) will increase in all HHS regions and be more than 70% in regions 7 and 8.
- B.1.1.7 (Alpha) is predicted to be less than 50% in all HHS regions.
- P.1 (Gamma) is predicted to be more than 10% in regions 1, 4, 5, 9, and 10.
- B.1.351 (Beta) is predicted to be less than or equal to 0.5% in all HHS regions.

Introducing Vira, the Vax Chatbot

COVID-19 vaccination is lagging in young adults nationally. Vira, the Vax Chatbot is designed to support and meet young people where they are with simple answers to common COVID-19 vaccine questions. Vira is adaptive, learning by listening to your questions and feedback to help scientists respond to emerging questions.

Vira was developed by the International Vaccine Access Center at the Johns Hopkins Bloomberg School of Public Health with experts from the Bloomberg School's Department of International Health and Johns Hopkins Whiting School of Engineering. Vira's knowledge base from Johns Hopkins vaccine scientists was developed with support from the COVID-19 Training Initiative, with funding from Bloomberg Philanthropies.

VaxChat, powered by IBM, was inspired by previous research that showed automated chatbots using AI can effectively communicate credible information and support health behavior changes.

Vira can help health workers or anyone who seeks help fielding questions from family and friends about the COVID-19 vaccines. Check out Vira, a vax chatbot that's here to help you and your loved ones make an informed decision. Explore at VaxChat.org. This information is provided by Johns Hopkins.

Vaccine Updates

A Needle Today Helps Keep COVID Away

The highly transmissible B.1.617.2 (Delta) variant continues to spread across the United States at a rapid pace. Early data suggest that B.1.617.2 now makes up more than 50% of COVID-19 cases. In some parts of the country, this percentage is even higher, especially in areas with low vaccination rates. This rapid rise is concerning and threatens the progress the United States has made toward ending the pandemic.

- As of July 8, 2021, 183.2 million people, or 55.2% of the total U.S. population, have received at least one dose of a COVID-19 vaccine. About 158.3 million people, or 47.7% of the total U.S. population, have been fully vaccinated.* However, cases and hospitalizations are on the rise in areas with low vaccination coverage. Data from recent weeks show that adults ages 18–49 account for more than 40% of COVID-19-associated hospitalizations.
- Fortunately, we have safe and effective vaccines that prevent severe disease, hospitalization, and death. People who are fully vaccinated are protected from B.1.617.2. We are turning the corner on the pandemic and starting to get back to normal. However, stopping the spread of B.1.617.2 requires all of us doing our part.

For more information, please see the current COVID Tracker Weekly Review and/or sign up for the newsletter.

* People are considered fully vaccinated 2 weeks after their second dose in a 2-dose series (such as the Pfizer or Moderna vaccines), or 2 weeks after a single-dose vaccine (such as Johnson & Johnson's Janssen vaccine).

Transfer of Vaccine Outside the U.S.

Additional information is often requested on the transfer of vaccine across international borders. Here are some key points for addressing this issue within your region, state, or community. Currently, it is not possible for states or awardees to transfer COVID-19 vaccine across international borders for the following reasons:

- Vaccine contracts with manufacturers prohibit the use, or authorization of use, of vaccines outside the U.S. and its territories (excluding Departments of Defense and State foreign compounds) which are covered under the PREP Act. Sharing of vaccine internationally would violate these contracts.
- USG limits donations of federal pharmaceutical assets to products that allow the U.S. to maintain pedigree knowledge to attest to the proper storage and handling of the vaccine. Even though COVID-19 vaccine is in state possession, it is still considered a federal asset (similar to vaccine in the VFC program).
- Countries are hesitant to accept vaccine that has been maintained outside of federally monitored storage and handling guidelines. Direct distribution of vaccine from USG helps ensure the safety of vaccine to foreign governments and limits liability to states.

CDC is working tirelessly to assist the U.S. Government with transfer and distribution of vaccine to foreign governments directly from federal depots. Through this channel of vaccine supply chain management, the global distribution of vaccine is both efficient and safe. Although contributing to this effort is desirable, the CDC appreciates your adherence to the policy at this time.

The Advisory Committee on Immunization Practices will meet next Wednesday, July 22 from 11:00 to 4:00 PM EST. Draft agenda can be found here.

Attached Documents

CDC Strategic Public Health Science AJPH early release.pdf

Evidence_Experience_Expertise.pdf

Website Updates

What's New & Updated | CDC

Critical Populations Webpages

V-safe COVID-19 Vaccine Pregnancy Registry

Toolkit for People with Disabilities

Videos about COVID-19 in American Sign Language

Vaccine Webpages

CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume

Selected Adverse Events Reported after COVID-19 Vaccination

Joint CDC and FDA Statement on Vaccine Boosters

Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination

Percent of Delivered First Vaccine Doses Administered by U.S. States and Territories

V-safe After Vaccination Health Checker

COVID-19 Webpages

Covid Data Tracker

CDC COVID-19 Response Staff Deployed Across America

Cruise Ship Color and Commercial Travel Status

Long-Term Effects of COVID-19

Science Brief: Transmission of SARS-CoV-2 in K-12 Schools and Early Care and Education Programs

Myths and Facts about COVID-19 Vaccines

SARS-CoV-2 Variant Classifications and Definitions

COVID-19 By the Numbers

Notable Publications

Acceptability of Adolescent COVID-19 Vaccination Among Adolescents and Parents of Adolescents

SARS-CoV-2 B.1.617.2 (Delta) Variant COVID-19 Outbreak Associated with a Gymnastics Facility

Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices

COVID-19 Vaccine Administration, by Race and Ethnicity — North Carolina

COVID-19 Vaccination Coverage Among Insured Persons Aged ≥16 Years, by Race/Ethnicity and Other Selected Characteristics — Eight Integrated Health Care Organizations

Calls, Trainings, + Webinars

President Biden Participated in Press Events This Week

President Biden participated in a joint press conference with German Chancellor Angela Merkel on **Thursday**,

July 15, who visited the White House for an official working visit. Please look out for a recording of this press briefing as they discussed the COVID-19 pandemic, including their shared desire to provide access to vaccines around the world, and to shore up global health security.

A press briefing by White House COVID-19 Response Team and Public Health Officials was held at **11:00 am, July 16**. Archived press briefings can be accessed here: Press Briefings Archives | The White House

cdc.gov/coronavirus

From: Weaver, Richard L COL USARMY NG MSARNG (USA)

To: Thompson, Brian L CIV USAF 81 TW (USA); Barrett, Colleen E CIV USN CBC GULFPORT MS (USA); Schneider, Nathan A CAPT USN SUPSHIP GULFCOAST MS (USA); Carter, Travis L CAPT USCG GULF COAST (USA); Burnett, William H SES USN COMNAVMETOCCOM SSC (USA); Howe, Bradley K COL USARMY NG MSARNG (USA); McCormick, Berry L Col USAF MS CRTC (USA); Watson, Britt A Col USAF 186 ARW (USA); Cole, Lynn E Col USAF 172 AW (USA); "Schlosser, Teresa A COL USARMY CEPOF (USA)"; Mccullouch, Murry Brent COL USARMY NG MSARNG (USA); Jody.m.smith2.mil; Thomas, Christopher M LTC USARMY NG MSARNG (USA); "Hilliard, Robert A COL USARMY CEMVK (USA)"; "Hinkebein, Andrew (Wicker)"; Ratcliffe, Andrew M III LTC USARMY NG MSARNG (USA); Austin, Lawrence B LTC USARMY NG MSARNG (USA); Dingler, Christopher Wayne 1SG USARMY NG MSARNG (USA); Hester, Colby D CPT USARMY NG MSARNG (USA); Hargett, Joe D COL USARMY NG MSARNG (USA); Smith, Cynthia Lea (Cindy) Col USAF 172 AW (USA); Williams, Stanley T CSM USARMY NG MSARNG (USA); "Craig Sumrall"; "DuVerger, Frank R III LTC USARMY CEMVK (USA)"; "Gargiulo, Michele"; "Laura Hipp"; "AnneHall Brashier"; Craig, Jim; Dobbs, Thomas E; McIngvale, James W CTR (USA); "Andrew McMillin"; Welborn, Jeffrey H Col USAF (USA); Reedy, Millard G IV COL USARMY NG MSARNG (USA); Shaffer, Perish Undrea MAJ USARMY NG MSANG (USA); Tillman, Tommy F Jr Col USAF 172 AW (USA); Moore, Timothy B (Brent) CAPT USN NAS MERIDIAN MS (USA); Blackwell, Heather W Col USAF US STRATCOM (USA); 14 FTW/CAT Organizational Mailbox; Powell, Jeffrey S (Jeff) CAPT USN CBC GULFPORT MS (USA)

Subject: ICC COVID 19 and weather update

Date: Thursday, October 8, 2020 7:38:21 AM

Attachments: DUB 10.08.2020.pdf

[redacted]

V/R

Rick

From: Weaver, Richard L COL USARMY NG MSARNG (USA)

To: Thompson, Brian L CIV USAF 81 TW (USA); Barrett, Colleen E CIV USN CBC GULFPORT MS (USA); Schneider, Nathan A CAPT USN SUPSHIP GULFCOAST MS (USA); Carter, Travis L CAPT USCG GULF COAST (USA); Burnett, William H SES USN COMNAVMETOCCOM SSC (USA); Howe, Bradley K COL USARMY NG MSARNG (USA); "Schlosser, Teresa A COL USARMY CEPOF (USA)"; Mccullouch, Murry Brent COL USARMY NG MSARNG (USA); Jody.m.smith2.mil; Thomas, Christopher M LTC USARMY NG MSARNG (USA); "Hilliard, Robert A COL USARMY CEMVK (USA)"; "Hinkebein, Andrew (Wicker)"; Ratcliffe, Andrew M III LTC USARMY NG MSARNG (USA); Austin, Lawrence B LTC USARMY NG MSARNG (USA); Dingler, Christopher Wayne 1SG USARMY NG MSARNG (USA); Hester, Colby D CPT USARMY NG MSARNG (USA); Hargett, Joe D COL USARMY NG MSARNG (USA); Smith, Cynthia Lea (Cindy) Col USAF 172 AW (USA); Williams, Stanley T CSM USARMY NG MSARNG (USA); "Craig Sumrall"; "DuVerger, Frank R III LTC USARMY CEMVK (USA)"; "Gargiulo, Michele"; "Laura Hipp"; "AnneHall Brashier"; Craig, Jim; Dobbs, Thomas E; McIngvale, James W CTR (USA); "Andrew McMillin"; Welborn, Jeffrey H Col USAF (USA); Reedy, Millard G IV COL USARMY NG MSARNG (USA); Shaffer, Perish Undrea MAJ USARMY NG MSANG (USA); Moore, Timothy B (Brent) CAPT USN NAS MERIDIAN MS (USA); Blackwell, Heather W Col USAF US STRATCOM (USA); 14 FTW/CAT Organizational Mailbox; Powell, Jeffrey S (Jeff) CAPT USN CBC GULFPORT MS (USA); Tillman, Tommy F Jr Col USAF 172 AW (USA); Cole, Lynn E Col USAF 172 AW (USA); Watson, Britt A Col USAF 186 ARW (USA); McCormick, Berry L Col USAF MS CRTC (USA); Mantooth, Randall P LTC USARMY NG MSARNG (USA)

Subject: ICC COVID 19

Date: Monday, November 9, 2020 6:38:20 AM

Attachments: DUB 11.09.2020.pdf

[redacted]

V/R

Rick

From: Weaver, Richard L COL USARMY NG MSARNG (USA)

To: Thompson, Brian L CIV USAF 81 TW (USA); Barrett, Colleen E CIV USN CBC GULFPORT MS (USA); Schneider, Nathan A CAPT USN SUPSHIP GULFCOAST MS (USA); Carter, Travis L CAPT USCG GULF COAST (USA); Burnett, William H SES USN COMNAVMETOCCOM SSC (USA); Howe, Bradley K COL USARMY NG MSARNG (USA); "Schlosser, Teresa A COL USARMY CEPOF (USA)"; Mccullouch, Murry Brent COL USARMY NG MSARNG (USA); Jody.m.smith2.mil; Thomas, Christopher M LTC USARMY NG MSARNG (USA); "Hilliard, Robert A COL USARMY CEMVK (USA)"; "Hinkebein, Andrew (Wicker)"; Ratcliffe, Andrew M III LTC USARMY NG MSARNG (USA); Austin, Lawrence B LTC USARMY NG MSARNG (USA); Dingler, Christopher Wayne 1SG USARMY NG MSARNG (USA); Hester, Colby D CPT USARMY NG MSARNG (USA); Hargett, Joe D COL USARMY NG MSARNG (USA); Smith, Cynthia Lea (Cindy) Col USAF 172 AW (USA); Williams, Stanley T CSM USARMY NG MSARNG (USA); "Craig Sumrall"; "DuVerger, Frank R III LTC USARMY CEMVK (USA)"; "Gargiulo, Michele"; "Laura Hipp"; "AnneHall Brashier"; Craig, Jim; Dobbs, Thomas E; McIngvale, James W CTR (USA); "Andrew McMillin"; Welborn, Jeffrey H Col USAF (USA); Reedy, Millard G IV COL USARMY NG MSARNG (USA); Shaffer, Perish Undrea MAJ USARMY NG MSANG (USA); Moore, Timothy B (Brent) CAPT USN NAS MERIDIAN MS (USA); Blackwell, Heather W Col USAF US STRATCOM (USA); 14 FTW/CAT Organizational Mailbox; Powell, Jeffrey S (Jeff) CAPT USN CBC GULFPORT MS (USA); Tillman, Tommy F Jr Col USAF 172 AW (USA); Cole, Lynn E Col USAF 172 AW (USA); Watson, Britt A Col USAF 186 ARW (USA); McCormick, Berry L Col USAF MS CRTC (USA); Mantooth, Randall P LTC USARMY NG MSARNG (USA)

Subject: ICC COVID 19

Date: Tuesday, November 10, 2020 9:57:04 AM

Attachments: DUB 11.10.2020.pdf [redacted]

Good morning to all

We will not have a call on this Friday (Nov. 13th) based on the ICC meeting on the 17th. If any questions please let me know and I will send out the final agenda Thursday.

V/R

Rick

From: [redacted]
To: Dobbs, Thomas E
Subject: Just got this from CDC
Date: Wednesday, December 8, 2021 12:25:54 PM
Attachments: PART+VI+FORMS+and+ATTACHMENTS.pdf
FY22+CDC+BAA+Solicitation+Posting+75D301-22-R-72097.pdf

Dr. Dobbs,
Thanks so much again for coming to our Rotary Club meeting. Hope you enjoyed it as much as the Rotarians did! I just attended a Zoom meeting with CDC in regards to Covid-19 Molecular Surveillance and these documents were distributed. Please feel free to share at will inside MSHD.
I am about to send the email out to Mrs. Fanning asking for the support to have my Orientation and the first 3 days through telework given the traveling circumstances.
Best and kind regards,
NA.

From:	Brooks, Richard
To:	Aldridge, Amanda; Allen, Tabitha; Bang, Elizabeth; Boxx, Robert; Byers, Paul; Campbell, Thomas; Chambers, Rita Kay; Collins, Heather; Cooper, Margaret; Craft, Christy; Craig, Jim; Darnell, Tim; Dawson, Lauren; Dobbs, Thomas E; Dreiling, Donna; Drumm, Kelly; eamundson@dps.ms.gov; Etheridge, Donna; Feldman, Alex; Flowers, Roderick; Hall, David; Head, Matthew; Holsapple, Wes; Hoover, Christy; Horn, Marshall; Hubanks, Jonathan; Jennings, Twyla; Jernigan, Curtis; Johnson, Rodney; Jones, Steven; Lewers, Debra; Manasco, Kimberly; McCain, Lalita M; McCain, Sharon; McLeod, Terry; McMinn, Sharon D.; Morrow, Yolanda; Musa, Lori A; Dowdy, Sharon; Parker, Melissa; Pearson, Meg; Sartin, Steven; Schmitz, Burton; Sharlot, Liz; Simkins, Festus; Smith, Bobby; Taylor, Lisa A; Tedford, Lisa; Trader, Sherika; Vail Fuller, Melanie; Vaughn1, Wayne; Ware, Daphne; Whitfield, Jim; Williams, Alisa; Winston, Melody; Woods, Alex; Worley, Richelle
Subject:	MSDH Daily Situation Report 7/30/20
Date:	Thursday, July 30, 2020 9:04:32 AM
Attachments:	OEPR SITREP 7.30.pdf image001.png

Good morning.

The daily situation reports are also posted on MSDH's HSIN webpages.

Please contact me if any changes or additions are needed to the daily report.

Thank you.

Richard A. Brooks
State Watch Officer
Office of Emergency Planning and Response
Mississippi State Department of Health
131 Freightways Drive
Jackson, Mississippi 39208
Office: 601-939-2660
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From:	Kate Heyer
To:	McLaughlin, Joseph B (HSS); David Lakey, MD; Shah, Nirav; Dobbs, Thomas E; ScottHarris; jose.romero@arkansas.gov; kristen.ehresmann@state.mn.us; Randall Mayer; Jeff Stover; Terry Dwelle
Cc:	Carolyn McCoy; Andy Baker-White; Marcus Plescia; Meredith Allen; Grace Lee; Ericka McGowan; Patricia Vinson; Griffin, Jenny
Subject:	Materials for Tuesday"s ASTHO IDPC call
Date:	Sunday, November 14, 2021 7:29:07 AM
Attachments:	image001.png IDPC Agenda November 2021.docx DRAFT - Public Health Authority Policy Statement.001.docx Preparing for the Next Pandemic white paper draft_11.11.21.docx

Hello IDPC members,

Attached please see the agenda and 2 documents for discussion at the IDPC meeting scheduled for **Tuesday, November 16 at 12:00 PM ET.**

We look forward to speaking with you then.

Kate

Kate Heyer, MPH
Senior Director, Infectious Disease Infrastructure and Policy
Association of State and Territorial Health Officials
(571) 318-5490
National Headquarters: 2231 Crystal Drive, Suite 450, Arlington, VA 22202
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(Pronouns: she/her/hers)

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From: Mississippi Health Advocacy Program
To: Byers, Paul
Subject: Medicaid News & Updates: October 13, 2020
Date: Tuesday, October 13, 2020 11:24:25 AM

October 13, 2020

Medicaid News & Updates

Mississippi lawmakers hear from doctors on what they'd

like to see in next Medicaid tech bill

October 12, WLBT, Courtney Ann Jackson - While Medicaid expansion wasn't brought up by lawmakers, the president of the state medical association ended his remarks with this request. "Inexcusably, we have forgone billions in federal assistance that would've helped our most vulnerable citizens," said Dr. Mark Horne. "We ask the legislature to act on expanding coverage in the upcoming session." The Mississippi Health Advocacy Program points to Medicaid expansion gaining new ground in other states that previously rejected it. "COVID 19 has caused us to re-evaluate our healthcare policies and choices," said Roy Mitchell, MHAP Executive Director. "So, it's time we re-evaluate our position on Medicaid expansion as well. Medicaid expansion has proven to save lives. We've got so far to go in correcting all the health inequities of this state. Let's start with Medicaid expansion."

Health care law on line at court, but is it likely to fall?

October 13, 2020, Associated Press, Jessica Gresko and Mark Sherman - The case before the court this year stems from Congress' decision in 2017 to eliminate the law's unpopular fines for not having health insurance. Despite repealing the fines, lawmakers left in place the law's requirement that virtually all Americans have coverage. Texas and other conservative-led states argue that the change makes the requirement unconstitutional and also dooms the rest of the law because the mandate was so central to it. But the court could simply "sever" the mandate from the law and leave the rest of the law alone. Many observers see that as a likely outcome and note the upheaval that would result across the American healthcare system if the law were to be struck down in its entirety. Before the Supreme Court's term began in October, Paul Clement, who argued in the 2012 Affordable Care Act case, said he wasn't sure that the addition of a new justice would change the outcome of the case. He suggested that it is unlikely that the whole statute will fall.

Mississippi Health Department makes free COVID-19 rapid testing available

October 12, 2020, The Clarion Ledger, Alissa Zhu - The Mississippi State Department of Health is making free rapid testing available at its drive-through community test sites, State Health Officer Dr. Thomas Dobbs announced Monday. Rapid test results will be returned within 15 minutes, but it's unclear how accurate they will be, Dobbs said. Rapid tests are done in the "front of the nose," as opposed to the deeper PCR tests MSDH has been using, he said. If people choose to take the rapid test, they will also receive a PCR test, the results of which will be returned within a few days, he said. They can also choose to take the PCR test only.

Almost two weeks without mask mandate, COVID-19 indicators trend in "wrong direction"

October 13, 2020, Mississippi Today, Alex Rozier - The seven-day average for new COVID-19 cases in Mississippi is now at 646, a 24% rise in the last week alone, and a 25% increase since Gov. Tate Reeves lifted the statewide mask mandate on Sept. 30.

Even as the Economy Grew, More Children Lost Health Insurance

October 9, The New York Times, Margot Sanger-Katz and Abby Goodnough - The share of children with health coverage in the United States fell for the third consecutive year in 2019, according to census data, after decades of increases. The decline occurred during a period of economic growth — before the coronavirus pandemic caused broad job losses that might have cost many more Americans their health insurance. A report Friday by the Georgetown Center for Children and Families found that the ranks of uninsured children grew the most in Texas and Florida, and that Latino children were disproportionately affected. Nationally, the number of children without health insurance rose by 320,000 last year alone, to a total of nearly 4.4 million children, the report found.

Cities and counties continue mask mandates as statewide order expires

October 8, 2020, MPB News, Kobee Vance - New coronavirus cases and hospitalizations have increased this week in Mississippi, and health officials have concerns about residents not wearing masks in public. The Governor chose not to extend his mask mandate last week, but some local officials have extended orders in their jurisdiction. Tupelo Mayor Jason Shelton has mandated face coverings be worn in public until November 11th. He says he's following recommendations of local health experts and says he's concerned that leaders like the President are discouraging mask usage. "The President kinda came across as anti-mask. That was [at] the debate on Tuesday. The next day you see his acolyte, Governor Reeves, do away with the mask requirement in the state of Mississippi," says Mayor Shelton. "That leads to people in the city of Tupelo refusing to wear a mask, and they're going to end up in the hospital or even worse."

Mississippi will not mandate masks at the polls ahead of Nov. 3 election

October 7, 2020, Daily Journal, Mississippi Center for Investigative Reporting, Jerry Mitchell - In Mississippi, those entering a school, a Wendy's or a Walmart must wear masks to prevent the spread of COVID-19. But those entering packed polling places don't have to don one."This is absolute insanity," said Dr. Claude Earl Fox III, a Mississippi native and former head of public health in Alabama. "What's to be gained by a no-mask requirement on Election Day?" Mississippi Secretary of State Michael Watson says masks can't be mandated at the polls this November because it's a federal election.
Assistant Secretary of State Kendra James explained that while their office recommends wearing masks, "the governor, nor anyone else, may impose requirements on voting. No entity other than Congress, the Mississippi Legislature or a validly enacted constitutional amendment may place requirements, such as wearing a mask, on voters."

Dr. Dobbs Warns Of COVID Surge, as State Fair Opens Without Mask Mandate

October 7, 2020, Jackson Free Press, Nick Judin - Only a week after Gov. Tate Reeves lifted the state's mask mandate, Mississippi's coronavirus numbers have reversed course, showing the first consistent signs of a new surge in what would be the third spike in the pandemic in the Magnolia State. The Mississippi State Department of Health announced 975 new cases of COVID-19 late last night, the highest single-day total since Aug. 19.

For-profit nursing homes in Mississippi had 3 times more COVID-19 deaths, analysis shows

October 7, 2020, The Clarion Ledger, Jerry Mitchell, Jayme Fraser and Kristine De Leon, Mississippi Center For Investigative Reporting - Twice as many residents caught COVID-19 at Mississippi's for-profit nursing homes, and nearly three times more died there, an analysis of health data by the Mississippi Center for Investigative Reporting shows. The average number of confirmed COVID-19 cases in these for-profit homes? Four in 10 residents. One possible factor: 80% of Mississippi's nursing homes had already been cited for infection-control problems before the pandemic hit. Charlene Harrington, a professor emeritus at the University of California at San Francisco who discovered similar results in a just-released study of nursing homes in California, said the current pandemic is exposing problems that have persisted for decades. "We've just looked the other way for 30 years," she said.

Mask Use Dropping Rapidly After Mississippi Mandate Ends, Dr. Dobbs Warns

October 6, 2020, Jackson Free Press, Julian Mills and Nick Judin - State Health Officer Dr. Thomas Dobbs is sounding the alarm, warning that mask usage is declining in Mississippi immediately after the governor lifted the statewide mask requirement. "Listen to the secret of Sweden's COVID response," Dobbs tweeted on Sunday, Oct. 4. "Near universal, voluntary compliance with public health guidance. Please mask up. Discouraging to see mask use dropping off so rapidly after mandate lifted."

Coalition calls for Medicaid expansion

October 2, 2020, MPB, Kobee Vance - Members of Southerners for Medicaid Expansion are holding a vigil honoring the more than 200,000 people who have died from the Coronavirus in the US. The coalition believes by not expanding the healthcare program, it has hurt the south's response to the coronavirus pandemic, especially for essential workers who's jobs are low pay. Dr. Charlene Collier with the state Department of Health says the coronavirus only made health disparities worse. "One of those being not having health insurance and access to adequate healthcare so even when you're thinking you're sick you don't have a doctor to start your care with, and then once you do finally get coverage, it's often for something that's more catastrophic, so not getting that early preventive care," says Dr. Collier.

Resource of the Week

Children's Uninsured Rate Rises by Largest Annual Jump in More Than a Decade

October 8, 2020, Georgetown University, Joan Alker and Alexandra Corcoran - For many years, the United States was on a positive trajectory in reducing the number and rate of uninsured children; in 2016, the nation attained a historic low of 3.6 million uninsured children. This progress occurred as a result of expansions of public coverage—primarily Medicaid and the Children's Health Insurance Program (CHIP)—and was accelerated by the implementation of the Affordable Care Act's (ACA) major coverage expansions in 2014. As employer-sponsored insurance became increasingly unaffordable for dependents, public coverage ameliorated the impacts of private coverage losses for children. However, the number of uninsured children began to increase in 2017 as Medicaid enrollment began to decline, and as Figure 1 shows, reached 4.4 million in 2019. This represents an increase of 726,000 children during this three-year period. The rate of uninsured children rose a full percentage point from 4.7 percent to 5.7 percent. Much of the gain in coverage that children made as a consequence of the ACA's major coverage expansions has now been eliminated. Moreover, the most recent year of data (2018 to 2019) shows the biggest one-year loss in children's coverage during this time period, with 320,000 more children becoming uninsured. These coverage losses occurred in a healthy economy with the lowest unemployment rate in decades prior to the economic shocks and job loss associated with the COVID-19 pandemic.

Mississippi Health Advocacy Program
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From: Kaye Bender
To: Dobbs, Thomas E
Cc: Griffin, Jenny
Subject: Modernizing Public Health Report
Date: Thursday, December 2, 2021 1:48:46 PM
Attachments: PublicHealthForwardReportfromBipartisanPolicyCenter.pdf

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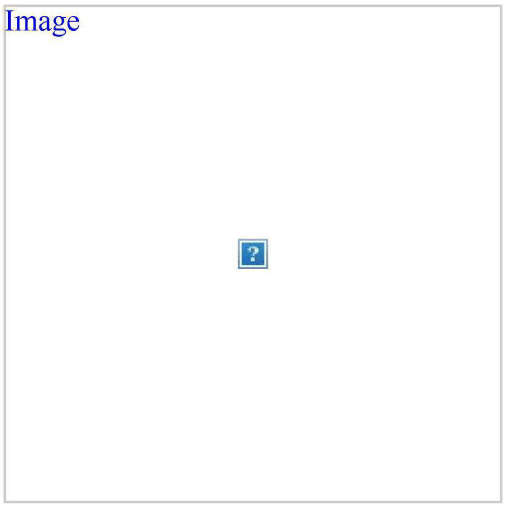
I am sure that you got this from ASTHO, but in case not, I am sending it along. Was released today.

Kaye

Kaye Bender, PhD, RN, FAAN
Executive Director
MS Public Health Association
P.O. Box 4834
Jackson, MS 39296
Phone 601-927-7515
Email: execdir@mspha.org

From: The Network for Public Health Law
To: Williams, Christin
Subject: Network Report 9/9: Town Hall - Assault on Public Health Authority to Act for the Collective Good
Date: Thursday, September 9, 2021 10:40:41 AM



Network Report

Thursday, September 9, 2021

Assault on Public Health Authority to Act for the Collective Good: Confronting the Danger — A Special Town Hall

This Town Hall at the close of the 2021 Virtual Public Health Law Conference will discuss the current climate of threats to public health officials, and to the legal infrastructure and public health's authority to act to protect the health of communities. After a brief introduction to current aspects of this challenge, Town Hall attendees will participate to share experiences: concerns and successes; strategies to address these threats; legal resources and research needs; and coordination of effort. Learn more and register.

Law & Policy Insights

The Network's Harm Reduction Legal Project Recognizes International Overdose Awareness Day

Like many others, the Network recently recognized the 20th International Overdose Awareness Day, an especially somber occasion

Image

given that more people have died from preventable overdose this past year than at any other time. Despite the seemingly endless stream of drug overdose deaths, restrictive laws and policies all too often increase, rather than decrease, the risk of overdose and other drug-related harm.

Image

Improving Childhood Health: The Unrealized Potential of Medicaid's EPSDT Program

In the United States, millions of children live in poverty and are at a much greater risk of experiencing adverse health outcomes compared to their contemporaries in higher income households. Medicaid's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) service was created to provide essential health screenings for at risk children. Despite requirements that states provide timely screenings for the majority of those eligible, the program consistently falls short of meeting these goals.

Image

Drought: It Doesn't Have to Leave Us High and Dry (and Unhealthy)

Nearly half of the United States is experiencing abnormally dry conditions this year. The public health implications of drought cannot be underestimated: drought can lead to a lack of clean drinking water, food insecurity, poor air quality, water-borne diseases, mental health concerns, wildfire, and poor sanitation. Solutions that prevent non-essential uses of water, increase natural storage of water in the soil and aquifers, or maintain water and lake levels, may help limit the public health impacts of future droughts by increasing the overall supply of useable water.

Public Health Law News Round-Up

Some of the public health law and policy issues in the headlines in recent weeks include Texas' new abortion law, the Supreme Court's decision on the federal eviction moratorium and states' responses; challenges to Florida Governor's ban on mask mandates; gaps in data concerning COVID-19 cases; accessibility of mental health care; and the growing suicide rate among communities of color.

Image

Resources

Image

Back-to-School Legal Trends and Challenges Related to COVID-19

K–12 schools and parents of K–12 students are facing numerous challenges and uncertainties with the widespread return of in-person learning for the 2021–22 school year. While the return of in-person learning is generally positive, the continued pervasive presence of COVID-19 implicates public health concerns related to the spread of the virus. This fact sheet offers a broad-level overview of issues associated with the return to in-person learning during the COVID-19 pandemic. It also serves as a starting point and initial resource for individuals seeking information on what actions can be taken to protect K–12 students, as well as school faculty and staff, from COVID-19 in a school setting.

Webinars

Image

Voting & Health: Opportunities to Expand Inclusion

September 15, 2021 | 2:00 - 3:00 p.m. ET

This webinar, co-sponsored by the Network, APHA, Vot-ER, Healthy Democracy Healthy People, and Roundtable on Population Improvement will review policies and approaches that impact voter registration, outline the current landscape of challenges and opportunities in registering the hardest-to-reach populations and explore innovative ways to promote voter registration, such as automatic voter registration specifically through state Medicaid programs.

Worth Sharing

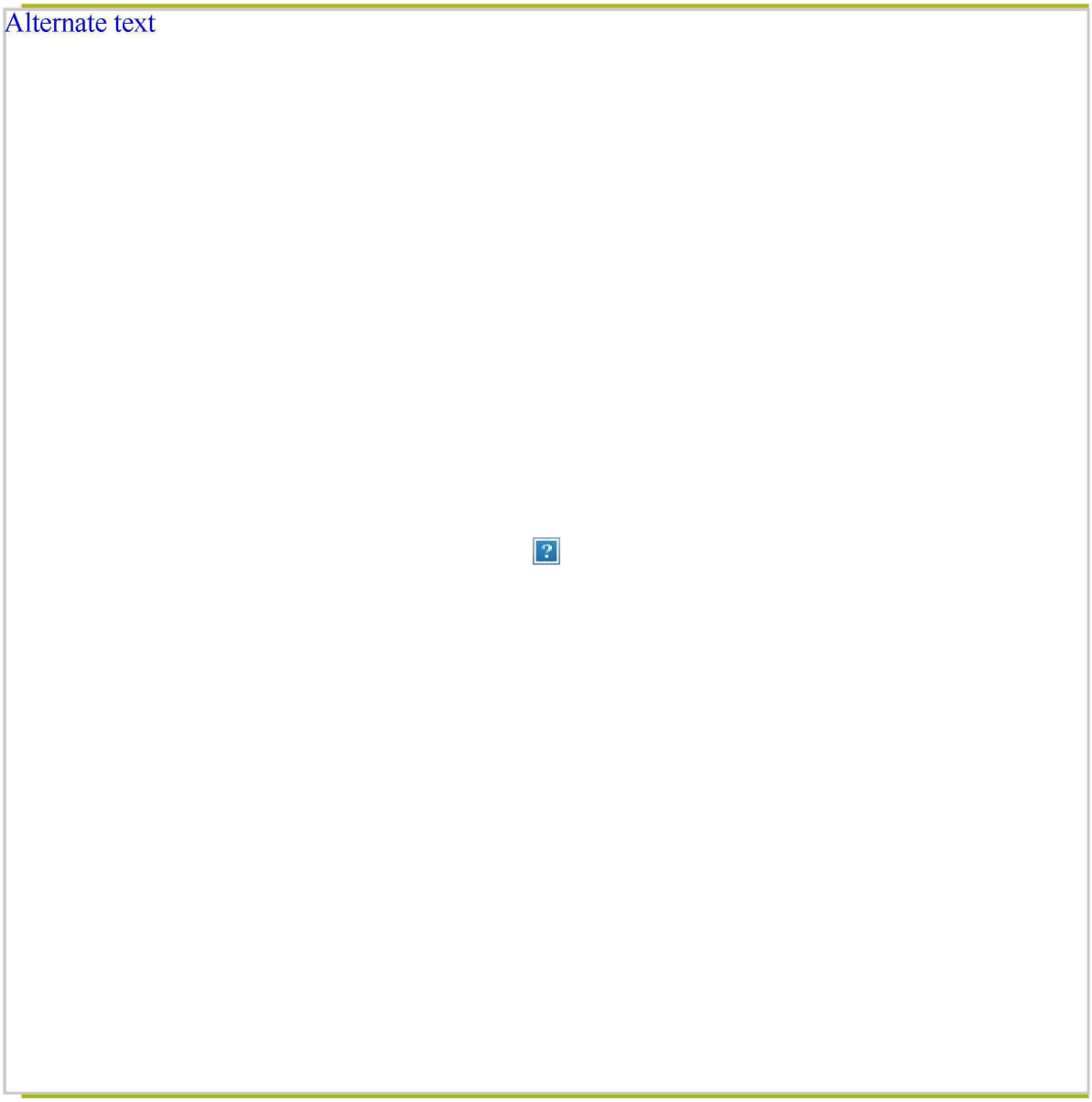
Commentary: Legal Interventions to Counter COVID-19 Denialism

James G, Hodge, director, Jennifer L. Piatt, deputy director, and Leila Barraza, senior consultant at the Network's Western Region Office have coauthored this commentary published in the *Journal Of Law, Medicine & Ethics* assessing a series of legal challenges and pathways under consideration or

in use to counter state-based legal efforts to limit or prohibit the use of known, effective public health powers in response to the continued spread of the Delta variant of COVID-19.

Public Health Law: Concepts and Case Studies

The Network's Donna Levin, Peter Jacobson, Denise Chrysler, James Hodge, Jennifer Piatt, and Corey Davis are among the contributing authors to the recently published book, *Public Health Law - Concepts and Case Studies*. The book aims to make law more accessible, empowering students, public health practitioners, and researchers to see law as simply another tool in their toolbox—just like epidemiology, surveillance, biostatistics, and other traditional public health tools.



Tell Us What You're Working On. We're Ready to Help.

Our law and policy experts can help you identify the key considerations central to your unique challenges and provide law and policy pathways you can leverage to make a difference.

Image

Request Assistance →

Thank you!
Your interest in the work of the Network is important. Together, we can advance law as a tool to improve public health. **Please forward the Network Report and encourage others to join the Network!**

The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, readers should consult a lawyer in their state.

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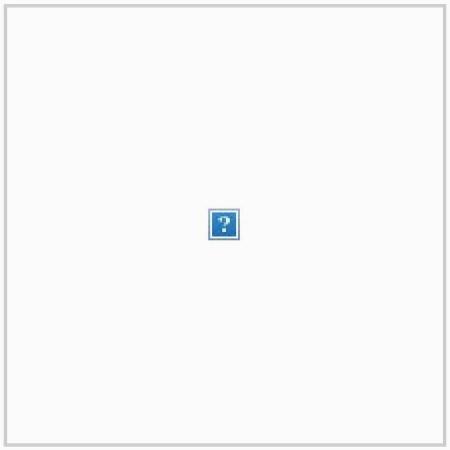
From: Dr. Tom Frieden
To: Dobbs, Thomas E
Subject: Now or Never
Date: Thursday, February 25, 2021 11:41:09 AM



February 25, 2021

Dear Colleague,

One year ago today, based on analysis by experts from around the world at Resolve to Save Lives, we and others predicted, sadly, that a Covid pandemic was inevitable.

In this past year, our team helped the world better understand and more effectively respond to the Covid pandemic that has, tragically, taken so many lives. Covid revealed stark and unacceptable gaps in our public health and primary care systems, and also validated Resolve's approach to help close these gaps.

None of this would be possible without our colleagues at Vital Strategies and the support of our donors. Bloomberg Philanthropies, the Bill and Melinda Gates Foundation, Gates Philanthropy Partners, which is funded with support from the Chan Zuckerberg Foundation, #StartSmall, the CDC Foundation, and the Stavros Niarchos Foundation all provided fast, flexible, and generous support.

Here are nine ways we've worked with partners to meet our goal of improving health using an approach centered on simplicity, speed, and scale.

1. Using 'Science' as a verb.

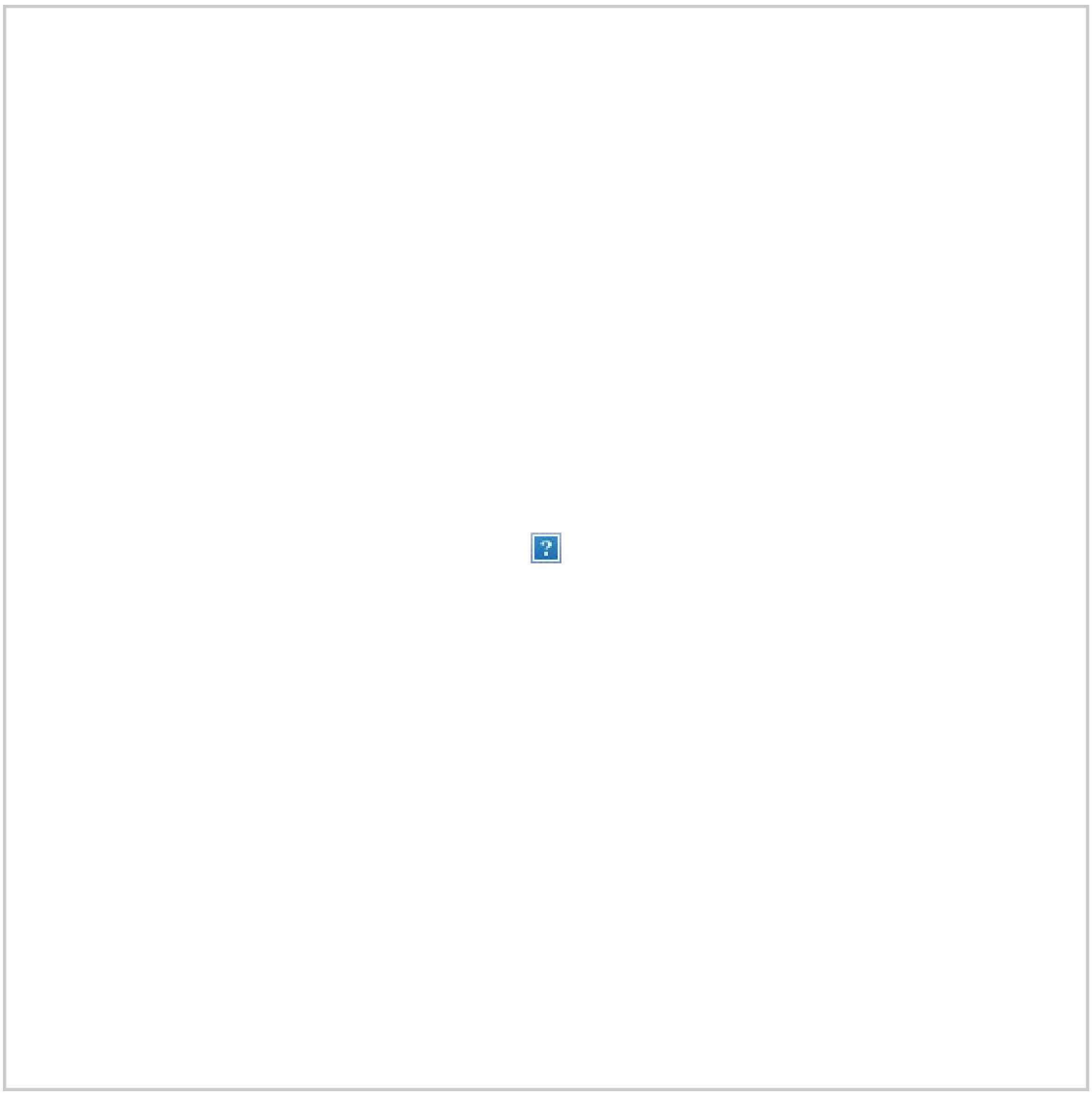
In "*The Martian*," Matt Damon plays a botanist stranded on Mars. He realizes that to get

back home, he's going to have to "science the s--- out of" the problem. Resolve's team of epidemiologists and public health specialists have been learning every day. As the evidence has changed, our approach has not – always base our recommendations on the best available science.

Governments across the United States and throughout the world adopted many of our evidence-based strategies to control the pandemic, including:

- Using an adaptive response to the pandemic, which we released more than a year ago and updated regularly as more information became available. The concept, and most of the details on phased reopening guidance, were adopted by the White House, although unfortunately the strategy wasn't followed.
- Best practice reports on the impact of public health and social measures led to wider adoption of these measures.
- Boxing in the virus to prevent explosive spread and reopen society as soon and as safely as possible.
- Establishing alert level systems to provide a framework to support clear decision-making, improve accountability, and better communicate with the public. Many states and countries adopt this tool, and we partnered with the *New York Times* to make a consistent system across the U.S. available to all.
- Reopening schools while prioritizing the safety of students and their families, teachers and staff, and the entire community.
- Communicating the importance of wearing masks and implementing mask mandates to prevent viral transmission and slow community spread.
- Measuring and reporting essential Covid indicators.
- Implementing, along with our Vital Strategies colleagues, rapid mortality surveillance to better track the pandemic.

Our Prevent Epidemics website had more than a million visits in the past year; our work continues to set the agenda for strong public health systems during and beyond the Covid response.



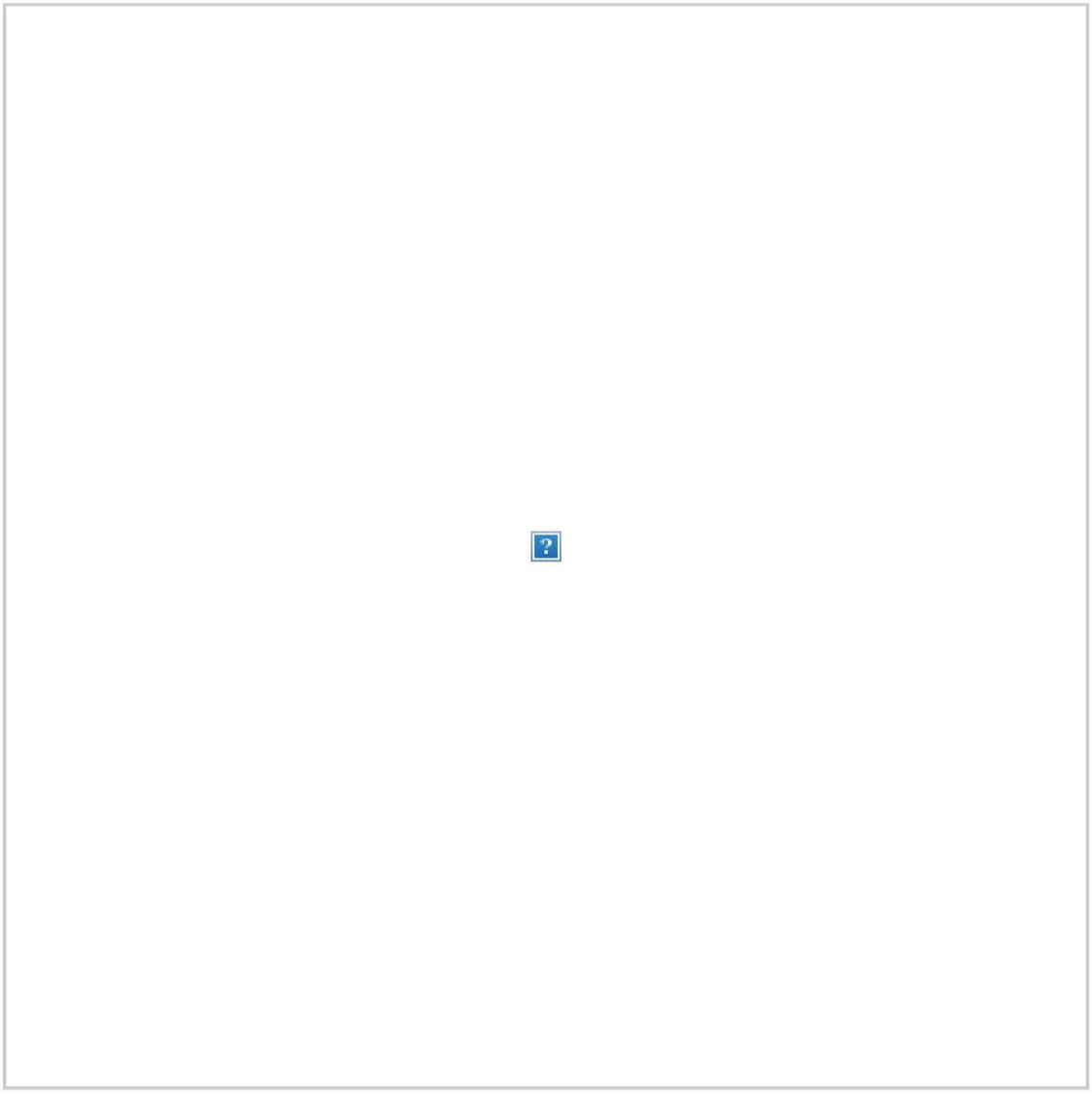
Partnership with the New York Times.

2. Funding to stop outbreaks – provided quickly.

Before and during the Covid pandemic, Resolve provided rapid response funds **to more than two dozen countries in Africa and elsewhere.** A systematic analysis in Nigeria found that time to outbreak response decreased from six to two days after the fund was implemented. Stopping an outbreak in a few days can cost a tiny fraction of what it would cost if allowed to spread for weeks or months. In Nigeria and other countries, these funds are now replenished by government funds.

We established “acceleration teams” of epidemiologists, veterinarians, evaluation experts, and other specialists that helped several African countries use national resources and World Bank funding better. In Uganda, preliminary data suggests that, with our support, the government resolved major weaknesses in epidemic preparedness; it would be the first

country on the continent outside of North Africa to have done so. In Nigeria and Liberia, these teams helped more than double World Bank disbursements within a year.



COVID-19 test preparations in Ogun, Nigeria. Rapid Response Teams in Nigeria were supported by Resolve to Save Lives.

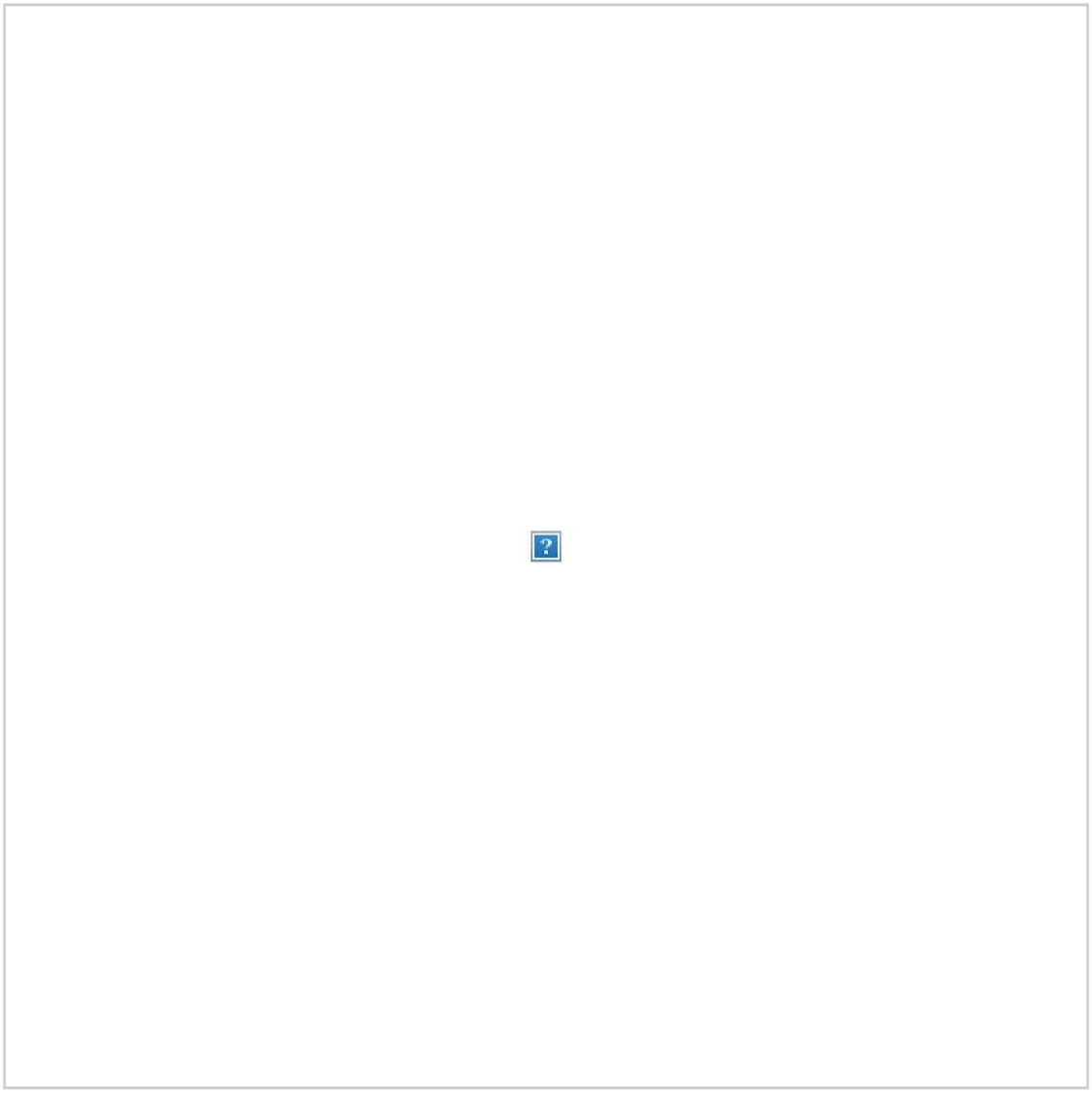
3. Working alongside partners to build capacity.

Collaboration is essential to protect health sustainably. In 2019, our training course, Program Management for Epidemic Preparedness, graduated 25 mid-level managers representing seven countries in Africa. This investment paid off during the Covid pandemic as these individuals and their teams were able to rapidly improve detection and response. Our second training program, planned before and conducted during the pandemic, was held in the Democratic Republic of Congo and helped to align ministry officials and World Bank staff to enable the timely and effective use of $150 million in

World Bank funds for epidemic preparedness.

Our global legal and advocacy teams issued guidance and provided detailed legal consultation to equip cities and countries to rapidly review existing legal frameworks, fill gaps, and ensure that public health and social measures to address Covid were in accordance with legal and ethical best practices.

With input from health departments in the US, we leveraged technology**, applying lessons learned from our successful** Simple app**.** Our digital team developed tools to improve case management and contact tracing for Covid. We supported the Africa Centres for Disease Control and Prevention to improve laboratory systems in Africa, launch a dashboardtracking the pandemic, and more.



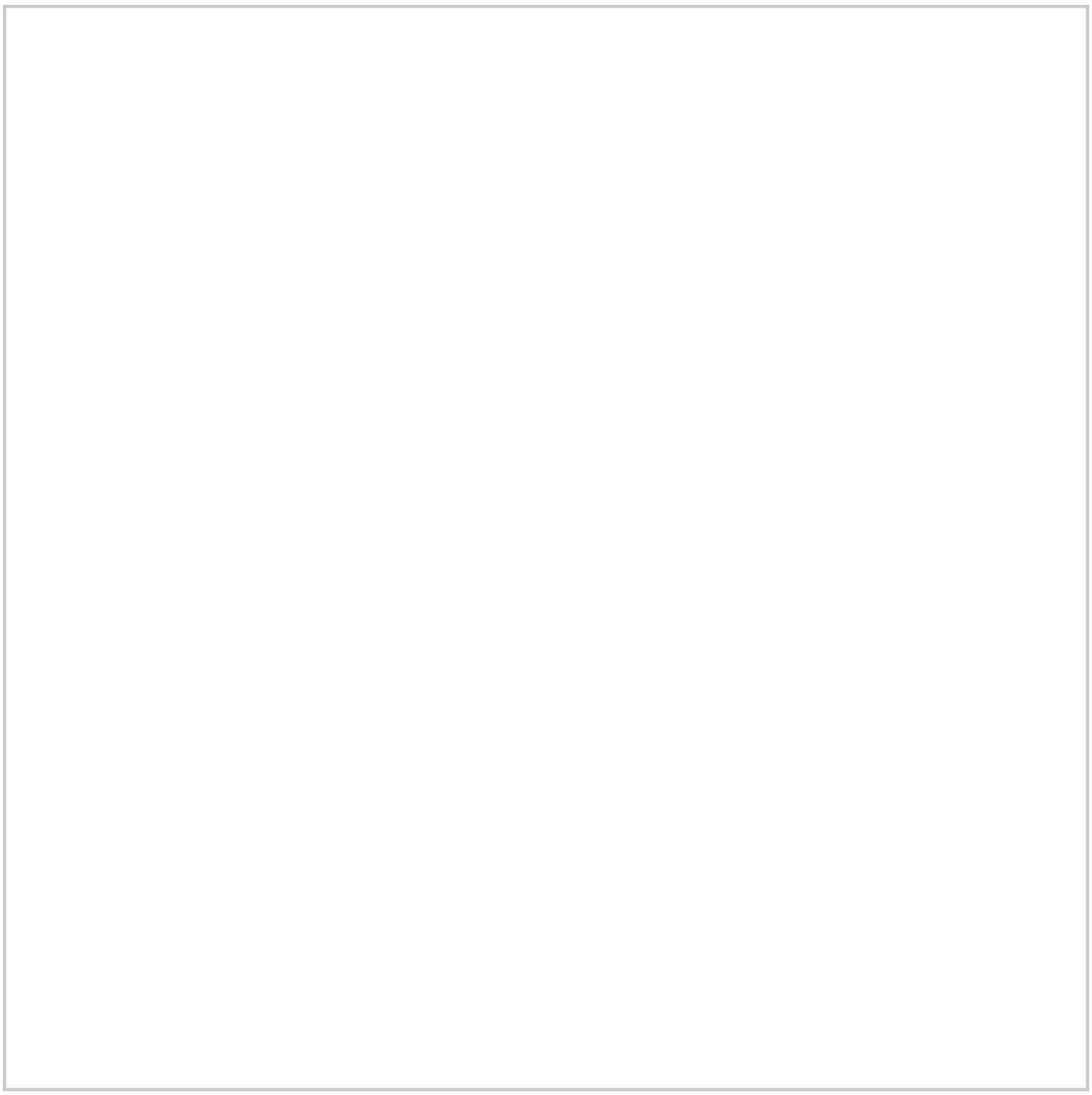
Left: Contact tracing team from the Ethiopian Public Health Institute (EPHI) conducting contact tracing at Addis Ketema sub-city.

Right: Health workers perform contact tracing in Malaba, Uganda. Resolve to Save Lives supported COVID-19 response activities in Uganda.

4. Fighting Covid in the U.S. – especially among vulnerable populations.

We started work in the U.S., creating a US Covid Response **team.** Our staff worked with public health departments across the country to strengthen prevention strategies, testing, isolation and quarantine, contact tracing, vaccination, and community engagement, all with a focus on equity. We also joined with other national public health organizations to advocate for improved funding and policies to address this pandemic and prevent the next.

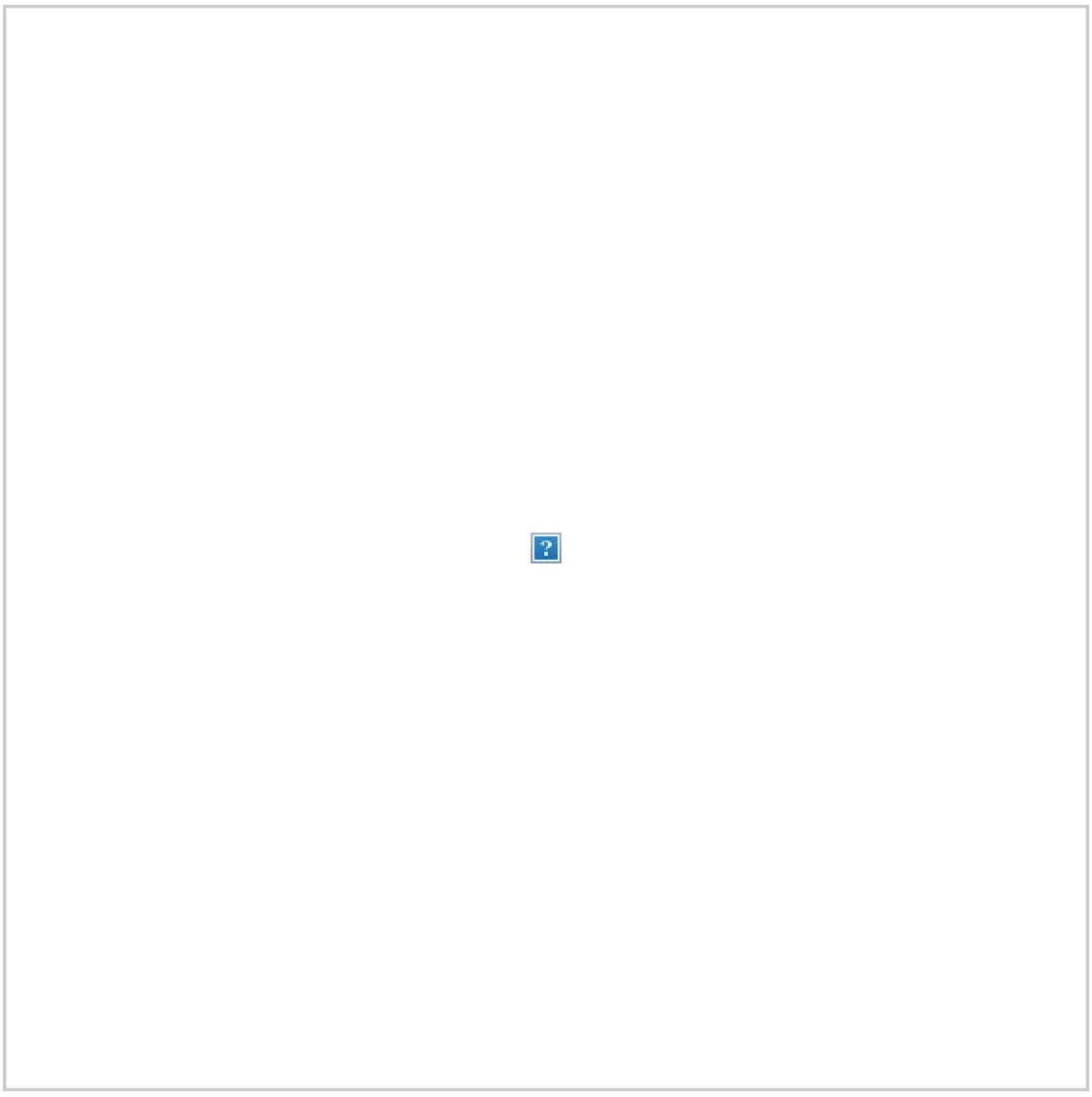
Recognizing the importance of reaching Black communities through faith leaders, we supported launch of the Black Clergy Choose Healthy Life Action Plan, a multi-city initiative to raise awareness of Covid, test those at highest risk, provide services for contact tracing, isolation, and quarantine, promote access to vaccination, and strengthen the infrastructure within the Black church network to end health disparities.



Resolve's Program Advisor in Marion County, Indiana, working at the county's first COVID-19 vaccine distribution center

5. Honoring our health care heroes by protecting them.

As soon as the pandemic hit, we established on-the-ground health care worker training focused on infection prevention and control. Our training was used by more than two dozen partners to train more than 35,000 staff in 7,000 facilities throughout Africa, facilitating safe screening of more than 4 million patients. Learning from this experience, in January 2021, we led a coalition of 17 organizations to publish a report that highlights the risks health care workers face every day and provides recommendations to protect them – and their patients – by making health facilities safer.



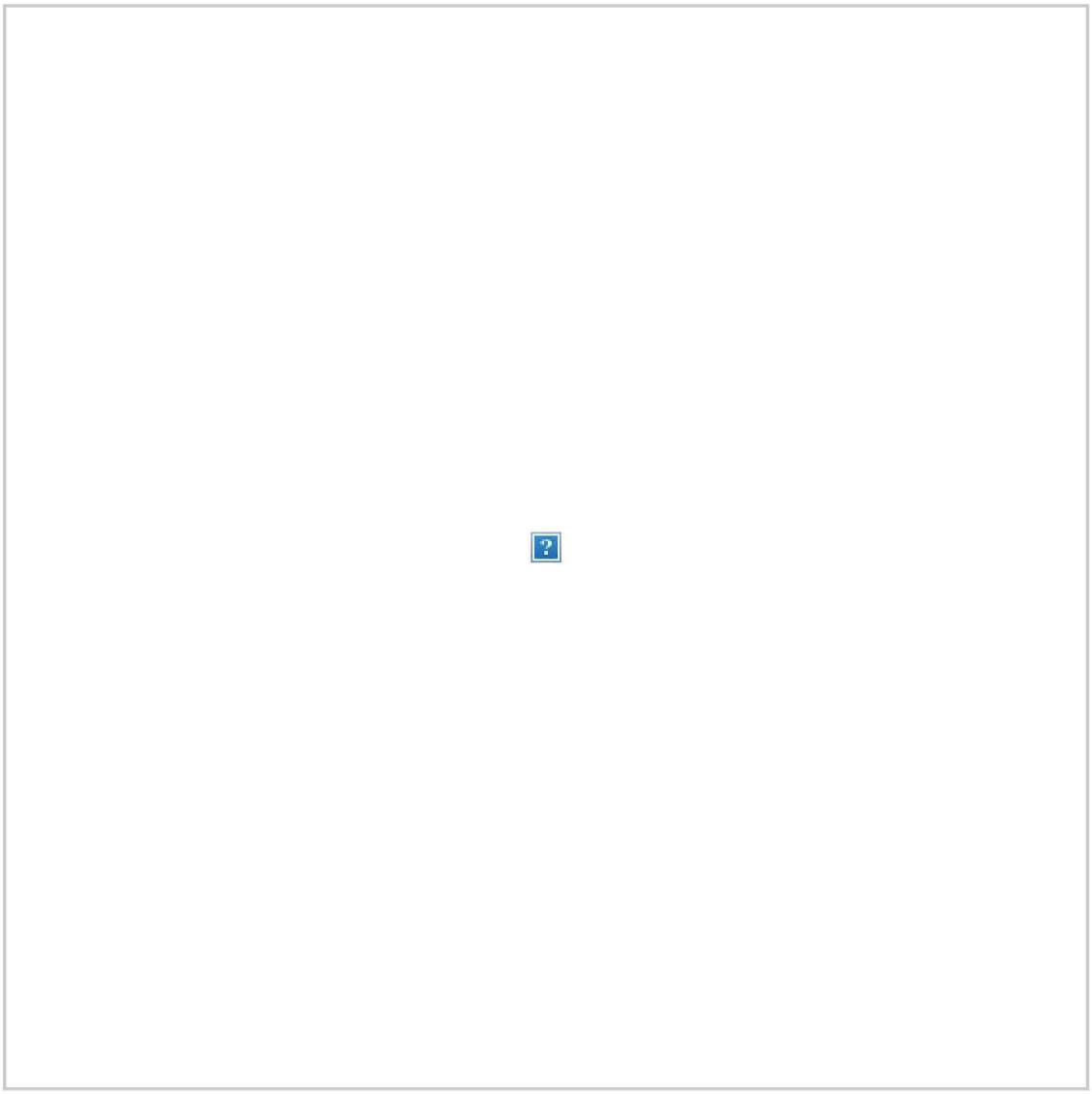
Personal Protective Equipment training in Ethiopia, supported by Resolve to Save Lives. Illustration from the Resolve to Save Lives and partner report Protecting Health Care Workers: A Need for Urgent Action launched January 13, 2021.

6. Basing action on evidence.

We spearheaded development of the Partnership for Evidence-Based Response **to Covid, a public-private partnership that supports evidence-based measures to reduce the impact of the pandemic on African Union Member States**. The partnership collected and analyzed social, economic, epidemiological, population movement, and security data from 20 countries to help determine the impact of public health and social measures.

Our report revealed that while effective in reducing disease spread, the Covid control measures quickly implemented by many member states caused severe secondary

impacts. Many communities across Africa reported difficulties accessing critical health services due to the extra burden placed on health systems, interruptions to medical supply chains, and restrictions on movement. People also reported being hesitant to seek care due to actual or perceived risk of transmission or inability to pay for care. This data led to policy changes to better balance control of Covid with protecting communities' social and economic stability.



Partnership for Evidence-Based Response report launched May 2020.

7. Primary care is primary.

Perhaps the key lesson from the Covid pandemic is the need for primary care to be at the center of health systems. Non-communicable diseases continue to be the leading global causes of death, and we must continue life-saving preventive care and treatment during the pandemic; in addition to saving lives today, this will promote community

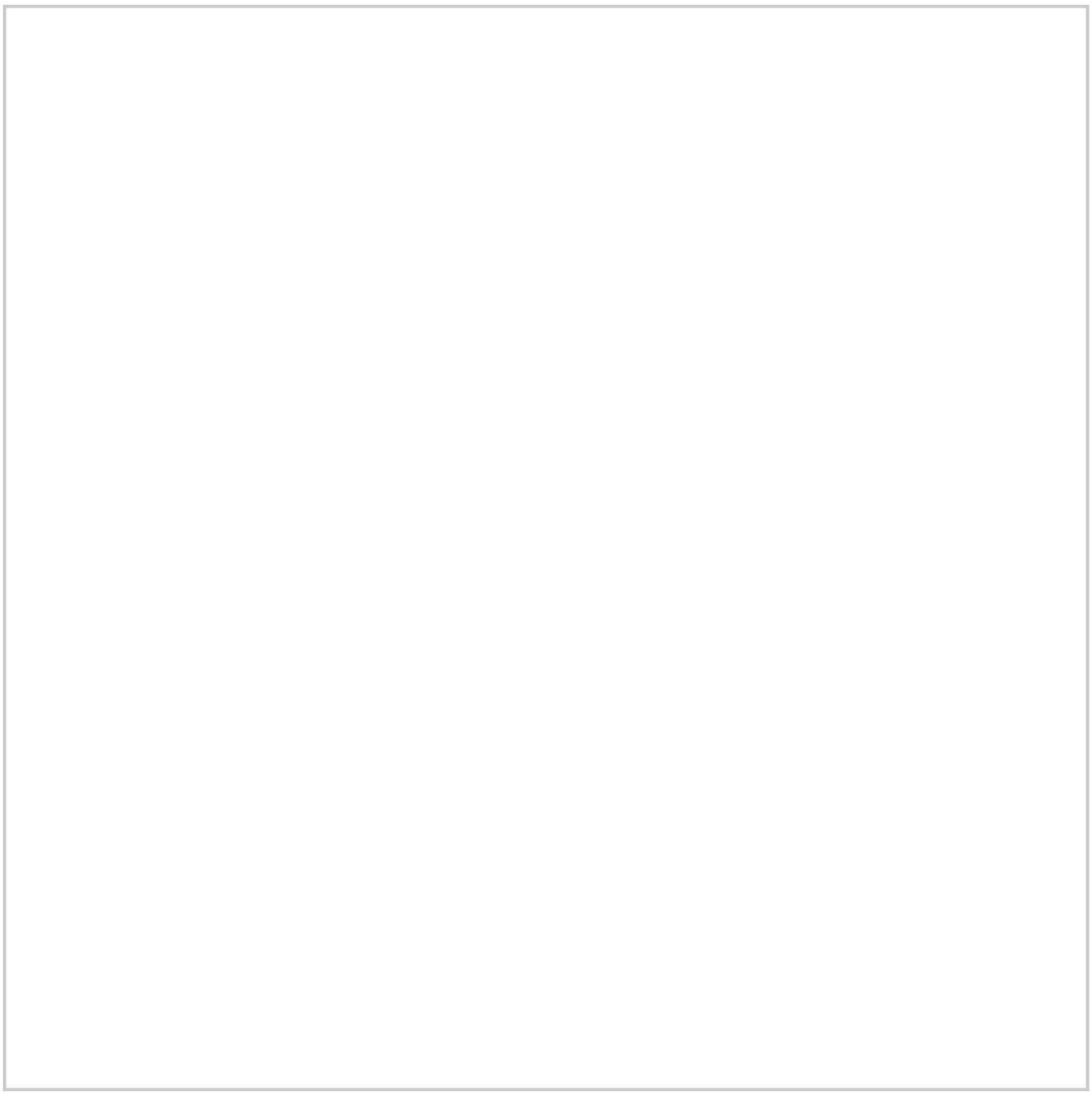
resilience against Covid and future health threats.

Resolve to Save Lives' cardiovascular health team developed guidance on how health systems can maintain life-saving hypertension care and leverage technology in the context of the Covid pandemic. The team produced fact sheets for patients and primary health care providers on how to reduce the risk of Covid transmission, which were translated into more than 15 languages and disseminated by partners around the world.

In countries across the globe, we also promoted simple but innovative patient-centered approaches to increase patient and provider safety during the pandemic:

- Dispensing 3-6 month prescriptions, such as hypertension medications, for stable patients.
- Delivering medications directly to patients.
- Increasing the use of telemedicine and other virtual technologies including phone, email, and text messaging.
- Treating and monitoring at convenient locations in the community.

More than 1.5 million individuals have received hypertension care and treatment through programs supported by Resolve's work. New programs were launched in the Philippines, Ethiopia, Mexico, and Nigeria.

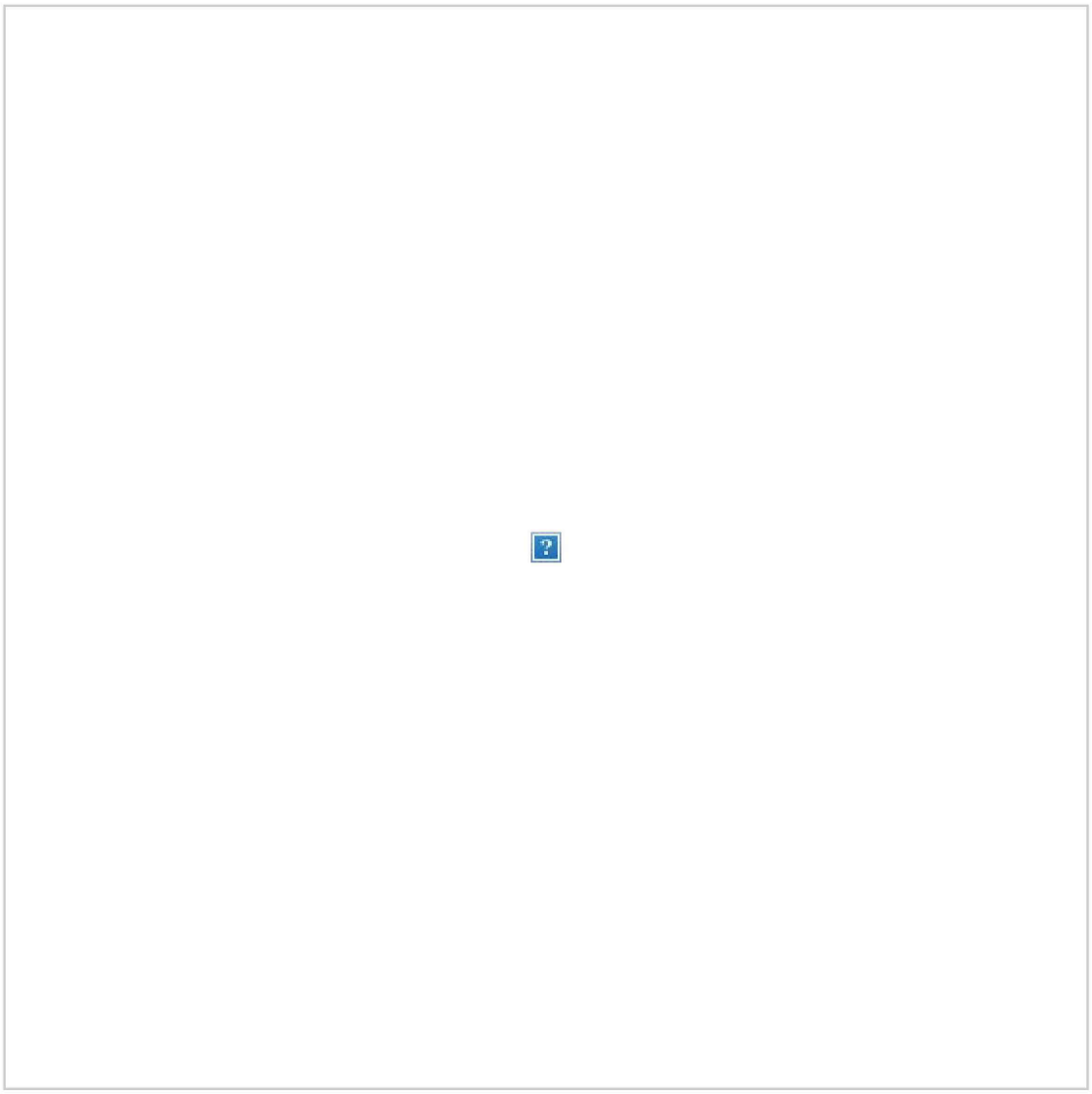


Left: Blood pressure measurement in Thailand before the COVID-19 pandemic.
Right: Community health workers in India deliver medications to hypertension patients.

8. Using policy to save lives.

We continued to advance policy actions to address cardiovascular disease. Global momentum to eliminate trans fat is growing, including an earlier win in Thailand and recent bold action by India to eliminate trans fat by 2022, a stunning victory for healthy nutrition. Turkey and Paraguay also acted to eliminate trans fat, and Nigeria, Bangladesh and the Philippines are now poised to do so. We partnered with the World Health Organization to launch the second annual progress report for the REPLACE initiative to eliminate artificial trans fat. Although 58 countries have introduced laws that will protect 3.2 billion people from trans fat by the end of 2021, more than 100 countries still need to take action to remove this toxic substance from their food supply.

Our team identified seven priority interventions to reduce sodium intake and save lives, including front-of-pack warnings, restrictions on food marketing to children, and taxes on high-sodium foods. We joined WHO to release a policy action framework on public procurement of healthy food, and helped launch four new projects to develop and implement policies on healthy public food procurement in Uganda, Togo, Nepal, and the Philippines. Our partners in Viet Nam and Ethiopia debuted each country's first national mass media campaign designed to encourage people to reduce their salt intake. We are sponsoring studies in China, India, Ethiopia and Thailand to determine the most effective front-of-pack label in order to provide evidence for policy change.



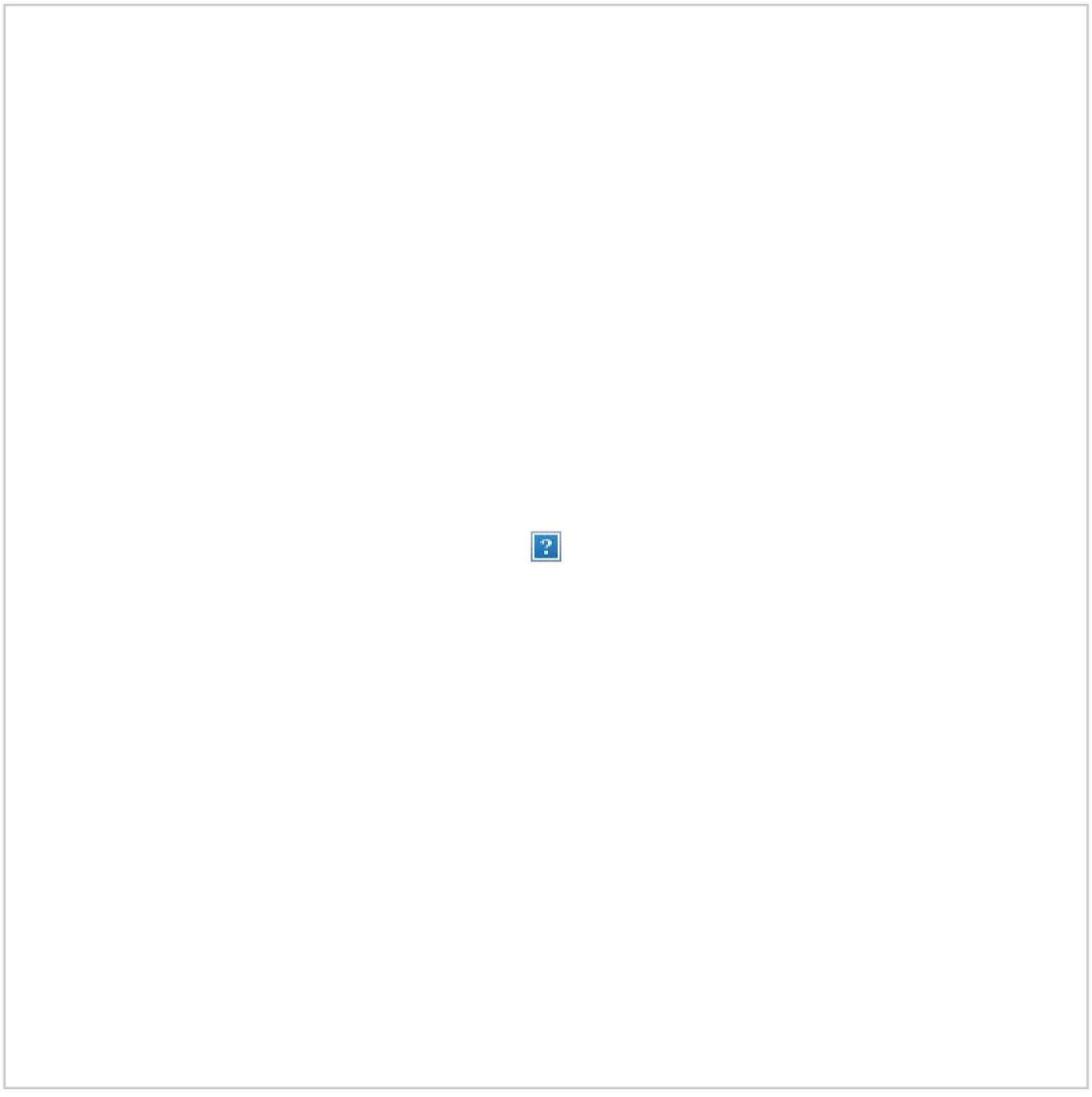
In countries without trans fat regulations, fried foods are a common source of the deadly additive.

9. Spreading truth.

The Covid pandemic was accompanied by an epidemic of competing and often inaccurate information spreading rapidly throughout the world. Our communications team filled a need for real-time, credible public health information by producing high-quality, evidence-based communications materials for diverse audiences.

We produced more than 400 communications products in 25 languages and supported 22 countries and 44 cities with mass media campaigns and the development of effective risk communications strategies. We shared our public health expertise in thousands of media interviews and dozens of peer-reviewed medical journal articles and op-ed pieces in leading global media outlets, and we were mentioned more than 25,000 times in news stories around the world.

Our "3 Ws" strategy – Wear a mask, Watch your distance, and Wash your hands – was disseminated by media outlets and partners worldwide and continues to be at the core of strategies to prevent disease transmission.



The '3-Ws' translated into French.

This moment brings a once-in-a-century opportunity. It's now or never.

Working together, we will take a giant step toward being able to find, stop, and prevent health threats faster in every country through public health systems that are understood, supported, and celebrated. This starts with expanding equitable access to vaccines to end the Covid pandemic. It's both ethically unacceptable and epidemiologically perilous that so much of the world is so far from having vaccine access. Uncontrolled spread anywhere threatens to prolong the pandemic everywhere, and we must scale up not only vaccine access but also vaccine manufacturing capacity in low- and middle-income countries. Beyond Covid, we need a public health renaissance so health threats are detected rapidly by accurate and sensitive tracking systems and laboratory networks, stopped quickly by trained epidemiologists and rapid response teams, and prevented wherever possible, including through ongoing vaccination programs and action to make our environment safer.

Working together, we will partner with governments, health systems, and civil society to make policy and program changes centered on improving equity that increase our personal and community resilience and promote heart and brain health so we live longer, healthier, more productive lives. We will help more countries follow India's trans fat elimination best practices. We will accelerate progress toward Resolve's goal of preventing 100 million deaths from cardiovascular disease in 30 years and achieve the Sustainable Development Goal of a one third reduction in today's leading killers by 2030.

Working together, we will make primary care central to our health systems – building teams, supporting patients, and holding all accountable for achieving the health that health care can deliver and for ending health disparities. By establishing accessible, responsive care systems, we'll find health problems when they emerge, prevent illness, injury, disability, and premature death, and accelerate a virtuous cycle toward healthier and more productive societies.

We resolve to work with partners to strengthen the hands of public health and primary care around the world so that, together, we build this healthier future.

Thank you for joining us.

Tom Frieden
President and CEO
Resolve to Save Lives, an initiative of Vital Strategies

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info@resolvetosavelives.org

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From: Roy Hart
To: Dobbs, Thomas E; Edney, MD, Daniel
Cc: Natalie Keller
Subject: RE: MSPHI Data Conversation Follow Up
Date: Friday, March 11, 2022 9:05:54 AM
Attachments: image002.png
image004.png
Empowering Communitites with Data.pdf
NNPHI-E2A-Kresge-Report-Web.pdf

Natalie,

Thanks very much for sending the information that we discussed Tuesday.

Dr. Dobbs and Dr. Edney, at the risk you feeling bombarded with information, I want to share 2 additional documents that are directly relevant to the conversation. The first is focused on the importance of sharing data with communities and it really gets to the critical aspects of how and why we should share information. The second is a very recent document prepared by the National Network of Public Health Institutes (NNPHI) with support from the Kresge Foundation that includes a description of public health data systems in the context of opportunities to strengthen public health infrastructure.

Thanks very much and have a great weekend.

Roy

Roy Hart MPH CPM
Chief Executive Officer
Office: 601 398 4406
Cell: 601 940 7235

10 YEAR ANNIVERSARY
msphi
Mississippi
Public Health
Institute

From: Natalie Keller
Sent: Thursday, March 10, 2022 3:49 PM
To: Thomas.Dobbs@msdh.ms.gov; Daniel.Edney@msdh.ms.gov
Cc: Roy Hart <rhart@msphi.org>
Subject: MSPHI Data Conversation Follow Up

Hi Dr. Dobbs and Dr. Edney,

Thank you for your time on Tuesday. I really appreciate the space you gave us to present the whole context of our idea. I'm attaching **the longer plan document** we developed with the steering committee and a **2 pager** pulled from the longer document. I appreciate your input and feedback around demonstrating this idea into more concrete terms before moving forward.

In pursuit of that, I'm sending along two examples of data visualization website. The first website is a local resource, Gulf Coast Community Exchange, funded through the REACH grant in Gulf Coast MS counties. It leverages some local and national datasets. The second website is known as CHORDS. This website utilizes FQHC data and mapping to demonstrate prevalence in the Denver metro area. Our vision for a website encompasses ideas demonstrated in both examples. We want to leverage local data as CHORDS has done successfully but utilizing newer technology for updating data closer to real-time. Additionally, we want a dynamic website interface that is easily utilized by non-experts. Our plan for incorporating these ideas into our own platform is detailed on pages 11 and 12 in the longer document.

Other good examples we would draw from: Arizona's Environmental Public Health Tracker (love the county-level reports with easy to understand explanations), Hope Rising's Substance Use Website (trove of local resources and personal touches), and Tri-County Health Department (issue-by-issue breakdowns).

Essentially, our project is investing in a data resource for community members. The other facets of the project, data literacy education and partnerships with larger health organizations, are part of our larger framework and strategy to address health issues in Mississippi by supporting individuals planning their own community-level projects. This principle of transparent data and distribution is essential in empowering local initiatives especially for marginalized people who are not in positions of power.

In our vision and approach, we are matching up with CDC's Data Modernization Initiative. In their Strategic Implementation Plan (p. 4), the first objective of priority 1 is "Develop a shared vision." Hopefully, that's what we're doing right

now!

Take a look at these documents, explore these website, and let us know next steps!

Natalie Keller
Health Policy Analyst
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Mississippi Public Health Institute
829 Wilson Drive Suite C, Ridgeland, MS 39157
(P) 601-398-4406 | (F) 769-524-4719 | Toll Free 1-877-740-9889
support@msphi.org | www.msphi.org
Mission "Engage in partnerships and activities that improve Mississippian's health."

From:	Kate Heyer
To:	Dobbs, Thomas E
Cc:	Grace Lee; Griffin, Jenny
Subject:	RE: Proposed IDPC agenda and white paper draft
Date:	Friday, November 12, 2021 3:18:22 PM
Attachments:	image001.png DRAFT - Public Health Authority Policy Statement.001.docx

Hi Dr. Dobbs,

Apologies for another e-mail so soon, but I wanted to check to see if you approve my sending the IDPC agenda and this white paper draft. I also received the ***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease*** policy statement draft, which is attached here.

Please let me know your thoughts and I will send the materials to the IDPC for Tuesday's call.

Kate

From: Kate Heyer
Sent: Thursday, November 11, 2021 3:34 PM
To: Dobbs, Thomas E <Thomas.Dobbs@msdh.ms.gov>
Cc: Grace Lee <glee@astho.org>; Griffin, Jenny <Jenny.Griffin@msdh.ms.gov>
Subject: Proposed IDPC agenda and white paper draft

Hi Dr. Dobbs,
Attached please see a proposed IDPC agenda for Tuesday and a draft of the **Preparing for the Next Pandemic/Public Health Crisis: Lessons from the Last Decade and Beyond** white paper. This is our first attempt at framing out a document to respond to the concerns you laid out in the e-mail to leadership in late September, so please do not hesitate to redirect us if we're off base. I've moved things around, so the references are out of order, but I'll wait to fix those until we get feedback on the scope of the document.
When you have a chance to review, please let me know what you think, and I'll share these materials as well as a the draft ***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease*** policy statement with the committee.

I'll also send a facilitator's agenda for you when the IDPC agenda is finalized.

Kate

Kate Heyer, MPH
Senior Director, Infectious Disease Infrastructure and Policy
Association of State and Territorial Health Officials
(571) 318-5490
National Headquarters: 2231 Crystal Drive, Suite 450, Arlington, VA 22202
Regional Office: 600 Peachtree Street NE, Suite 1000, Atlanta, GA 30308

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(Pronouns: she/her/hers)

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From:	state_ph_counsel - Public Health Law Program on behalf of Ferrell, Abigail (CDC/DDPHSIS/CSTLTS/OD)
To:	STATE_PH_COUNSEL@LISTSERV.CDC.GOV
Subject:	Resources from today"s call
Date:	Thursday, July 22, 2021 2:37:59 PM
Attachments:	Klaassen v. Indiana University - Opinion and Order.pdf ASTHO Vaccine Messaging Kit.pdf

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Public Health Emergency Law Training: If you are interested in having PHLP deliver public health emergency law (PHEL) training to your jurisdiction, please email Greg Sunshine at GSunshine@cdc.gov. PHEL training is free and in-person.

Contact for CSTE Legal:
Sunbal Virk svirk@cste.org
CSTE legal mailbox: publichealthlaw@cste.org

Request for IIS law Examples:
Please send the citation to Patricia.Segal.freeman@state.mn.us

Opioid Settlement Information:
State Opioid Settlement Allocation Plans

https://nationalopioidsettlement.com/

Book recommendations:
Deaths of Despair

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From: Health Law360
To: Walter, Cassandra
Subject: SEC Nabs $6M Settlement In Earnings Management Sweep
Date: Wednesday, August 25, 2021 3:53:41 AM

HEALTH

Wednesday, August 25, 2021

TOP NEWS

SEC Nabs $6M Settlement In Earnings Management Sweep

The U.S. Securities and Exchange Commission on Tuesday announced a $6 million settlement of the third enforcement action to come out of its data-focused initiative targeting violations linked to earnings management practices.

Order attached | Read full article »

FTC, Illumina Clash On Merger's Potential To Win Cancer War

Federal Trade Commission staffers opened their in-house challenge to Illumina's $8 billion reacquisition of Grail with a warning Tuesday that the merger will inhibit competition necessary to win "the war on cancer," painting a picture that served as a mirror image of the companies' arguments.

Read full article »

11th Circ. Suggests Lab Ignored Mintz Advice Over Fees

Eleventh Circuit judges hinted Tuesday that a lower court properly ended legal malpractice claims against Mintz Levin Cohn Ferris Glovsky and Popeo PC over its advice to a defunct diagnostic lab that ran afoul of federal anti-kickback laws.

2 documents attached | Read full article »

Talc Users Seek Court Order To Bar J&J Liability Spinoff

Amid media reports that Johnson & Johnson may offload its sizable talc legal liabilities into an entity destined for bankruptcy, ovarian cancer patients asked a Missouri court Tuesday for a restraining order against a move they say would deprive them of damages.

2 documents attached | Read full article »

Calif. Jury Clears C.R. Bard Over Design Of Vein Filter Implant

A California federal jury on Tuesday cleared C.R. Bard of a retired carpenter's product liability claims alleging the company negligently designed a blood clot-stopping IVC vein filter that easily broke up and sent metal shards into the plaintiff's lungs and heart.

Verdict attached | Read full article »

Analysis

Avenatti Gains Edge As Feds Show Hand In Mistrial

Michael Avenatti scored a major tactical win in his California fraud case when a federal judge declared a mistrial Tuesday, giving the disgraced lawyer a chance to fortify his defense after seeing a monthlong dress rehearsal by the

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COMPANIES

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American Civil Liberties Union
American Express Co.
Anadarko Petroleum Corp.
Apple Inc.
Atherotech Inc.
Baltimore Ravens
Boehringer Ingelheim Vetmedica Inc.
Burford Capital LLC

government.
Read full article »

POLICY & REGULATION

Green Card Applicants Must Be Fully Vaxxed Against Virus

Foreigners applying for a U.S. green card must be fully vaccinated against COVID-19 under a new policy from the U.S. Centers for Disease Control and Prevention.
Read full article »

ENFORCEMENT & COMPLIANCE

Former NFL Player Pleads Guilty As $3.9M Fraud Trial Begins

A former Baltimore Ravens linebacker pled guilty Tuesday to his role in a $3.9 million scheme to pilfer from a National Football League health plan, just as he was about to face trial alongside two fellow ex-players.
☐ *1 document attached* | Read full article »

Mass. Vet Home Head Says Elder Laws Don't Fit Virus Charges

The former supervisor of a Massachusetts veterans' home said Tuesday he can't be charged with criminal elder neglect over alleged decisions that prosecutors say sparked a deadly COVID-19 outbreak at the facility.
Read full article »

LITIGATION

J&J Must Face Ill. Pelvic Mesh Suit, 7th Circ. Says

Johnson & Johnson must face an Illinois woman's lawsuit claiming she received a faulty pelvic mesh device that caused her continuing pain and medical issues, the Seventh Circuit ruled Tuesday, finding that there are still questions as to when the statute of limitations started running.
☐ *Opinion attached* | Read full article »

FCC Urges DC Circ. To Back New Antenna Rules

The Federal Communications Commission and the U.S. Department of Justice told the D.C. Circuit on Monday to toss a challenge to an FCC rule meant to facilitate the installation of wireless internet equipment in residential areas.
☐ *Brief attached* | Read full article »

QVC, Suzanne Somers Can't Stop Dispute From Going To Trial

Home shopping channel QVC failed to stop pitchwoman Suzanne Somers' claims the network pushed her out of the dietary supplement market during its merger with HSN, after a Pennsylvania federal judge denied both sides' bids for summary judgment Tuesday.
☐ *2 documents attached* | Read full article »

Esperion Class Attys Nab $6M In Fees From $18M Settlement

The attorneys who secured an $18.25 million settlement for Esperion Therapeutics investors in a securities class action will be awarded a 32.5% portion of the settlement amount plus expenses in the amount of $833,716.99, according to an order filed in Michigan federal court Tuesday.
☐ *Order attached* | Read full article »

ICE Must Test Migrants Before Sending Them To Wash. Center

U.S. Immigration and Customs Enforcement must test immigrants for COVID-19 before transferring them to a Washington state detention center, after a federal judge blamed the agency for 240 detainees and facility staff contracting the virus over the past three months.
☐ *Order attached* | Read full article »

C.R. Bard Inc.
Citigroup Inc.
Commerzbank
Credit Suisse Group AG
DKSH Holding AG
Epic Games Inc.
Esperion Therapeutics Inc.
Florida Blue
Fulton Financial Corp.
Glenmark Pharmaceuticals Ltd.
Google LLC
Grant Thornton LLP
GuideWell Inc.
HSN Inc.
Healthcare Services Group Inc.
Houston Texans
Human Rights Campaign
Illumina Inc.
Imerys SA
JPMorgan Chase & Co.
Johnson & Johnson
Kansas City Chiefs
Lexington Insurance Co.
LinkedIn Corp.
Monsanto Co.
NFL Enterprises LLC
Nike Inc.
Pershing Square Capital Management LP
Pfizer Inc.
QVC Inc.
Sanofi SA
SoftBank Group Corp.
Solutia Inc.
Spotify Technology SA
State Bar of California
TC Global Inc.
Triple-S Management Corp.
Tronox Holdings PLC
Trump Organization Inc.
University of Toledo
Walmart Inc.
Washington Redskins
Wells Fargo & Co.
Yahoo! Inc.
YouTube Inc.

LAW FIRMS
Abel Bean
Aldous Walker
Alexander Dubose

Texas Judge Considers Mask Mandate Debate 'Stunning'

A Texas state judge weighed Tuesday whether Dallas County can enforce a local mask mandate despite Gov. Greg Abbott's effort to ban such requirements, calling it "stunning" that state and local officials are arguing over masks when both sides agree the devices work against the coronavirus.

Read full article »

Suit Over Botched Hip Replacements Revived In Missouri

A Missouri appeals court on Tuesday revived some claims in a suit alleging a doctor employed by SSM Regional Health Services botched a man's hip replacements, saying the dispute over the left hip can go forward, while claims about the right hip were correctly tossed.

☐ *Opinion attached* | Read full article »

Florida Nursing Home Arbitration Ruling Tees Up Conflict

A Florida appeals court has ruled that a suit blaming a nursing home for a patient's death was properly sent to arbitration, certifying a conflict with two sister courts over whether a purportedly prohibitively expensive arbitration fee can serve as a valid, standalone argument to escape arbitration.

☐ *Opinion attached* | Read full article »

Glenmark Still Fighting To End DOJ Interviews Of India Execs

Glenmark has asked for a chance to respond to the U.S. Department of Justice's denial of assertions by Teva and Glenmark that the government inappropriately used its Israeli and Indian counterparts to force foreign executives to sit for interviews without going through counsel.

☐ *Brief attached* | Read full article »

Zantac Makers, Retailers Urge Nix Of Medical Monitoring Class

Manufacturers and retailers of the heartburn medication Zantac urged a Florida federal judge on Monday to dismiss the medical monitoring claims of a class of consumers in multidistrict litigation because they had failed to show that their exposure to the carcinogen in the drug was enough to increase their risk of cancer.

☐ *2 documents attached* | Read full article »

Fla. Argues Challenge To Trans Athlete Ban Is Unripe

Florida's governor and other defendants have called upon a federal court to dismiss a lawsuit against the state's ban on transgender girls participating in girls' and women's school sports, arguing the 13-year-old plaintiff's claims are premature and the "commonsense policy" does not run counter to the laws and rights she has raised.

☐ *Motion attached* | Read full article »

Apple Says It Has No Obligation To Host Rival COVID Apps

Apple has urged a California federal court to throw out a suit claiming it blocked competing coronavirus tracking apps from its stores, arguing that it doesn't have any obligation to distribute apps that are "inconsistent with its guidelines or policies or that threaten its consumers' health or safety."

☐ *Motion attached* | Read full article »

Fla. Claims There's Little Evidence For Masking Kids In School

Florida's star witness took the virtual stand on Tuesday in the fight over Gov. Ron DeSantis' ban on school mask mandates amid the COVID-19 pandemic, testifying that children are inefficient spreaders of the coronavirus and there's little evidence to show that masks prevent spread.

Read full article »

Native American Tribes See Mixed Bag In Virus Coverage Suits

Native American tribes and nations have seen mixed results in federal and

Anapol Weiss
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Associated Attorneys of New England
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Ballard Spahr
Barnes & Thornburg
Beasley Allen
Bernstein Litowitz
Blank Rome
Bruce Harvey Law Firm
Bryan Cave Leighton Paisner
Buckley LLP
Burns Bowen Bair
Butler Snow LLP
Carlton Fields
Choate Hall
Christian & Small
Cole Schotz
Cole Scott
Costello McMahon
Covington & Burling
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Dechert
Dickinson Wright
Doherty Wallace
Epstein Becker Green
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Goodwin Procter
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Greenberg Traurig
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Hunton Andrews
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Jones Foster
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PEOPLE

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Epstein Becker Green bolstered its ranks in Boston by luring over a seasoned attorney from Ogletree Deakins who specializes in helping life sciences companies navigate the full gamut of labor and employment issues.

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Bureau of Citizenship and Immigration Services
Centers for Disease Control and Prevention
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Oklahoma Supreme Court
Pechanga Band of Luiseno Indians
Texas Supreme Court
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U.S. Attorney's Office for the Eastern District of Pennsylvania
U.S. Attorney's Office for the Western District of Washington
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Cranford, New Jersey

Environment & Energy Associate - (Washington, DC Office)
McCarter & English, LLP
Washington, DC, District of Columbia

Corporate partner for NY office of well-known NY/NJ mid-sized firm
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Sr. Corp Assoc. sought by sexy NYC Boutique
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From: Health Law360
To: Dobbs, Thomas E
Subject: SEC Nabs $6M Settlement In Earnings Management Sweep
Date: Wednesday, August 25, 2021 4:02:51 AM

HEALTH

Wednesday, August 25, 2021

TOP NEWS

SEC Nabs $6M Settlement In Earnings Management Sweep

The U.S. Securities and Exchange Commission on Tuesday announced a $6 million settlement of the third enforcement action to come out of its data-focused initiative targeting violations linked to earnings management practices.

Order attached | Read full article »

FTC, Illumina Clash On Merger's Potential To Win Cancer War

Federal Trade Commission staffers opened their in-house challenge to Illumina's $8 billion reacquisition of Grail with a warning Tuesday that the merger will inhibit competition necessary to win "the war on cancer," painting a picture that served as a mirror image of the companies' arguments.

Read full article »

11th Circ. Suggests Lab Ignored Mintz Advice Over Fees

Eleventh Circuit judges hinted Tuesday that a lower court properly ended legal malpractice claims against Mintz Levin Cohn Ferris Glovsky and Popeo PC over its advice to a defunct diagnostic lab that ran afoul of federal anti-kickback laws.

2 documents attached | Read full article »

Talc Users Seek Court Order To Bar J&J Liability Spinoff

Amid media reports that Johnson & Johnson may offload its sizable talc legal liabilities into an entity destined for bankruptcy, ovarian cancer patients asked a Missouri court Tuesday for a restraining order against a move they say would deprive them of damages.

2 documents attached | Read full article »

Calif. Jury Clears C.R. Bard Over Design Of Vein Filter Implant

A California federal jury on Tuesday cleared C.R. Bard of a retired carpenter's product liability claims alleging the company negligently designed a blood clot-stopping IVC vein filter that easily broke up and sent metal shards into the plaintiff's lungs and heart.

Verdict attached | Read full article »

Analysis

Avenatti Gains Edge As Feds Show Hand In Mistrial

Michael Avenatti scored a major tactical win in his California fraud case when a federal judge declared a mistrial Tuesday, giving the disgraced lawyer a chance to fortify his defense after seeing a monthlong dress rehearsal by the

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Burford Capital LLC

government.
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POLICY & REGULATION

Green Card Applicants Must Be Fully Vaxxed Against Virus

Foreigners applying for a U.S. green card must be fully vaccinated against COVID-19 under a new policy from the U.S. Centers for Disease Control and Prevention.
Read full article »

ENFORCEMENT & COMPLIANCE

Former NFL Player Pleads Guilty As $3.9M Fraud Trial Begins

A former Baltimore Ravens linebacker pled guilty Tuesday to his role in a $3.9 million scheme to pilfer from a National Football League health plan, just as he was about to face trial alongside two fellow ex-players.
1 document attached | Read full article »

Mass. Vet Home Head Says Elder Laws Don't Fit Virus Charges

The former supervisor of a Massachusetts veterans' home said Tuesday he can't be charged with criminal elder neglect over alleged decisions that prosecutors say sparked a deadly COVID-19 outbreak at the facility.
Read full article »

LITIGATION

J&J Must Face Ill. Pelvic Mesh Suit, 7th Circ. Says

Johnson & Johnson must face an Illinois woman's lawsuit claiming she received a faulty pelvic mesh device that caused her continuing pain and medical issues, the Seventh Circuit ruled Tuesday, finding that there are still questions as to when the statute of limitations started running.
Opinion attached | Read full article »

FCC Urges DC Circ. To Back New Antenna Rules

The Federal Communications Commission and the U.S. Department of Justice told the D.C. Circuit on Monday to toss a challenge to an FCC rule meant to facilitate the installation of wireless internet equipment in residential areas.
Brief attached | Read full article »

QVC, Suzanne Somers Can't Stop Dispute From Going To Trial

Home shopping channel QVC failed to stop pitchwoman Suzanne Somers' claims the network pushed her out of the dietary supplement market during its merger with HSN, after a Pennsylvania federal judge denied both sides' bids for summary judgment Tuesday.
2 documents attached | Read full article »

Esperion Class Attys Nab $6M In Fees From $18M Settlement

The attorneys who secured an $18.25 million settlement for Esperion Therapeutics investors in a securities class action will be awarded a 32.5% portion of the settlement amount plus expenses in the amount of $833,716.99, according to an order filed in Michigan federal court Tuesday.
Order attached | Read full article »

ICE Must Test Migrants Before Sending Them To Wash. Center

U.S. Immigration and Customs Enforcement must test immigrants for COVID-19 before transferring them to a Washington state detention center, after a federal judge blamed the agency for 240 detainees and facility staff contracting the virus over the past three months.
Order attached | Read full article »

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Citigroup Inc.
Commerzbank
Credit Suisse Group AG
DKSH Holding AG
Epic Games Inc.
Esperion Therapeutics Inc.
Florida Blue
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Google LLC
Grant Thornton LLP
GuideWell Inc.
HSN Inc.
Healthcare Services Group Inc.
Houston Texans
Human Rights Campaign
Illumina Inc.
Imerys SA
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Johnson & Johnson
Kansas City Chiefs
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Monsanto Co.
NFL Enterprises LLC
Nike Inc.
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Pfizer Inc.
QVC Inc.
Sanofi SA
SoftBank Group Corp.
Solutia Inc.
Spotify Technology SA
State Bar of California
TC Global Inc.
Triple-S Management Corp.
Tronox Holdings PLC
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Washington Redskins
Wells Fargo & Co.
Yahoo! Inc.
YouTube Inc.

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Alexander Dubose

Texas Judge Considers Mask Mandate Debate 'Stunning'

A Texas state judge weighed Tuesday whether Dallas County can enforce a local mask mandate despite Gov. Greg Abbott's effort to ban such requirements, calling it "stunning" that state and local officials are arguing over masks when both sides agree the devices work against the coronavirus.

Read full article »

Suit Over Botched Hip Replacements Revived In Missouri

A Missouri appeals court on Tuesday revived some claims in a suit alleging a doctor employed by SSM Regional Health Services botched a man's hip replacements, saying the dispute over the left hip can go forward, while claims about the right hip were correctly tossed.

☐ *Opinion attached* | Read full article »

Florida Nursing Home Arbitration Ruling Tees Up Conflict

A Florida appeals court has ruled that a suit blaming a nursing home for a patient's death was properly sent to arbitration, certifying a conflict with two sister courts over whether a purportedly prohibitively expensive arbitration fee can serve as a valid, standalone argument to escape arbitration.

☐ *Opinion attached* | Read full article »

Glenmark Still Fighting To End DOJ Interviews Of India Execs

Glenmark has asked for a chance to respond to the U.S. Department of Justice's denial of assertions by Teva and Glenmark that the government inappropriately used its Israeli and Indian counterparts to force foreign executives to sit for interviews without going through counsel.

☐ *Brief attached* | Read full article »

Zantac Makers, Retailers Urge Nix Of Medical Monitoring Class

Manufacturers and retailers of the heartburn medication Zantac urged a Florida federal judge on Monday to dismiss the medical monitoring claims of a class of consumers in multidistrict litigation because they had failed to show that their exposure to the carcinogen in the drug was enough to increase their risk of cancer.

☐ *2 documents attached* | Read full article »

Fla. Argues Challenge To Trans Athlete Ban Is Unripe

Florida's governor and other defendants have called upon a federal court to dismiss a lawsuit against the state's ban on transgender girls participating in girls' and women's school sports, arguing the 13-year-old plaintiff's claims are premature and the "commonsense policy" does not run counter to the laws and rights she has raised.

☐ *Motion attached* | Read full article »

Apple Says It Has No Obligation To Host Rival COVID Apps

Apple has urged a California federal court to throw out a suit claiming it blocked competing coronavirus tracking apps from its stores, arguing that it doesn't have any obligation to distribute apps that are "inconsistent with its guidelines or policies or that threaten its consumers' health or safety."

☐ *Motion attached* | Read full article »

Fla. Claims There's Little Evidence For Masking Kids In School

Florida's star witness took the virtual stand on Tuesday in the fight over Gov. Ron DeSantis' ban on school mask mandates amid the COVID-19 pandemic, testifying that children are inefficient spreaders of the coronavirus and there's little evidence to show that masks prevent spread.

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Native American Tribes See Mixed Bag In Virus Coverage Suits

Native American tribes and nations have seen mixed results in federal and

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U.S. Attorney's Office for the Eastern District of Kentucky
U.S. Attorney's Office for the Eastern District of Pennsylvania
U.S. Attorney's Office for the Western District of Washington
U.S. Court of Appeals for the District of Columbia Circuit
U.S. Court of Appeals for the Eleventh Circuit
U.S. Court of Appeals for the Fifth Circuit
U.S. Court of Appeals for the Fourth Circuit
U.S. Court of Appeals for the Seventh Circuit
U.S. Department of Homeland Security
U.S. Department of Justice
U.S. Department of the Treasury
U.S. District Court for the Central District of California
U.S. District Court for the District of Delaware
U.S. District Court for the Eastern District of Kentucky
U.S. District Court for the Eastern District of Louisiana
U.S. District Court for the Eastern District of Michigan
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From:	Tim Hughes
To:	Tim Hughes
Subject:	TFAH"s Ready or Not report releasing this Wednesday - (Sent by Tim Hughes on behalf of Rhea Farberman)
Date:	Monday, March 8, 2021 3:02:58 PM
Attachments:	New Report Measures States" Health Emergency Preparedness[1].pdf TFAH-2021-ReadyOrNot-FnlEmb.pdf

Dear State Health Official,

TFAH will release its annual report *Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism* measuring states' health emergencies preparedness on Wednesday, March 10. Not surprisingly, this year the report has a special focus on the impact of COVID-19, highlighting the need to increase resources for emergency preparedness. We clarify that our report measures all-hazards preparedness and is not a measure of any state's COVID-19 response.

As we have done in past years, we measure 10 health security indicators in each state and discuss the relationship of each to all-hazard preparedness. We placed states into one of three performance tiers (high, middle and low) based on these indicators. Twenty states and the District of Columbia placed in the high-performance tier, 15 states placed in the middle performance tier and 15 states placed in the low performance tier.

Particularly significant in this year's report is our emphasis on how the pandemic demonstrated the importance of the federal government's role in a health emergency on the scale of a pandemic, the impact of structural racism on a community's resilience during a health emergency, and, the critical need for core public health funding including workforce and infrastructure support.

The report is being shared with news media ahead of the Wednesday morning lift of the embargo. It is likely to be covered in news markets across the country. I recommend you share these materials with your communications staff today so they can prepare for any media requests.

I'd be happy to answer any questions.

Thank you,
Rhea

Rhea K. Farberman, Director
Strategic Communications and Policy Research
Trust for America's Health
rfarberman@tfah.org

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To: Hancock, Breanne
Subject: The Coronavirus Pandemic: The Mental Health Impacts of Reopening Society
Date: Thursday, June 24, 2021 10:26:18 AM

The Forum Harvard T.H. Chan School of Public Health

Surfacing solutions to global public health problems.

Coming Up at The Forum

Tuesday, June 29, 2021

Image Credit: iStock.com/Rike_

The Coronavirus Pandemic: The Mental Health Impacts of Reopening Society

Presented jointly with The World from PRX & GBH

Live stream on Facebook, YouTube, and The Forum site, Tuesday, June 29, 2021, 12pm ET

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EXPERT PARTICIPANT

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MODERATOR
Elana Gordon, Reporter and Producer, The World

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Surfacing solutions to global public health problems.

Coming Up at The Forum

Tuesday, June 29, 2021

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Subject:	long article-abstract plus discussion
Date:	Friday, November 19, 2021 10:30:34 AM
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Use of face masks cuts COVID-19 transmission risk in half, review suggests

Bloomberg (11/18, Fourcade) reports "donning a face mask more than halves the risk of getting COVID," as well as hand-washing, "according to a review of eight studies published in the British Medical Journal." Furthermore, physical distancing "cuts the risk by a quarter."

Sandor Feldman MD
Professor Emeritus of Pediatrics
Billy S. Guyton Distinguished Professor
Chief of Pediatric Infectious Diseases (ret.)
University Mississippi Medical Center
Immunization and Epidemiology Consultant
Mississippi State Dept of Health
sfeld2222@gmail.com

From:	SANDY f
To:	Dobbs, Thomas E; Byers, Paul; Taylor, Kathryn; Edney, MD, Daniel; Raju, Whitney
Subject:	nice study on masks
Date:	Monday, October 4, 2021 9:56:30 AM
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From: Health Law360
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Subject: 1 Year Later, How Coronavirus Has Changed The Legal Profession
Date: Friday, March 12, 2021 1:16:46 PM

Coronavirus Special Report

Friday, March 12, 2021

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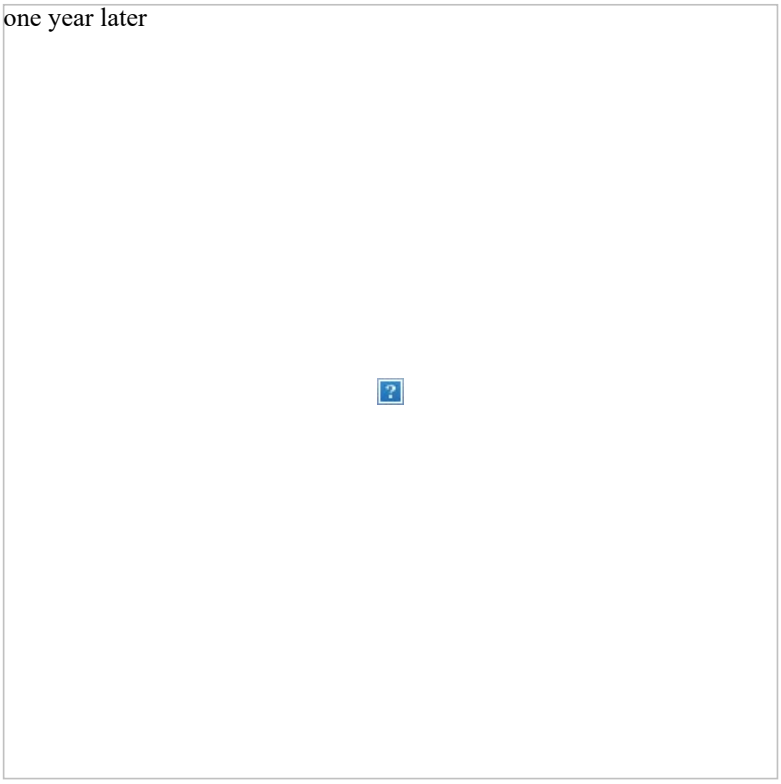

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For 'Essential' Cannabis Businesses, Pandemic Year A Boom

The pandemic marked a turning point for the cannabis industry, which was facing its first real downturn when state officials chose it as one of the businesses that could stay open amid the closure orders designed to curb COVID-19.

REGIONAL IMPACT

Texas Judges See Lasting Benefits From Pandemic Practices

Virtual hearings are largely what has allowed Texas courts to keep the administration of justice trudging along during a year of the global pandemic, and what started as the short-term necessity of remote proceedings will have lasting impacts on court operations.

How COVID Strengthened Texas As A Bankruptcy Hub

The Southern District of Texas saw a surge in commercial bankruptcy filings during 2020, drawing a caseload second only to Delaware's during the coronavirus pandemic, which attorneys attribute to the accessibility, ingenuity and predictability of a pair of Houston judges who have spent years giving the district a high profile.

5 Pennsylvania Cases That Shaped A Year Of COVID

Pennsylvania's 2020 docket related to the COVID-19 pandemic was a series of flashpoints that reflected the tensions throughout the nation as the courts dealt with emergency shutdown orders, mask mandates and the limits of state power to enforce them.

Ill. Courts Stare Down Backlog As Jury Trials Start To Resume

Navigating COVID-19 has left Illinois courts staring down a massive jury trial backlog of both civil and criminal cases, and when trials resume in the coming weeks, state and federal courts will have a tremendous amount of work to do to clear their dockets.

How Florida's Courts Have Been Forever Changed By COVID

The technological revolution in Florida's legal industry brought on by the COVID-19 pandemic has improved efficiency and saved clients money, but the necessary shift to online interactions has made mentoring young attorneys a challenge, and delays in jury trials are expected to clog up courts in the coming years.

Ga. Probate Judges Want Relief After Year Of COVID Havoc

Georgia probate court judges and clerks, hardest hit by the coronavirus pandemic of any group in the state's legal community, feel mounting frustration over the lack of protections they've gotten from the state in the last year.

'Sorry For The Disruption': A Year Of Remote Court In The UK

It was a lawyer's star turn in a London courtroom lost to a poor internet connection. Such is the world of remote hearings, forced out of courtrooms a year ago amid the pandemic. And while the experience has improved, lawyers say hitches remain.

Lawyers Predict UK's Virtual Hearings May Outlast Pandemic

When March rolled around last year, no one using the English civil courts would have guessed the judiciary was on the verge of going digital. But many practitioners now predict some of the drastic technological changes will be here to stay.

ONGOING CLOSINGS

Coronavirus: The Latest Court Closures And Restrictions

UPDATED March 11, 2021, 4:14 PM EST | As courts across the country take

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Giant Eagle Inc.
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Hannaford Brothers Co.
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LeafLink Inc.
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measures to prevent the spread of the coronavirus, some are restricting access and altering their procedures. Click state or court to jump to section.

EXPERT ANALYSIS

1 Year Into Pandemic, It's Time To Rethink Law Firm Billing

The particular tasks for which a law firm client can expect to be billed have become unpredictable in the era of COVID-19, making flat fees and other alternative fee arrangements more attractive for both in-house and outside counsel, says Jessica Hodkinson at Panasonic.

What Companies Should Know About SIGPR Oversight

Brian Miller, the special inspector general for pandemic recovery, discusses what companies and attorneys can do to avoid CARES Act fraud, how his team approaches protecting taxpayer money, and some of the challenges and successes SIGPR faced building an agency from the ground up amid a pandemic.

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European Union
Executive Office of the President
Federal Bureau of Investigation
Federal Reserve System
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Georgia Supreme Court
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National Institutes of Health
National Labor Relations Board
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Pennsylvania Supreme Court
Texas Supreme Court
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one year later

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For 'Essential' Cannabis Businesses, Pandemic Year A Boom

The pandemic marked a turning point for the cannabis industry, which was facing its first real downturn when state officials chose it as one of the businesses that could stay open amid the closure orders designed to curb COVID-19.

REGIONAL IMPACT

Texas Judges See Lasting Benefits From Pandemic Practices

Virtual hearings are largely what has allowed Texas courts to keep the administration of justice trudging along during a year of the global pandemic, and what started as the short-term necessity of remote proceedings will have lasting impacts on court operations.

How COVID Strengthened Texas As A Bankruptcy Hub

The Southern District of Texas saw a surge in commercial bankruptcy filings during 2020, drawing a caseload second only to Delaware's during the coronavirus pandemic, which attorneys attribute to the accessibility, ingenuity and predictability of a pair of Houston judges who have spent years giving the district a high profile.

5 Pennsylvania Cases That Shaped A Year Of COVID

Pennsylvania's 2020 docket related to the COVID-19 pandemic was a series of flashpoints that reflected the tensions throughout the nation as the courts dealt with emergency shutdown orders, mask mandates and the limits of state power to enforce them.

Ill. Courts Stare Down Backlog As Jury Trials Start To Resume

Navigating COVID-19 has left Illinois courts staring down a massive jury trial backlog of both civil and criminal cases, and when trials resume in the coming weeks, state and federal courts will have a tremendous amount of work to do to clear their dockets.

How Florida's Courts Have Been Forever Changed By COVID

The technological revolution in Florida's legal industry brought on by the COVID-19 pandemic has improved efficiency and saved clients money, but the necessary shift to online interactions has made mentoring young attorneys a challenge, and delays in jury trials are expected to clog up courts in the coming years.

Ga. Probate Judges Want Relief After Year Of COVID Havoc

Georgia probate court judges and clerks, hardest hit by the coronavirus pandemic of any group in the state's legal community, feel mounting frustration over the lack of protections they've gotten from the state in the last year.

'Sorry For The Disruption': A Year Of Remote Court In The UK

It was a lawyer's star turn in a London courtroom lost to a poor internet connection. Such is the world of remote hearings, forced out of courtrooms a year ago amid the pandemic. And while the experience has improved, lawyers say hitches remain.

Lawyers Predict UK's Virtual Hearings May Outlast Pandemic

When March rolled around last year, no one using the English civil courts would have guessed the judiciary was on the verge of going digital. But many practitioners now predict some of the drastic technological changes will be here to stay.

ONGOING CLOSINGS

Coronavirus: The Latest Court Closures And Restrictions

UPDATED March 11, 2021, 4:14 PM EST | As courts across the country take

Financial Industry Regulatory Authority Inc.
Friendly Ice Cream Corp.
GameStop Corp.
Giant Eagle Inc.
HIMSS
Hannaford Brothers Co.
Inovio Pharmaceuticals, Inc.
InterDigital Inc.
International Business Machines Corp.
J.C. Penney Co. Inc.
LVMH Group
LeafLink Inc.
Leafly Holdings Inc.
Lenovo Group Ltd.
LexisNexis Group
Marijuana Policy Project
Massachusetts Mutual Life Insurance Co.
Microsoft Corp.
Mirae Asset Financial Group
Moderna Inc.
NPC International Inc.
National Employment Law Project
Neiman Marcus Group
Panasonic Corp.
Pizza Hut Inc.
RELX PLC
Reddit Inc.
SRS Acquiom Inc.
Simon Property Group Inc.
Skype Technologies SA
Smarsh Inc.
Sorrento Therapeutics Inc.
Taubman Centers, Inc.
The Atlanta Journal-Constitution
The Florida Bar
Twitter Inc.
Tyson Foods Inc.
Valve Corp.
Volkswagen AG
Zoom Video Communications Inc.
iAnthus Capital Holdings Inc.

GOVERNMENT AGENCIES

Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services
Competition Appeal Tribunal
Congressional Budget Office
Council of Inspectors General on Integrity and Efficiency

measures to prevent the spread of the coronavirus, some are restricting access and altering their procedures. Click state or court to jump to section.

EXPERT ANALYSIS

1 Year Into Pandemic, It's Time To Rethink Law Firm Billing

The particular tasks for which a law firm client can expect to be billed have become unpredictable in the era of COVID-19, making flat fees and other alternative fee arrangements more attractive for both in-house and outside counsel, says Jessica Hodkinson at Panasonic.

What Companies Should Know About SIGPR Oversight

Brian Miller, the special inspector general for pandemic recovery, discusses what companies and attorneys can do to avoid CARES Act fraud, how his team approaches protecting taxpayer money, and some of the challenges and successes SIGPR faced building an agency from the ground up amid a pandemic.

Delaware Court of Chancery
Equal Employment Opportunity Commission
European Union
Executive Office of the President
Federal Bureau of Investigation
Federal Reserve System
Financial Crimes Enforcement Network
Florida Supreme Court
Food and Drug Administration
Georgia Supreme Court
Government Accountability Office
National Institutes of Health
National Labor Relations Board
Occupational Safety and Health Administration
Pennsylvania Supreme Court
Texas Supreme Court
U.S. Bankruptcy Court for the Northern District of Illinois
U.S. Court of Appeals for the Federal Circuit
U.S. Court of Appeals for the Ninth Circuit
U.S. Department of Defense
U.S. Department of Health and Human Services
U.S. Department of Justice
U.S. Department of Labor
U.S. Department of Veterans Affairs
U.S. Department of the Treasury
U.S. District Court for the Southern District of New York
U.S. Environmental Protection Agency
U.S. General Services Administration
U.S. Patent and Trademark Office
U.S. Postal Service
U.S. Securities and Exchange Commission
U.S. Senate
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To:	Dobbs, Thomas E; David Lakey, MD; ScottHarris; Joe Mclaughlin; jose.romero@arkansas.gov; Randall Mayer; Jeff Stover; Terry Dwelle; Shah, Nirav; Kristen.ehresmann@gmail.com; McLaughlin, Joseph B (HSS); Manisha.juthani@ct.gov; Gold, Rebecca (CDC/DDID/NCEZID/OD)
Cc:	Griffin, Jenny; Peggie Lawrence; Patricia Vinson; Meredith Allen; Marcus Plescia; Andy Baker-White; Ericka McGowan; Grace Lee
Subject:	Agenda and materials for 2/15 IDPC call
Date:	Thursday, February 10, 2022 6:56:23 PM
Attachments:	image001.png IDPC Agenda February 2022.docx Preparing for the Next Pandemic White Paper_narrative draft_2_8_22.docx DRAFT - Public Health Authority Policy Statement.003.docx

Hello, IDPC members,

Attached please see the agenda and materials for the ASTHO IDPC call scheduled for next Tuesday, February 15.

We look forward to speaking with you then.

Best, Kate

Kate Heyer, MPH
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PUBLIC HEALTH AUTHORITY TO PREVENT AND CONTROL THE SPREAD OF COMMUNICABLE AND INFECTIOUS DISEASE

POSITION

The Association of State and Territorial Health Officials (ASTHO) supports the establishment of more robust public health legal authorities to facilitate the timely and targeted response to communicable and infectious disease outbreaks. These legal authorities are often exercised without the need of an emergency declaration and may allow, among other things, the abatement of nuisances, investigation of the causes of disease, institution of quarantine measures, ordering individuals or groups to isolate, conducting contact tracing and case investigations, collecting data, temporarily limiting or canceling public events, temporarily restricting or closing venues, and requiring vaccination verification for certain conduct and activities (e.g., school attendance). Beyond their use in the response to the historic pandemic caused by the novel coronavirus, in the past, these powers have been routinely exercised for more commonly experienced disease outbreaks, such as mumps and measles. Most societal sectors, such as business, education, cultural, and religion, depend on public health to stop the spread of infectious disease, prevent widespread disruptions, and reduce morbidity and mortality. Strengthening, maintaining, and, where necessary, restoring these state and territorial legal authorities are key to overcoming the COVID-19 pandemic and preparing for communicable and infectious disease outbreaks in the future.

Summary of Recommendations:

- Build and maintain sufficient public health authority to effectively respond to the ongoing pandemic and future disease outbreaks.
- Support public health authority that is guided by data and science.
- Provide for public health response capacity that protects the public's interest and well-being

BACKGROUND

Establishing and using legal authority to control the spread of infectious disease predates the founding of the country. For example, colonial governments implemented isolation and quarantine precautions for incoming ships to prevent the introduction and spread of smallpox and other contagions.[1] These powers and activities were recognized not only as a way of protecting the health of the local communities, but also as protective of trade and commerce.[2] As the scientific understanding of communicable and infectious disease grew, new tools such as contact tracing, disease investigation, data collection, and vaccines were added to public health's legal authority and practice.

Highly contagious illnesses, like measles, can be effectively contained through the public health measures and activities that are now being questioned and criticized during the COVID-19 pandemic. Public health authority to implement non-medical and medical interventions swiftly and adeptly must be maintained and, where necessary, established. The creation of administrative burdens that delay public health action endangers the public well-being and leaves communities vulnerable to infectious disease outbreaks and should be avoided. During the current pandemic, public health legal authority has been used, with evidenced benefit, to slow the spread of the coronavirus by limiting the size of gatherings, encouraging social distancing, temporarily closing high-risk venues, and requiring the use of face coverings in certain places.[3,4,5,6,7,8,9]

Despite demonstrative success of exercising public health authority during the COVID-19 response, the use of these longstanding public health powers has come under attack, hampering the response to COVID-19 and future infectious disease outbreaks. Over the last year, the critical attitude of a vocal minority and misinformation about the pandemic and public health response have contributed to the rolling back of public health authority in several jurisdictions.[10,11,12] The reductions in public health legal authority will undoubtedly make it more difficult to respond to future disease outbreaks and protect the public health.

As we approach one million American deaths from COVID-19, state and territorial policy makers are encouraged to consider the grave consequences that insufficient public health authority will have on the ability to respond to this pandemic, and the next public health threat.

RECOMMENDATIONS

- **Ensure public health legal authority that is timely and necessary for the prevention and control of future communicable and infectious disease outbreaks.** To do this, ASTHO recommends that legislatures cooperate with their jurisdiction's public health agency to ensure public health agencies can issue orders limit gatherings, require masking and social distancing, mandating ventilation improvements in public spaces, and other steps that may help to abate epidemic respiratory diseases.
- **Support evidence-based laws and policies for the identification, prevention, and control of communicable and infectious diseases and other public health emergencies.** ASTHO recommends working with and advising the legislative body on the relevant science, emphasizing that, because we are unsure how the next major disease outbreak will spread or how the next public health emergency will present, public health authorities must be ready and able to respond to future diseases and other emergencies.
- **Ensure that laws and policies that undermine and encumber a public health agency's obligations or arbitrarily limit the agency's authority are amended or overturned.** Consider working directly with community partners to promote public health education. There is value in holding daily or weekly press conferences during public health emergencies to speak directly to the public and call out those who are serving as obstacles to public health goals. Design public health authority to encourage implementation of practices to best protect the wellbeing of the public, and particularly persons who may be unable to provide for their own safety.

APPROVAL DATES

Prevention Policy Committee Approval:
Board of Directors Approval:
Policy Expires:

ASTHO membership supported the development of this policy, which was subsequently approved by the ASTHO Board of Directors. Be advised that the statements are approved as a general framework on the issue at a point in time. Any given state or territorial health official must interpret the issue within the current context of his/her jurisdiction and therefore may not adhere to all aspects of this Policy Statement.

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[8] Howard J, Huang A, Li Z, et al. “An evidence review of face masks against COVID-19." *Proc. Natl. Acad. Sci.* 2021. 118 (4):1-12. Available at: https://doi.org/10.1073/pnas.2014564118. Accessed 9-28-2021.

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[10] Weber L, Barry-Jester AM. “Over Half of States Have Rolled Back Public Health Powers in Pandemic.” *Kaiser Health News*. Sept. 15, 2021. Available at https://khn.org/news/article/over-half-of-states-have-rolled-back-public-health-powers-in-pandemic/. Accessed 11-1-2021.

[11] Yee BY. “Poll: Majority Of Americans Favor Covid-19 Vaccine And Face Mask Requirements.” *Forbes*. Sept. 16, 2021. Available at https://www.forbes.com/sites/brucelee/2021/09/16/poll-majority-of-americans-favor-covid-19-vaccine-and-face-mask-requirements/?sh=5e38fe5d7e59. Accessed on 2-10-2022.

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Infectious Disease Policy Committee
Agenda
February 15, 2022
12:00 p.m. ET

Join Zoom Meeting
https://astho.zoom.us/j/96647102227?pwd=T1I3WWRqRWllUUZ5VHpsN2tnNFM3dz09

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Thomas Dobbs (MS), Scott Harris (AL), Jose Romero (AR), Nirav Shah (ME), Manisha Juthani (CT), Terry Dwelle (Alumni-ND), Kristen Ehresmann (AIM rep – MN alum), David Lakey (Alumni-TX), Randy Mayer (NASTAD Rep – IA), Joe McLaughlin (CSTE Rep - AK), Jeff Stover (NCSD Rep -VA)

Call Agenda:

12:00 p.m.	**Roll Call**	Dr. Thomas Dobbs (MS), Chair
12:05 p.m.	**Welcome**	Dr. Thomas Dobbs (MS), Chair
12:10 p.m.	***Preparing for the Next Pandemic/Public Health Crisis*** white paper overview and discussion	Dr. Thomas Dobbs (MS), Chair
12:25 p.m.	***Public Health Authority to Prevent and Control the Spread of Communicable and Infectious Disease*** draft policy statement update	Andy Baker-White, Senior Director, State Health Policy (ASTHO)
12:35 p.m.	***Viral Hepatitis Elimination*** workshop discussion	Geetika Nadkarni (MPH), Director, Infectious Disease Infrastructure and Policy (ASTHO) Dr. Thomas Dobbs (MS), Chair
12:45 p.m.	**Open Discussion/Topics for Future IDPC Calls**	Dr. Thomas Dobbs (MS), Chair
1:00 p.m.	**Adjourn**	

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***Preparing for the Next Pandemic* white paper**

DRAFT: February 7, 2022

Executive Summary

Pandemic and outbreak preparedness and response are foundational to governmental public health. The pandemics of the past decade and beyond have tested our nation's public health infrastructure, including our ability to implement infectious disease surveillance, prevent the emergence of infectious disease outbreaks, respond to the spread of infections, and promote overall health every day. State health departments, a key part of the governmental public health infrastructure, play a vital role in public health messaging, community education, enacting public health policies, and implementation of evidence-based interventions. A public health infrastructure that is both strong and resilient at the federal, state, and local level requires consistent, long-term investments to ensure the nation is better prepared for future pandemics.

The ongoing COVID-19 pandemic has exposed fundamental flaws and gaps in the public health's infrastructure to prepare for, respond to, and recover from crises and ensure the delivery of high-quality healthcare across the country. Furthermore, the negative outcomes from these pandemics have exacerbated deep-rooted health disparities that have been linked to race, socioeconomic status, and other social and demographic factors.

This white paper will discuss the lessons learned from the challenges public health leaders faced during the COVID pandemic and recent emergency responses and make recommendations to sustain gains and respond to gaps that were identified to strengthen the capacity of our public health infrastructure for the future.

Background

Throughout history, infectious diseases have been a companion of humans as they have migrated around the world. Over the past decade and beyond, infectious diseases such as Influenza A (H1N1), Ebola, Zika, and most recently, the COVID-19 pandemic, have challenged humanity. Beyond their toll on health, these infectious diseases have led to severe disruptions on human activity, economic dynamics, and social development.

Major consequences have emerged from the pandemics of the past decade. The ongoing COVID-19 pandemic, as of January 2022, has a death toll of 879, 971 lives in the United States thus far, and rising.[1] A total of $3.59 trillion has been spent by the federal government in response to the COVID-19 pandemic in the form of aid such as stimulus checks, supplemental legislation, and vaccine distribution.[2] Furthermore, the COVID-19 pandemic has exposed longstanding gaps in our public health infrastructure, especially in terms of health equity amongst our country's most vulnerable populations. Given the devastating outcomes that have and continue to emerge from COVID-19, public health and health security have been an increased focus of many sectors around

the world to not only respond to the current pandemic, but also learn how to better respond to the inevitability of future pandemics to ensure the health and wellbeing of humanity.

This white paper will discuss how public health leaders and policymakers can build a stronger public health infrastructure for combatting the next pandemics.

Barriers, Challenges, and Lessons Learned

The COVID-19 pandemic has shed light on barriers within the nation's public health infrastructure. While these challenges complicated the outbreak response, state and territorial health departments adapted to implement novel solutions to protect the wellbeing of their communities. Below are key areas for action to prepare for the next pandemic or crisis:

- **Ensuring Accurate and Apolitical Communication**

The COVID-19 pandemic quickly became a highly politicized crisis. Political ideologies drove many of the public health actions, behaviors, and policies when COVID-19 was first discovered in the United States. In many cases, divisions remain, and have impacted vaccine uptake, compliance with public health measures and mandates, spread of misinformation and disinformation, and challenges to public health authority. For example, as of November 2021, a Kaiser Family Foundation COVID-19 Vaccine Monitor analysis found that political partisanship is the strongest demographic factor that can predict vaccine uptake. Uptake has been slow amongst those who are or lean Republican, who make up 60% of the adult unvaccinated population.[3] This group is also more likely to believe in viewpoints that pose as challenges to further increase vaccine uptake, such as believing news that exaggerates the severity of the COVID-19 and getting vaccinated is a personal choice.[3]

A major struggle for public health leaders has been combatting the spread of misinformation and disinformation. Misinformation is false information shared by people who do not intend to mislead others, while disinformation is false information that is deliberately distributed with malicious intent.[4] As rates of cases and deaths increased and the virus spread, misinformation caused confusion, resistance to COVID-19 vaccination among some populations, rejection of public health measures, and harassment and violence against public health, health, and other frontline workers, as stated by the Surgeon General's call to action statement.[5] Misinformation has been spread through many modes, but social media has been the primary channel.[4] It has greatly impacted vaccine confidence and vaccination rates as most misinformation has focused on vaccine development, safety, and effectiveness.[5]

Many strategies have been deployed to prevent and combat the consequences of misinformation. The Centers for Disease Control developed a Rapid Community Assessment Guide, which includes steps and tools to quickly gather information to

better understand community needs and focus to better direct public health messaging for specific communities.

To be better prepared for future pandemics, S/THOs can implement tools to listen to and analyze circulating misinformation, engage with and listen to the community needs through a community assessment, share accurate, clear, and easy-to-find and access information, and use trusted messengers to improve public health credibility.[4]

Depoliticizing Public Health

Alongside the need for more control of misinformation is the need to depoliticize and increase the credibility of public health. Credibility of public health authority requires clear, concise, and frequent communication to best inform communities on evidence-based and evidence-informed practices. State health departments can convene partner organizations, increase investments in research on misinformation, continue to modernize public health communications, increase resources and technical assistance to state and local public health agencies, and expand efforts to build long-term resilience.[6]

In addition to the need to address misinformation and disinformation during an emergency response, the need exists to actively work to depoliticize public health and work across party lines to build support for and respect for public health in non-crisis times. With depoliticization of public health and clearer crisis communication comes the need for well-defined roles for political and public health officials. With the COVID-19 pandemic as one example, opportunities exist for government officials to initiate a review process to define the respective roles and responsibilities of public health officials more clearly at all levels of government during a pandemic.[7]

- **Sustainable, Flexible, and Accessible Funding**

Historically, public health and pandemic preparedness has been inconsistently and inadequately funded, which has impacted the emergency response to disease outbreaks and emergencies and disasters, requiring state health agencies to adjust the public health services provided throughout the response. A key opportunity for strengthening public health infrastructure before, during, and after a public health emergency includes establishing funding mechanisms that are sustainable, consistent, flexible, and readily accessible to improve surveillance, preparedness, and prevention to provide core public health services and respond to future infectious disease outbreaks. One strategy to accomplish this is to establish a future pandemic/disaster fund to expand infection prevention capacity, increase and strengthen the public health and clinical workforce, improve public health messaging and communication, implement measures and policies, and address health disparities and health inequities for future outbreaks.

Additionally, efforts need to be made to allow for flexibility in funding during and after emergency responses. Recent response experiences have resulted in public health

receiving significant funding at one time, which funds activities for a predetermined period, and often do not address the longer-term public health preparedness needs of a jurisdiction. Additionally, funding cycles often do not align with the public health needs during an emergency. Furthermore, significant funding prescribed to some public health efforts without flexibility to respond to the evolving needs of a response can result in inefficient spending and waste that impacts future public health funding.

Another essential requirement for future pandemic funds is availability. The federal funding strategy for infectious disease preparedness and prevention has primarily favored a crisis-response approach, rather than a robust, sustained investment; and fiscal challenges at the state and local levels have further compounded the pressures on state health departments nationwide.[8] This funding cycle also creates challenges for state health departments to manage a series of grants that are released sequentially, which not only is extremely difficult to manage, but also robs valuable staff time to administer during an ongoing public health emergency response.

A future pandemic fund should be more flexible, and funding priorities should be made based on input from state and local jurisdictions who understand the needs of their communities. These funds should always support long-term resiliency and preparedness based on the community's needs. The COVID-19 pandemic has also highlighted how much of the outbreak response has been, in part, fighting yesterday's public health battles. The public health sector experienced this during both the Zika and Ebola crises: once funding and guidance was made readily available to respond to the infectious disease outbreak, many of the emerging needs were over, causing a disconnect between the funded activities and the response needs. A future pandemic fund would support steady and sustainable investments in core infectious disease areas and include collaboration from all stakeholder voices at the table to ensure all community needs are visible and met.

State public health departments need to be in a perpetual state of readiness with clear and available sources of funding to respond to infectious disease outbreaks quickly and efficiently, and to effectively plan for attracting, recruiting, and retaining professionals with the skills need to prevent and respond to infectious disease outbreaks.[9]

- **Strong Leadership and Stakeholder Engagement**

Effective pandemic response requires strong leadership at all levels of government and among private sector partners. During the COVID-19 pandemic, public health agencies and state health departments sought support from leadership and partners to modify staffing structures, implement policy, acquire and distribute funding and resources, deliver public health messages to communities, and provide focused support to healthcare facilities.[10] Effective leadership can help state health departments maintain a sense of security and credibility during a pandemic with effective communication.[10] This not only allows for clear, accurate, timely, and consistent messaging, but also instills a level of trust with partners, stakeholders, and most importantly, the public.[11]

In addition to strong leadership is the need for clear and effective stakeholder engagement. Utilizing partner relationships could have delineated clear responsibilities within these roles, as well as created mechanisms to hire people for these positions. Effective stakeholder engagement for future pandemic responses should start with an engagement strategy, which includes having all partners having a seat at the table with a set vision that leverages their community's assets and addresses the community's needs. Clear roles and position descriptions for partners and stakeholders are vital for effective engagement.

- **Policy Solutions**

Future pandemic response requires increased prevention and response capacity. During the COVID-19 pandemic, policy changes allowed people to access some healthcare services more readily, such as telehealth services, while also waiving cost sharing, requiring reimbursement parity between telemedicine and in-person services, and coverage of audio-only services, when many facilities and patients were facing immense stress from the pandemic.[12] Future pandemic planning should consider opportunities to retain or modify policies to address an emergency environment.

State and territorial governments also made efforts to control the spread of COVID-19 through stay-at-home orders, gathering limits, face mask and vaccine protocols, and business restrictions.[13] Additionally, policy allowed for new federal funding investments that improved infection prevention and control activities across the public health and healthcare sectors, such as the $2.1 billion investment from the American Rescue Plan to strengthen state, local, and territorial health department capacity.[6] These investments bolster infection prevention capacity for a more coordinated and timely response for future outbreaks.

Administrative change is another vital tool for responding to the next pandemic. During the COVID-19 pandemic, state and territorial health officials adapted programs to triage and deliver care to patients. Key federal investments supported and propped up the nation's public health infrastructure, which provided a foundation that served a critical role in collecting and using data on COVID-19 infections and delivering test kits, personal protective equipment, laboratory reagents, and vaccines to the public.[14]Many health departments also experienced shifts in staffing and organizational responsibilities due to COVID response activities, which allowed for a more coordinated response. Administrative change, detailed by the White House' statement on pandemic preparedness, can allow for the transformation of medical defenses such as vaccines, therapeutics, and diagnostics, ensuring situational awareness, strengthening public health systems, building core capabilities, and managing the outbreak response.[15]

Workers have taken on additional roles in agencies, emphasizing the need for a trained and sustainable workforce. The pandemic has resulted in lagging skills among workers due to changes in technology, a lack of systems and data to assess and monitor

workforce needs and hiring barriers at all levels of government that prevent rapid utilization of contract or other non-state employees.

- **Emphasis on Health Equity**

Finally, the COVID-19 pandemic has exacerbated the persistent health disparities for marginalized, underserved, and vulnerable populations. Black, Latinx, American Indian and Pacific Islander communities have age-adjusted mortality rates 2 to 3 times greater than that of White communities due to COVID-19.[16] In addition, the COVID-19 pandemic's impact on other races, ethnicities, gender identities, and sexual orientations is still largely unknown due to inconsistent data collection and reporting. Social determinants of health have historically prevented populations from having fair opportunities for economic, physical, mental, and emotional health, and the pandemic has exacerbated these factors.[17] Many factors disproportionately impact these populations, such as limited access to testing and vaccination sites, mistrust in healthcare, language barriers, inadequate protective equipment to essential workers, disproportionate burden of comorbidities, etc.[18] The health disparities observed during the COVID-19 pandemic are the unfortunate consequences of deep-rooted health inequities and discrimination that have been embedded in our society for hundreds of years. Public policy addressing these gaps in data collection and reporting, barriers in access to healthcare, and the critical need for additional funding and resources at the systemic level are vital in ensuring the health and well-being of our society's most vulnerable. Health equity should be at the forefront of every public health initiative and future pandemic response.

Community engagement, with a core value of social justice, has been a cornerstone of public health. While risk communication is necessary during pandemic responses, it is not at all sufficient for sustainable and consistent community engagement. There is a critical role of communities in supporting the emergency response in pandemics to ensure health equity. Communities played a critical role in surveillance, testing, and contact tracing efforts.[19] To best serve vulnerable populations in future pandemic responses, state health departments should strive to learn, partner, work collectively, share, and advocate for the health and wellbeing of their communities.

Conclusion

Policies have allowed for essential funding to be issued to bolster pandemic responses, allowing states to increase their capacity for outbreak response activities. While these temporary funding opportunities have assisted with the pandemic response, public health professionals are preparing for a shift back into traditional underfunding patterns for the public health sector after the pandemic. S/THOs and their partners should consider leveraging lessons learned during the decade's past pandemics and use evidence-based practices to advocate for the dire need for long-term investments. Additionally, S/THOs should ensure that future public health initiatives, especially during pandemics, emphasize and prioritize health equity for our most vulnerable populations.

Preparing for the next pandemic will require a multi-faceted approach with a commitment to sustainable, long-term investments to public health infrastructure.

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From: CDC IMS 2019 NCOV Response STLT Partner Engagement
To: CDC All STLT COVID19 Update Call; Simone, Patricia (Pattie) (CDC/DDPHSIS/CSELS/DSEPD); Sera Josef, Carissa (CDC/DDID/NCHSTP/DTE); Hayes, Nikki (CDC/DDNID/NCCDPHP/DCPC); Davis, Mark A. (CDC/DDPHSIS/CPR/DSLR); Barton Behravesh, Casey (CDC/DDID/NCEZID/OD); Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED); Patel, Manisha (Mo) (CDC/DDNID/NCIPC/ODD); Marshall, Katherine E. (CDC/DDID/NCEZID/DFWED); Gaines, Jennifer M. (CDC/DDPHSIS/CPR/OD); Posey, Drew (CDC/DDID/NCEZID/DGMQ); Olson, Victoria (CDC/DDID/NCEZID/DHCPP); Bower, William (CDC/DDID/NCEZID/DHCPP); Smith, Rachel M. (CDC/DDID/NCEZID/DHQP); Chen, Jessica (CDC/DDID/NCEZID/DFWED); Arvay, Melissa (CDC/DDID/NCIRD/DIBD); Gallardo-Romero, Nadia F. (CDC/DDID/NCEZID/DD); Belay, Ermias (CDC/DDID/NCEZID/DHCPP); Srinivasan, Arun (CDC/DDID/NCEZID/DHQP); McQuiston, Jennifer H. (CDC/DDID/NCEZID/DHCPP); Blain, Amy (CDC/DDID/NCIRD/DBD); Tansey, Cassandra (CDC/DDID/NCEZID/DSR); Young, Andrea (CDC/DDPHSIS/CSTLTS/DO); Tiller, Rebekah (CDC/DDID/NCEZID/DHCPP); Smith, Jacinta L. (CDC/DDPHSIS/CPR/DSAT); Williams, Holly G. (CDC/DDNID/NCCDPHP/DDT); Harrington, Allison (CDC/DDPHSIS/CGH/DQHP); Phoenix Weir, Ursula (CDC/DDNID/NCBDDD/DOD); Lee, Kinzie (CDC/DDNID/NCIPC/COD); Kunnir, Molly Regina (CDC/DDPHSIS/CSELS/DSEPD); Peacock, Joanne L. (CDC/DDPHSIS/CPR/DSLR); Joshi, Namita (CDC/DDPHSIS/CGH/DPDM); Oliver, Angela (CDC/OD/OCS); McLeod, Timothy (CDC/DDID/NCEZID/DHCPP); Kadolk, Melissa (CDC/DDID/NCEZID/OD); Lutgring, Joseph (CDC/DDID/NCEZID/DHQP); Randolph, Jean (CDC/DDPHSIS/CPR/DSLR); Robertson, Angela C. (CDC/DDNID/NCBDDD/DBDID); Judd, Michael (CDC/DDPHSIS/OD); Kirloch, Ryan D. (CDC/DDNID/NCCDPHP/OD); Erdozia, Julia (CDC/DDPHSIS/CGH/DGHT); Leach, Caitlin (CDC/DDID/NCHHSTP/OD); Painter, Elizabeth (CDC/DDID/NCHHSTP/DHMPIRS); Chatham-Stephens, Kevin (CDC/DDNID/NCBDDD/DHDD); Samuel, Lee (CDC/DDPHSIS/CGH/DPDM); Figueroa, Erica (CDC/DDID/NCHHSTP/OD); McCulloch, Audrey (CDC/DDPHSIS/CGH/OD); Meyers, Anne (CDC/DDNID/NCEH/DEHSP); Labar, Kristin A. (CDC/DDNID/NCEH/DEHSP); Patrick, Mary E. (CDC/DDNID/NCBDDD/DHDD); Coleman, Erik W. (CDC/DDNID/NCEH/DEHSP); Fraire, Marissa (CDC/DDID/NCIRD/DBD); McMillen, Amy (CDC/DDID/NCEZID/OD); Kohr, Jennifer M. (CDC/OD/OADPS); Casillas, Shannon (CDC/DDNID/NCIPC/DOP); Cloonan, Kate (CDC/DDNID/NCIPC/DOP); Peacock, Nykiconia (ATSDR/OAO/OCHIA); Miller, Kirk (CDC/OCOO/OFR/OA); Ghanjure, Radhika (CDC/DDID/NCIRD/DVD); Walter-Garcia, Madison (CDC/DDID/NCIRD/OD); Bjork, Adam C. (CDC/DDID/NCIRD/ISD); Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Bhatt, Achal (CDC/DDID/NCIRD/ISD)
Cc: CDC IMS 2019 NCOV Response IM-POIN Special Asstz; CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships; CDC IMS AV/Communications; CDC IMS Response Coordinator -2
Subject: CDC All-State, Tribal, Local, and Territorial (STLT) Update Call
Attachments: 10.04.2021 CDC All STLT Update Call Agenda.pdf
09.27.2021 All STLT update Call Summary.pdf

Call Purpose: CDC's 2019 Novel Coronavirus (COVID-19) response team will continue to host a national call series every Monday from 2:00 p.m. to 2:45 p.m. EST to provide state, tribal, local, and territorial (STLT) partners with the latest information on the COVID-19 outbreak and U.S. preparedness efforts.

Invited call participants include STLT preparedness directors, epidemiologists, health officials, public health laboratory directors, and nongovernmental partners.

CDC will continue to share the agendas and call notes weekly.

Participant Information: The CDC All-STLT Update Call will now be held as a Zoom webinar and requires a one-time registration. After registering, you will receive a unique participant link via email. Please note that your unique participant link will be the same for all calls in the series, through December 2021; you do not need to register for each individual call. Click here to register <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcdc.zoomgov.com%2Fwebinar%2Fregister%2FWN_hHZj-YpdTHiDHOK1ILDU0w&data=04%7C01%7CThomas.Dobbs%40msdh.ms.gov%7Cb1c40bb990dc4a1e17d208d8869c0646%7C5590424dc8bf84d869fc0fbf4c7503c7%7C0%7C0%7C637688826981243992%7CUnknown%7CTWFpbGZsb3dkeyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTGkIk1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=eV4dYI1i2%2BACJCvv%2Bb95nfzFLXvVynkIgywjr%2BLvo%3D&reserved=0> for the call series. The link can also be found here: https://cdc.zoomgov.com/webinar/register/WN_hHZj-YpdTHiDHOK1ILDU0w <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcdc.zoomgov.com%2Fwebinar%2Fregister%2FWN_hHZj-YpdTHiDHOK1ILDU0w&data=04%7C01%7CThomas.Dobbs%40msdh.ms.gov%7Cb1c40bb990dc4a1e17d208d8869c0646%7C5590424dc8bf84d869fc0fbf4c7503c7%7C0%7C0%7C637688826981243992%7CUnknown%7CTWFpbGZsb3dkeyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTGkIk1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=eV4dYI1i2%2BACJCvv%2Bb95nfzFLXvVynkIgywjr%2BLvo%3D&reserved=0>

Please do not share your participant link. After registering, the link you receive is unique to you and should not be shared. If you would like to invite a colleague to this call series, please request they email eocevent424@cdc.gov <mailto:eocevent424@cdc.gov> .

Add the link to your calendar as a reoccurring weekly event: To add this link to your calendar, select the "Add to Calendar" link within the email you receive. This will download the .ics file. Open the file and save the event to your calendar. Please ensure that you set this invitation to reoccur weekly.

All-STLT Update Call Dates 2021

The All-STLT Update Call will be on Mondays from 2 to 2:45 PM EST except for the dates below where the call will be held on a Tuesday.

* Tuesday, June 1 (Memorial Day May 31)
* Tuesday, July 6 (Independence Day July 5)
* Tuesday, September 7 (Labor Day September 6)
* Tuesday, October 12 (Columbus Day October 11)

CDC All-STLT Update Call - Monday, September 27, 2021 (2:00-2:45 PM ET)

I. **Welcome and introductions:** Christine Kosmos, Senior Advisor, STLT Support Task Force (STLT TF), CDC COVID-19 Response

2. **Incident Manager's update:** Barbara Mahon, Incident Manager, CDC COVID-19 Response
   - **Epi update:**
     - National seven-day average (as of September 27): Cases decreased by 18.6%, hospital admissions decreased by 16%, COVID-19 related deaths increased by 2.1%, and case positivity decreased by 9.4%.
     - Updated variant proportions can be found on the COVID Data Tracker.
     - Vaccines administered to date can be found on the COVID Data Tracker.

3. **MMWRs for the week of September 25 – October 1, 2021:**
   - Disparities in COVID-19 Vaccination Status, Intent, and Perceived Access for Noninstitutionalized Adults, by Disability Status — National Immunization Survey Adult COVID Module, United States, May 30–June 26, 2021
   - Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks — Maricopa and Pima Counties, Arizona, July–August 2021
   - COVID-19–Related School Closures and Learning Modality Changes — United States, August 1–September 17, 2021
   - Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements — United States, July 1–September 4, 2021
   - Safety Monitoring of an Additional Dose of COVID-19 Vaccine — United States, August 12–September 19, 2021
   - COVID-19 Outbreaks at Youth Summer Camps — Louisiana, June–July 2021
   - Multicomponent Strategies to Prevent SARS-CoV-2 Transmission — Nine Overnight Youth Summer Camps, United States, June–August 2021

4. **Other updates:**
   - **Variant classification update:** Summer Galloway, Laboratory & Testing Task Force (Lab TF), CDC COVID-19 Response, provided an overview on the new update on the SARS-CoV-2 Variant Classifications and Definitions page, which includes a new section of Variants Being Monitored (VBM).
   - **COVID-19 vaccine update:** Kimberly Fox, Vaccine Task Force (VTF), CDC COVID-19 Response, provided an update on the new CDC recommendation of the COVID-19 Vaccine booster shots for the Pfizer-BioNTech vaccine for eligible recipients who completed their initial series at least six months ago. For more information about the recommendations visit: Who Is Eligible for a COVID-19 Vaccine Booster Shot?
   - **Notes from the field: Monitoring COVID-19 Related School Disruptions, United States 2021:** Sharyn Parks Brown, STLT TF, CDC COVID-19 Response, provided an overview of a CDC report in collaboration with Johns Hopkins University Applied Physics Laboratory on school disruptions to in-person learning over the last two school years due to the COVID-19 pandemic.
   - **MMWR: Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements — United States, July 1–September 4, 2021:** Sharyn Parks Brown, STLT TF, CDC COVID-19 Response, provided and overview of the newly released MMWR that assessed the impact of masking in schools on COVID-19 incidence among K–12 students across the United States.
   - **MMWR: Association Between K-12 School Mask Policies and School-Associated COVID-19 Outbreaks -- Maricopa and Pima Counties, Arizona, July-August 2021:** Lisa Barrios, STLT TF, CDC COVID-19 Response, summarized the newly released MMWR that evaluated school mask policies and school-associated COVID-19 outbreaks in K–12 public non-charter schools open for in-person learning in Maricopa and Pima Counties, Arizona, during July 15–August 31, 2021.
   - **Topic for this week's COVID-19 Community of Practice:** Christine Kosmos, Senior Advisor, STLT TF, CDC COVID-19 Response, shared that this week's Community of Practice Call topic will be, "The Role of Prevention Measures, Testing Strategies, and Vaccinations to Prevent the Spread of COVID-19 at Summer Youth Camps". The webinar will include presentations from CDC as well as state public health partners who will present best practices and lessons learned from camps during the summer

2021 session, which could inform K-12 schools' practices, policies, and procedures. For more information, please email ecoevent424@cdc.gov.

5. **Question summary:**

- **Vaccine update:**
  - Do you anticipate the CDC Clinical Considerations page being updated with booster recommendations?
  - Any discussion of mixing vaccines?
  - Have Moderna boosters been approved and are they actively being administered

  Related resources:
  - The Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States was updated with a new section on considerations for use of a Pfizer-BioNTech COVID-19 vaccine booster dose after completion of a Pfizer-BioNTech primary vaccine series.
  - COVID-19 vaccines are not interchangeable. If you received a Pfizer-BioNTech or Moderna COVID-19 vaccine, you should get the same product (or brand) for your second shot. You should get your second shot even if you have side effects after the first shot unless a vaccination provider or your doctor tells you not to get it.
  - What to Do if You Had an Allergic Reaction After Getting a COVID-19 Vaccine
  - Who Is Eligible for a COVID-19 Vaccine Booster Shot? | CDC
  - Getting Your COVID-19 Vaccine
  - Understanding mRNA COVID-19 Vaccines
- **Variant classification update:**
  - Is there an estimate of the degree that at-home tests are impacting our ability to estimate positivity and case rates, and to compare them now to prior surges in states or in the US?
  - People are refusing weekly testing because of the use of ethylene oxide for sterilization, and they think they are going to increase their chance of cancer. Can you please address this and reference documents that we can share to dispute misinformation?
  - Do we know if Delta variant sub-lineages AY.1 and AY.2 (Delta Plus) are more transmissible than other delta variant sub-lineages, or more resistant to monoclonal antibodies?
  - Do you know if any of the VBM's are as or more virulent than Delta?
  - Is there a SIG website we can check for updates?

  Related resources:
  - Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab And Etesevimab 09162021 from FDA.gov
  - There is no official SIG website. CDC coordinates the SARS-CoV-2 Interagency Group. As such, relevant updates to the variant classifications are communicated through CDC's SARS-CoV-2 Variant Classifications and Definitions page.
- **Notes from the Field: Monitoring COVID-19 Related School Disruptions, United States 2021:**
  - Could you please provide an update on the test to stay pilot studies that CDC is conducting?

  Related resources:
  - COVID-19–Related School Closures and Learning Modality Changes — United States, August 1–September 17, 2021 | MMWR (cdc.gov)
- **MMWRs: COVID-19 Pediatric Case Burden in Counties with and without Mask Mandates:**
  - Many are suggesting long term health impacts or questioning safety of long-term mask wearing. Lots of publications suggesting all sorts of hazards. CDC currently has info about risk of CO2 retention on the mask page. Do you have an evidence review or other info on safety of face masks that addresses other concerns you can share?

  Related resources:
  - Studies on the effects of wearing masks have shown there is no change in oxygen or carbon dioxide levels when people wear cloth and surgical masks (Brooks et al., 2021; Samannan et al., 2021).

- Additional information is available on CDC's Your Guide to Masks: Your Guide to Masks and via Science Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2 | CDC
- COVID-19 Testing to Sustain In-Person Instruction and Extracurricular Activities in High Schools — Utah, November 2020–March 2021 | MMWR (cdc.gov)

CDC COVID-19 All STLT Update Call

Monday, October 4, 2021
2:00–2:45 PM ET

AGENDA

I. **Welcome and Introductions:** Chris Kosmos, Senior Advisor, STLT Support Task Force, CDC

II. **Incident Manager's Update:** Barbara Mahon, Incident Manager, CDC

III. **Other Updates:**
- CDC COVID-19 Risk Factor and Behaviors Online Assessment: Brendan Flannery, CDC
- Investigating Myocarditis Health Effects after COVID-19 Vaccination: *Tom Shimabukuro, CDC*
- MMWR: Multi-layered Mitigation Strategies to Prevent SARS-CoV-2 Transmission - Nine Overnight Summer Camps across the United States (US), June-August, 2021: *Sarah Lee, CDC*
- MMWR: Increase in Louisiana Summer Camp Outbreaks corresponding with predominance of Delta Variant– Louisiana, June to July 2021: Phillippa Chadd, CDC
- Community of Practice: *Chris Kosmos, CDC*

IV. **Question and Answer Session**
Following today's call, additional questions can be directed to: eocevent424@cdc.gov

Next ALL STLT Update Call: TUESDAY, October 12, 2021

From:	Dunajcik, Alicia (CDC/DDID/NCEZID/DPEI)
To:	Byers, Paul; Craig, Jim; Jefferson, Randy (CDC/DDID/NCHHSTP/DSTDP); Ware, Daphne; Vaughn, Wayne
Cc:	Green, Jamilla (CDC/DDID/NCEZID/DPEI); CDC IMS 2019 NCOV Response HDTF 4/6 Regional Support TM
Subject:	CDC COVID-19 Weekly Digest of Resources: 1/23 - 1/29
Date:	Monday, February 1, 2021 8:05:41 AM
Attachments:	2021-01-29-Science-Update_Public_Final_v2.pdf CDC COVID-19 Vaccine Technical Key Points 1.25.21.pdf COVID Vaccine Social Listening Report 1_27_21.pdf CDC Resources for Case Investigations and Contact Tracing_01082021.pdf

Hi Mississippi colleagues-

Here is your weekly digest of CDC resources.

CDC COVID-19 Science Update: See the latest science update, released on 1/29/2021, attached to this email. Previous science updates can be viewed at ***https://www.cdc.gov/library/covid19*.**

MMWR Articles: Below are links to recent COVID MMWR articles

- **January 29, 2021** Impact of COVID-19 on Cervical Cancer Screening Rates Among Women Aged 21–65 Years in a Large Integrated Health Care System — Southern California, January 1–September 30, 2019 and January 1–September 30, 2020
- **January 29, 2021** Trends in Outbreak-Associated Cases of COVID-19 — Wisconsin, March–November 2020
- **January 29, 2021** Response to a COVID-19 Outbreak on a University Campus — Indiana, August 2020
- **January 29, 2021** COVID-19 Cases and Transmission in 17 K–12 Schools — Wood County, Wisconsin, August 31–November 29, 2020
- **January 29, 2021** SARS-CoV-2 Transmission Associated with High School Wrestling Tournaments — Florida, December 2020–January 2021
- **January 29, 2021** Implementation and Evolution of Mitigation Measures, Testing, and Contact Tracing in the National Football League, August 9–November 21, 2020
- **January 29, 2021** Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021

*Older MMWR COVID-19 Reports can be viewed at
https://www.cdc.gov/mmwr/Novel_Coronavirus_Reports.html

CDC Website Updates: Please find updated CDC website pages for 1/23-1/29

Response Website Updates (1/23/21-1/29/21)

- Cases in the U.S. Friday, January 29, 2021
- COVID-19 Vaccination for Communities Friday, January 29, 2021
- COVID-19 Vaccine Communication Toolkit for Essential Workers: Getting Started Friday, January 29, 2021
- COVID-19 Vaccine Communication Toolkit for Community-Based Organizations: Getting Started Friday, January 29, 2021
- Requirement for Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States Friday, January 29, 2021
- US COVID-19 Cases Caused by Variants Friday, January 29, 2021
- Wear Face Masks on Public Transportation Conveyances and at Transportation Hubs Friday, January 29, 2021
- Federal Register Notice: Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19 Friday, January 29, 2021

- How CDC Determines the Level of a Country's COVID-19 Travel Health Notice Friday, January 29, 2021
- Crew Disembarkations through Commercial Travel Friday, January 29, 2021
- COVID-19 Forecasts: Deaths Friday, January 29, 2021
- Staffing Resources Friday, January 29, 2021
- COVIDView Weekly Summary Friday, January 29, 2021
- Coronavirus Disease 2019 (COVID-19) Friday, January 29, 2021
- COVID-19 Travel Recommendations by Country Friday, January 29, 2021
- Travel Friday, January 29, 2021
- Large Gatherings Thursday, January 28, 2021
- Non-Hospital Settings and COVID-19 Thursday, January 28, 2021
- Small Gatherings Thursday, January 28, 2021
- Toolkit for Pregnant People and New Parents Thursday, January 28, 2021
- Emerging SARS-CoV-2 Variants Thursday, January 28, 2021
- New Variant of Virus that Causes COVID-19 Detected Thursday, January 28, 2021
- Workplaces and Businesses Thursday, January 28, 2021
- Guidance for SARS-CoV-2 Point-of-Care Testing Thursday, January 28, 2021
- Ensuring the Safety of COVID-19 Vaccines in the United States Thursday, January 28, 2021
- Holiday Celebrations Thursday, January 28, 2021
- COVID-19 One-Stop Shop Toolkits Thursday, January 28, 2021
- Information for Healthcare Professionals about Coronavirus (COVID-19) Thursday, January 28, 2021
- Workplace Vaccination Program Wednesday, January 27, 2021
- Essential Workers & Employees: When & How to Get Vaccinated Wednesday, January 27, 2021
- Importance of COVID-19 Vaccination for Essential Workers Wednesday, January 27, 2021
- Frequently Asked Questions about v-safe Wednesday, January 27, 2021
- Wastewater Surveillance Data Reporting & Analytics Wednesday, January 27, 2021
- Previous COVID-19 Forecasts: Cases Wednesday, January 27, 2021
- COVID-19 Forecasts: Cases Wednesday, January 27, 2021
- Donate Blood Plasma and Help Save Lives Wednesday, January 27, 2021
- Previous COVID-19 Forecasts: Hospitalizations Wednesday, January 27, 2021
- COVID-19 Forecasts: Hospitalizations Wednesday, January 27, 2021
- CDC Seroprevalence Survey Types Wednesday, January 27, 2021
- Previous Forecasts of Total Deaths Wednesday, January 27, 2021
- Correctional and Detention Facilities Wednesday, January 27, 2021
- Household Checklist Wednesday, January 27, 2021
- Health Departments Wednesday, January 27, 2021
- Building Confidence in COVID-19 Vaccines Tuesday, January 26, 2021
- COVID-19 Vaccinations Tuesday, January 26, 2021
- K-12 Schools COVID-19 Mitigation Toolkit Tuesday, January 26, 2021
- Construction COVID-19 Checklists for Employers and Employees Tuesday, January 26, 2021
- Testing and International Air Travel Tuesday, January 26, 2021
- Training Case Investigators and Contact Tracers Tuesday, January 26, 2021
- What Construction Workers Need to Know about COVID-19 Tuesday, January 26, 2021
- Publications about COVID-19 for Laboratories Tuesday, January 26, 2021
- Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories Tuesday, January 26, 2021
- How to Report COVID-19 Laboratory Data Tuesday, January 26, 2021

- COVID-19 Contact Tracing Training Tuesday, January 26, 2021
- Related Materials Tuesday, January 26, 2021
- FAQs for Correctional and Detention Facilities Tuesday, January 26, 2021
- Travelers Prohibited from Entry to the United States Tuesday, January 26, 2021
- Information about the Moderna COVID-19 Vaccine Monday, January 25, 2021
- Information about the Pfizer-BioNTech COVID-19 Vaccine Monday, January 25, 2021
- Frequently Asked Questions about COVID-19 Vaccination Monday, January 25, 2021
- Training for Healthcare Professionals Monday, January 25, 2021
- K-12 Schools and Childcare Programs Monday, January 25, 2021
- Clinical Questions about COVID-19: Questions and Answers Monday, January 25, 2021

*Daily website updates are now viewable at https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html

Federal Emergency Management Agency (FEMA) Vaccination Distribution Updates

In a recent press release, FEMA has now obligated more than $1.2 billion to governmental partners with vaccination sites, as the agency continues its increased support in the ongoing battle against COVID-19.

That number is expected to grow in the days ahead.

Federal Funding to Accelerate State Vaccine Efforts: FEMA will provide reimbursement to state, local, tribal and territorial governments and the District of Columbia for use of their National Guard to respond to COVID-19 and other assistance, which may include support for vaccination distribution and administration, at a 100% cost share until Sept. 30, 2021.

The agency is expediting reimbursement for eligible emergency work projects to ensure resources are available to support vaccine distribution and administration. Funding covers emergency protective measures, such as:

- Supplies and commodities needed to safely store and administer the vaccine
- Transportation support and reasonable, necessary security for refrigerated trucks and support for leasing space to store and/or administer vaccines, including utilities, maintenance and security.
- Medical and support staff, including onsite infection control measures, personal protective equipment for staff, cloth face coverings for patients, temperature scanners, physical barriers and disinfection of the facility in accordance with CDC guidance.
- Dissemination of public information and communication regarding vaccinations.

The Coronavirus Response and Relief Supplemental Appropriations Act of 2021 appropriates $2 billion to FEMA to provide financial assistance to individuals and households for COVID-19-related funeral expenses at a 100% federal cost. The appropriation covers eligible funeral expenses incurred through Dec. 31, 2020. FEMA is reviewing the legislation and evaluating potential options for implementation.

Federal Coordination to Identify and Fill Resource Gaps: FEMA released "FEMA COVID-19 Vaccination Planning FAQ," a document to help assist governments with their vaccine distribution efforts and reimbursements for associated costs. The agency will work with the U.S. Department of Health and Human Services and other federal agencies to ensure a coordinated approach to using Defense Production Act authorities wherever necessary so private sector companies can increase vaccine supply and spur vaccine manufacturing.

FEMA Supporting and Establishing Vaccine Sites: FEMA will provide support to established vaccination locations, establish new community vaccination centers, and support National Guard operations to expand access to vaccines. To reach underserved and rural communities, FEMA, in collaboration with federal partners, will coordinate efforts to establish and support fixed facilities and establishing pop-up or temporary vaccination sites and mobile vaccination clinics.

Massachusetts Department of Public Health: Communications and Community Engagement for COVID-19 Vaccines

Check out this interesting and informative presentation that the Massachusetts DPH gave to the Vaccine Task Force last week, all about what has worked best when it comes to targeted community engagement strategies to promote COVID-19 vaccination. By utilizing a variety of tools such as Jamboard exercises and community focus groups, they identified themes around barriers to vaccination, vaccine hesitancy, how to increase adherence and improve community trust.

Upcoming Trainings/Meetings

- Below is a link to a series of accredited education about COVID-19 vaccine in general, safety, and administration considerations. Please distribute this information with your next regular communication with states.
    - Vaccine Courses, Broadcasts, Webcasts and Self Study Training | CDC
- Tiberius users can access the training video on submitting transfer requests at the following link: https://protect-ows.hhs.gov/workspace/compass/view/ri.compass.main.folder.c95b290c-2561-4cd1-85f7-e31dac51d34b [protect-ows.hhs.gov

Upcoming NACCHO Webinar: Tuesday, February 9 at 12 pm ET: COVID-19 Action in the Biden Era: A Fireside Chat with Dr. Fauci

Upcoming CDC Foundation Webinar: February 24 at 1:00-2:00 pm EST - Updates and Resources from CDC and Ad Council

COVID-19 Resources

- COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex
    - Considerations for Increasing COVID-19 Vaccination: Reaching and Increasing Uptake in Priority Populations
- COVID-19 Vaccine Technical Key Points (attached)
- FEMA Social Listening Report (attached)
    - Includes highlights from each HHS Region concerning COVID-19 vaccine rumors, supply chain, vulnerable populations and more.
- COVID-19 Vaccination Communication Toolkits for Community- Based Organizations and Essential Workers
    - COVID-19 vaccines will be available to essential workers and other community members soon. CDC has designed two toolkits to help build confidence in this new vaccine. The toolkits will help community-based organizations (CBOs) and employers to educate community members and workers about COVID-19 vaccines, raise awareness about the benefits of vaccination, and address common questions and concerns.
- CDC Resources for Case Investigation and Contact Tracing (attached)

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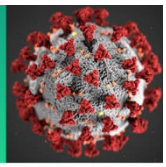
COVID-19 Science Update



From the Office of the Chief Medical Officer, CDC COVID-19 Response, and the CDC Library, Atlanta, GA.
Intended for use by public health professionals responding to the COVID-19 pandemic.

***** Available on-line at https://www.cdc.gov/library/covid19 *****

Section headings in the COVID-19 Science Update have been changed to align

with the CDC Science Agenda for COVID-19.

Prevention, Mitigation, and Intervention Strategies

PEER-REVIEWED

Mask-wearing and control of SARS-CoV-2 transmission in the USA: a cross-sectional study. Rader *et al.* Lancet Digital Health (January 19, 2021).

Key findings:

- 84.6% of respondents reported they were very likely to wear a face mask to the grocery store, 40.2% reported they did so to visit friends and family, and 4.7% reported they were not likely at all to wear a mask in either setting.
- A 10% increase in self-reported mask-wearing was associated with a significantly increased odds of community transmission control (OR 3.53, 95% CI 2.03-6.43).
- Communities with both high reported mask-wearing and physical distancing had the highest predicted probability of transmission control.
- Reported mask usage continued to increase after statewide mask mandates were introduced; however, the increases were not significant.

Methods: Self-reported mask-wearing was assessed using online survey responses from 378,207 US individuals between June 3 and July 27, 2020. Multivariate logistic regression models controlling for variables such as physical distancing and population demographics estimated the association between mask-wearing and community transmission control defined as an instantaneous reproductive number (R_t) <1. *Limitations*: Survey relies on self-reported behavior; survey bias; ecologic study design; model assumptions.

Implications: A higher proportion of mask-wearing and physical distancing was associated with a higher probability of SARS-CoV-2 transmission control; however, mask mandates alone are not sufficient to control the ongoing pandemic and additional health interventions are needed.

Airflows inside passenger cars and implications for airborne disease transmission. Mathai *et al.* Science Advances (January 1, 2021).

Key findings:

- Air changes per hour (ACH) varied based on which windows were open in the car:
  - Highest (250) when all 4 car windows were open.
  - Intermediate (approximately 150) when 3 windows were open (all 3 except the window next to the driver or the passenger respectively), *and* when only the 2 windows (front right and left rear) across from the 2 occupants were open (Figure).

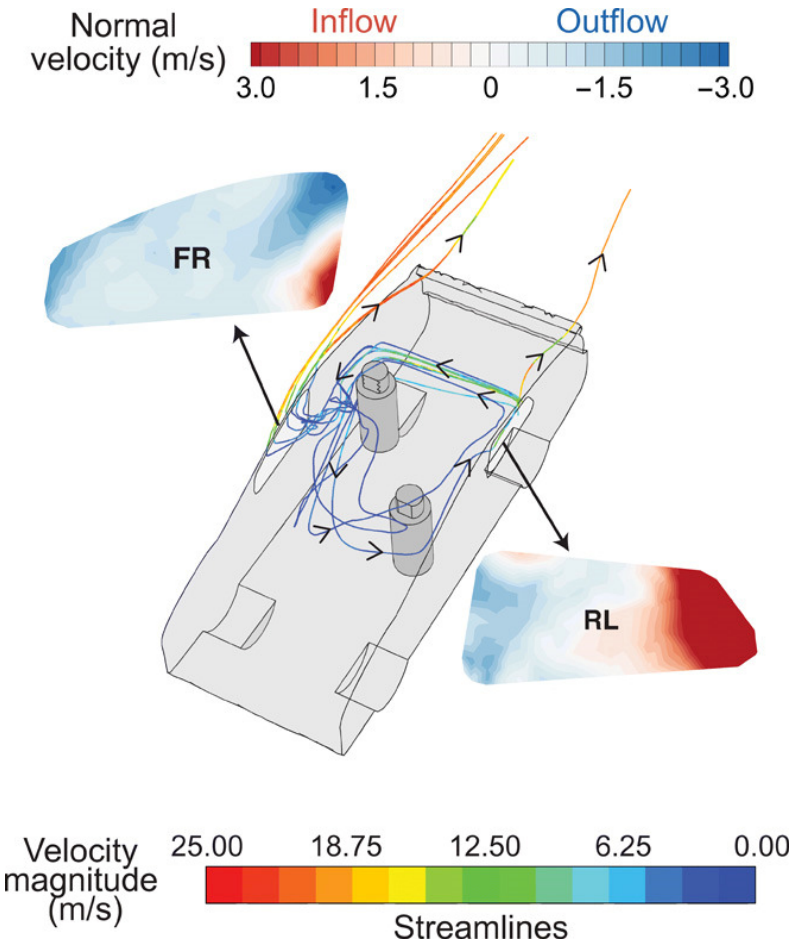
MS-DOH-21-1816-A-001518

  - Relatively low (89) when only the front left and right rear windows were open.
  - Lowest (62) when all were closed.
- When the rear left and front right windows were open, a strong incoming clean air stream from the rear left window acted as an “air curtain” that could reduce infectious particles reaching the passenger (Figure).

Methods: Calculated flow patterns associated with a range of ventilation options using 6 combinations of fully open and closed windows in a model 4-door car moving at 50 miles per hour, with 2 occupants—a driver in the front left seat and a passenger sitting in the rear right seat. ***Limitations***: Variations such as slower car speeds, larger vehicles, and open moonroofs could be associated with different airflow patterns.

Implications: Travelling with all car windows open and all occupants masked is likely the most effective way to minimize cross-contamination between car occupants. When more practical to open only some windows, choice of seat location and which windows are opened might impact air flow and transmission risk. Further study is warranted in light of the global importance of mitigation of SARS-CoV transmission in passenger cars.

Figure:



Note: Adapted from Mathai *et al*. A typical streamline pattern in the car when the rear left and front right windows are open. The streamline color indicates the flow velocity from **0.00** to **25.00 meters/second (m/s)**. Insets show the opened front right (FR) and rear left (RL) windows, colored by the normal velocity, from **-3.0** to **3.0 m/s**. A **strong air current** enters the cabin from the rear left window due to the car’s motion, travels along the back seat, turns at the closed rear right window, and most of the air exits at the front right window. Licensed under CC BY-NC 4.0.

Detection, Burden, and Impact

PEER-REVIEWED

The epidemiological and radiographical characteristics of asymptomatic infections with the novel coronavirus (COVID-19): A systematic review and meta-analysis. Chen *et al*. International Journal of Infectious Diseases (January 12, 2021).

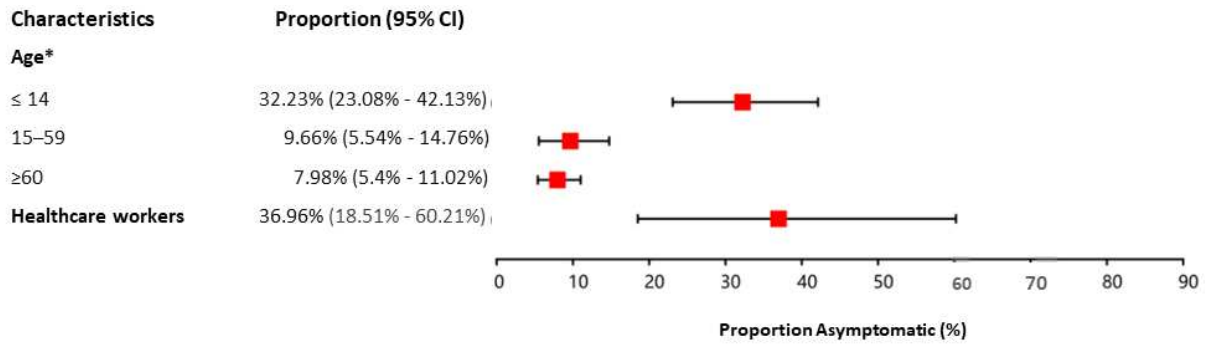
Key findings:

- 13% (95% CI 11%-16%) of all persons with COVID-19 were asymptomatic including:
  - 32% (95% CI 23%-42%) of children and 37% (95% CI 19%-60%) of healthcare workers (Figure).
- 48% (95% CI 31%-73%) of all persons with asymptomatic infection had radiographic lung abnormalities the most common being ground-glass opacities (41%, 95% CI 20%-86%), unilateral (31%, 95% CI 22%-43%), and bilateral pneumonia (27%, 95% CI 17%-43%).

Methods: A systematic literature review, of studies published between January 1 and May 13, 2020, and meta-analysis (n = 104 studies with 20,152 cases) were conducted to summarize the epidemiological and radiographical characteristics of asymptomatic SARS-CoV-2 infections. *Limitations:* Heterogeneity between studies; majority of the studies conducted in one country (China).

Implications: The findings reinforce the importance of self-isolation, mask wearing, and social distancing to prevent SARS-CoV-2 transmission, particularly among children and healthcare workers.

Figure:



Note: Adapted from Chen *et al*. Proportion of asymptomatic SARS-CoV-2 infection by characteristic. *Statistical differences between subgroups ($p < 0.05$). Licensed under CC BY-NC-ND 4.0.

Reductions in 2020 US life expectancy due to COVID-19 and the disproportionate impact on the Black and Latino populations. Andrasfay *et al*. Proceedings of the National Academy of Science of the United States of America (February 2, 2021).

Key findings:

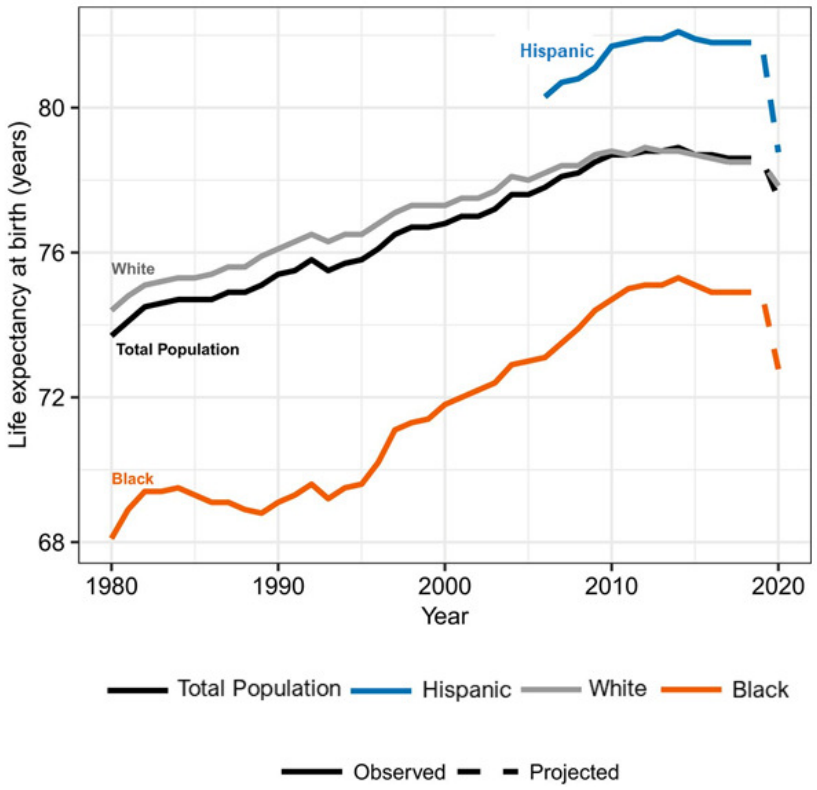
- COVID-19 is projected to reduce US life expectancy in 2020 by 1.13 years.
- Life expectancy reductions for non-Hispanic Black persons (2.10 years) and Hispanic persons (3.05 years) are projected to be 3 to 4 times higher than for non-Hispanic White persons (0.68 years) (Figure).

Methods: Life expectancy was calculated based on an Institute for Health Metrics and Evaluation (IHME) projection of 321,000 COVID-19 deaths through December 31, 2020 using 2019 population estimates. Provisional death counts due to COVID-19 by race, ethnicity, and age were obtained from the National Center for Health

Statistics through October 3, 2020. *Limitations:* Projection assumes distributions of deaths by age and race/ethnicity through October 3, 2020 will be the same through the end of the year.

Implications: The COVID-19 pandemic has reduced life expectancy and impacted progress in reducing the gap in life expectancy between Black and White persons. A rapid return to pre-pandemic life expectancy is unlikely due to the continued presence of SARS-CoV-2 and its detrimental health impacts including prolonged effects in those who recovered from the virus, deaths from other health conditions, and social and economic losses.

Figure:



Note: From Andrasfay *et al.* Trends in life expectancy at birth by race and ethnicity for **Total Population** of the US, and for **Hispanic**, **White**, and **Black** persons: 1980–2020. Note that the data for Black and White persons prior to 2006 include Hispanic persons; data for these groups from 2006 onward are for the non-Hispanic Black and non-Hispanic White persons. The projections for 2020 are based on the IHME current projection scenario (October 9, 2020 update). Copyright 2021 National Academy of Sciences.

An external exposome-wide association study of COVID-19 mortality in the United States. Hu *et al.* Science of the Total Environment (January 7, 2021).

Key findings:

- Two air toxicants, one vacant land measure, and one food environment measure were associated with COVID-19 mortality.
    - NO_2 increased mortality risk (adjusted mortality rate ratios [aMRR] 1.19, 95% CI 1.13–1.26) and benzidine decreased mortality risk (aMRR 0.92, 95% CI 0.88–0.95).
    - Greater occupancy (aMRR 0.89, 95% CI: 0.85–0.92) and greater eligibility for reduced-price student lunches (aMRR 0.90, 95% CI: 0.87–0.93) reduced mortality risk.

Methods: Adjusted associations of 337 long-term environmental exposures with COVID-19 mortality at the county-level across the US were assessed through an exposome-wide association study. The external exposome can be defined as the totality of the external environment to which an individual is exposed across the lifespan. Natural, built, and social environment data were collected before 2020 and included air quality, walkability, food, building vacancies, crime, and industry. *Limitations*: Potential ecological bias, associations don't prove causation; assumes pre-pandemic characteristics were stable during pandemic.

Implications: Environmental factors are associated with COVID-19 mortality and warrant further investigation.

Transmission

PEER-REVIEWED

Household transmission of SARS-CoV-2 and risk factors for susceptibility and infectivity in Wuhan: A retrospective observational study. Fang *et al.* Lancet Infectious Diseases (January 18, 2021).

Key findings:

- The estimated secondary attack rate for household transmission was 15.6% (95% CI 15.2-16.0).
    - Compared with adults ≥60 years old, individuals <20 years old were 66-84% less susceptible to infection and 60% more likely to infect others.
- Asymptomatic individuals were less infectious than symptomatic individuals (OR 0.21, 95% CI 0.14-0.31), and symptomatic individuals were more likely to infect others before symptom onset than after (OR 1.42, 95% CI 1.30-1.55).
- After the implementation of control measures (e.g., case isolation and quarantine of contacts) household reproductive numbers declined by 52% among primary cases and by 63% among secondary cases.

Methods: Retrospective cohort including 27,101 households of laboratory- or clinically-confirmed COVID-19 cases and laboratory-confirmed asymptomatic SARS-CoV-2 infections in Wuhan, China identified between December 2, 2019, and April 18, 2020. Transmission model to estimate household secondary attack rates, assuming mean incubation and maximum infectious period of 5 and 22 days, respectively. *Limitations*: Asymptomatic infections may be underestimated; model assumed a long (up to 22 days) infectious period, some results may not be generalizable.

Implications: While children and adolescents were less susceptible to SARS-CoV-2 infection, they were more infectious than older individuals. These findings warrant consideration when planning for school re-opening and developing interventions for reducing household transmission.

Natural History of SARS-CoV-2 Infection

PEER-REVIEWED

Evolution of antibody immunity to SARS-CoV-2. Gaebler *et al*. Nature (January 18, 2021).

Key findings:

- IgM and IgG anti-SARS-CoV-2 spike protein receptor-binding domain (RBD) antibodies and plasma neutralizing activity decreased significantly between 1.3 and 6.2 months after infection.
- Clones of memory B cells exhibited turnover after 6.2 months resulting in antibodies with the ability to evolve, increased potency, and resistance to RBD mutations.

Methods: Humoral memory response was characterized in 87 COVID-19-convalescent persons approximately 1.3 and 6.2 months after SARS-CoV-2 infection. All participants tested RT-PCR negative for SARS-CoV-2 at the 6-month study visit. *Limitations*: Small sample size.

Implications: Findings suggest that persons can mount an effective immune response that continues to evolve following recovery, reducing likelihood of re-infection by even some variant strains within 6 months after initial infection.

Protection in Healthcare and Non-Healthcare Work Settings

PREPRINTS (NOT PEER-REVIEWED)

Continued need for non-pharmaceutical interventions after COVID-19 vaccination in long-term care facilities. Love *et al.* medRxiv (January 6, 2021).

Key findings:

- The modeled number of infections, severe infections, hospitalizations, and deaths were lowest in long term care facilities (LTCF) when vaccine deployment was paired with strong adherence to nonpharmaceutical interventions (NPI).
- Prevention of deaths was higher with strategies that prioritize vaccination of residents compared with strategies that prioritize vaccination of health care workers (HCW).
- Impact of HCW vaccination was dependent on NPI adherence more so than resident vaccination.

Methods: Model to simulate disease spread in LTCF based on vaccine influence on disease dynamics and accounting for combinations of vaccination routines and levels of NPI adherence. *Limitations:* Assumed theoretical vaccine efficacy.

Implications: In addition to vaccination in LTCF, continued emphasis on NPIs is essential. Given pandemic fatigue and the associated decline in NPI adherence, limiting visitors and the interactions between residents, is essential to support vaccination efforts (Kim *et al*. Looking beyond COVID-19 vaccine phase 3 trials. Nature Medicine).

mRNA vaccine-elicited antibodies to SARS-CoV-2 and circulating variants. Wang *et al.* bioRxiv (January 19, 2021).

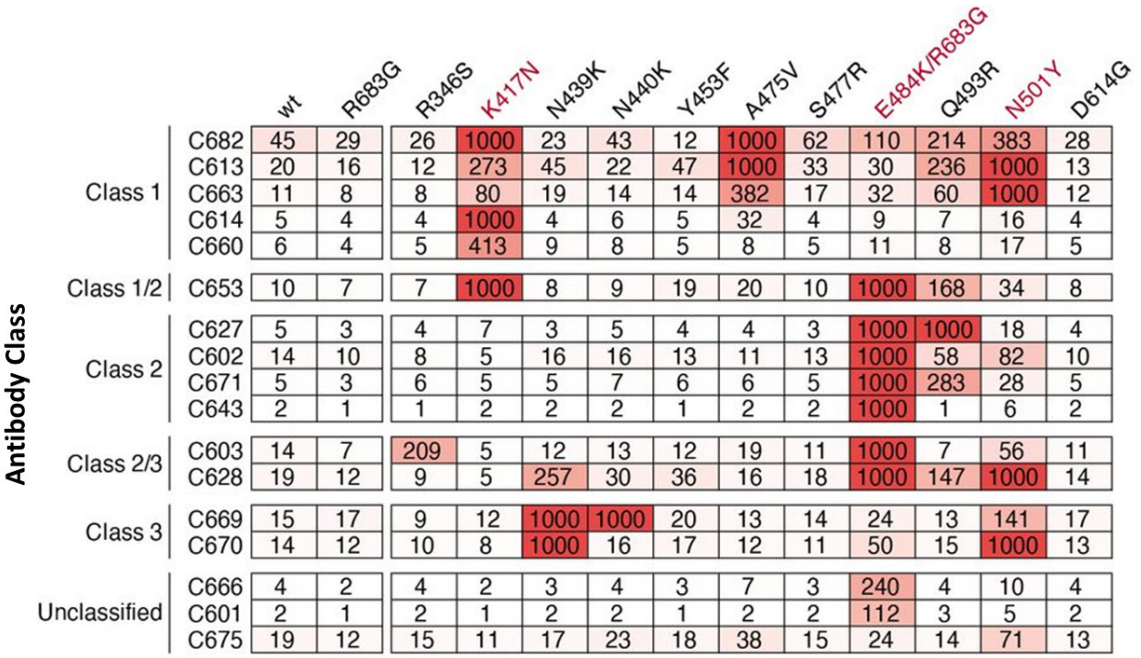
Key findings:

- While selected antibodies generated after receiving mRNA vaccines had some effect, they were overall less effective in neutralizing circulating variants with K417N, N501Y, and E484K mutations, in some cases displaying greater than ten-fold less activity (Figure).
- Presence of specific neutralizing monoclonal antibodies from vaccinated individuals selected for mutations within the receptor binding domain (RBD).

Methods: Sera and monoclonal antibodies from 20 adults without history of SARS-CoV-2 infection and who were vaccinated with either Moderna or Pfizer-BioNTech vaccines were assessed for neutralizing activity against SARS-CoV-2 spike protein and RBD mutants N501Y, K417N, E484K. *Limitations*: Small sample; not generalizable.

Implications: mRNA vaccines available in the US elicit an antibody response against SARS-CoV-2 variants but might have reduced neutralizing activity against new variants of concern with certain RBD mutations.

Figure:



Antibody Class		wt	R683G	R346S	K417N	N439K	N440K	Y453F	A475V	S477R	E484K/R683G	Q493R	N501Y	D614G
Class 1	C682	45	29	26	1000	23	43	12	1000	62	110	214	383	28
	C613	20	16	12	273	45	22	47	1000	33	30	236	1000	13
	C663	11	8	8	80	19	14	14	382	17	32	60	1000	12
	C614	5	4	4	1000	4	6	5	32	4	9	7	16	4
	C660	6	4	5	413	9	8	5	8	5	11	8	17	5
Class 1/2	C653	10	7	7	1000	8	9	19	20	10	1000	168	34	8
Class 2	C627	5	3	4	7	3	5	4	4	3	1000	1000	18	4
	C602	14	10	8	5	16	16	13	11	13	1000	58	82	10
	C671	5	3	6	5	5	7	6	6	5	1000	283	28	5
	C643	2	1	1	2	2	2	1	2	2	1000	1	6	2
Class 2/3	C603	14	7	209	5	12	13	12	19	11	1000	7	56	11
	C628	19	12	9	5	257	30	36	16	18	1000	147	1000	14
Class 3	C669	15	17	9	12	1000	1000	20	13	14	24	13	141	17
	C670	14	12	10	8	1000	16	17	12	11	50	15	1000	13
Unclassified	C666	4	2	4	2	3	4	3	7	3	240	4	10	4
	C601	2	1	2	1	2	2	1	2	2	112	3	5	2
	C675	19	12	15	11	17	23	18	38	15	24	14	71	13

Note: Adapted from Wang *et al*. Half-maximal inhibitory concentrations [IC_{50}] for selected antibodies. Columns are wild-type (wt) and variant viruses tested. Rows are the monoclonal antibodies tested. Classes 1 and 2 antibodies bind within the receptor binding domain. Class 3 antibodies bind outside the receptor binding domain but are neutralizing. Increasing redness from white indicates reduced neutralizing capacity. The **dark red** is IC_{50} 1000 ng/mL. Used by permission of authors.

In Brief

Detection, Burden, and Impact

- Casanova *et al.* **Epidemiology of coronavirus disease 2019 in US Immigration and customs enforcement detention facilities.** JAMA Network Open (January 19, 2021). Cumulative COVID-19 case rates among persons detained by Immigration and Customs Enforcement (ICE) are higher than in the general population but may be underestimated because cases are likely underreported.

- Jering *et al.* **Clinical characteristics and outcomes of hospitalized women giving birth with and without COVID-19.** JAMA Internal Medicine (January 15, 2021). In a large US cohort, pregnant women with COVID-19 had higher rates of preterm birth, preeclampsia, thrombotic events, and death than women without COVID-19.

- Anesi *et al.* **Characteristics, outcomes, and trends of patients with COVID-19–related critical illness at a learning health system in the United States**. Annals of Internal Medicine (January 19, 2021). In a study of 468 patients with COVID-19 requiring admission to the ICU between March and May 2020, 28-day all-cause mortality decreased over time from 43.5% to 19.2% despite stable patient characteristics.

- Moreno-Perez *et al.* **Post-acute COVID-19 syndrome. incidence and risk factors: A Mediterranean cohort study.** Journal of Infection (January 11, 2021). Among a prospective cohort of 277 patients who recovered

from COVID-19 between February and April 2020, 141 (50.9%; 95% CI 45.0-56.7) had post-acute COVID-19 syndrome defined as persistence of at least one clinically relevant symptom, or abnormalities in spirometry or chest radiology on an evaluation 10-14 weeks after disease onset.

Transmission of SARS-CoV-2

- Wibmer *et al.* **SARS-CoV-2 501Y.V2 escapes neutralization by South African COVID-19 donor plasma**. bioRxiv (January 19, 2021). The new lineage of SARS-CoV-2, 501Y.V2, that emerged in South Africa in December, contains nine spike mutations and is resistant to neutralizing antibodies found in convalescent serum from patients who recovered from wild-type infection, posing a significant risk of reinfection.

- Muik *et al.* **Neutralization of SARS-CoV-2 lineage B.1.1.7 pseudovirus by BNT162b2 vaccine-elicited human sera.** bioRxiv (January 19, 2021). The B.1.1.7 lineage of SARS-CoV-2 that was detected in the United Kingdom in September 2020, is unlikely to escape protection by the BioNTech-Pfizer mRNA vaccine.

Natural History of SARS-CoV-2 Infection

- Gottlieb *et al.* **Effect of bamlanivimab as monotherapy or in combination with etesevimab on viral load in patients with mild to moderate COVID-19.** JAMA (January 21, 2021). In this randomized phase 2/3 trial at 49 centers across the US, combination therapy with bamlanivimab and etesevimab, but not bamlanivimab alone, resulted in a significant reduction in SARS-CoV-2 viral load at day 11 among non-hospitalized patients with mild to moderate COVID illness.

- Weinreich *et al.* **REGN-COV2, a neutralizing antibody cocktail, in outpatients with COVID-19.** NEJM (January 21, 2021). Randomized controlled trial of REGN-COV2, a cocktail of two monoclonal antibodies, was safe and showed reduction in viral load, especially in persons who had a high viral load at baseline or who had not yet mounted an immune response (see Editorial by Cohen *et al.* **Monoclonal antibodies to disrupt progression of early COVID-19 infection**. NEJM).

- Veiga *et al.* **Effect of tocilizumab on clinical outcomes at 15 days in patients with severe or critical coronavirus disease 2019: randomised controlled trial.** BMJ (January 20, 2021). In a randomized clinical trial of 129 patients with severe COVID-19 enrolled in Brazil between May and July 2020, tocilizumab, an anti–interleukin-6 receptor monoclonal antibody, was not superior to standard care and might increase mortality; the trial was stopped early due to an increased number of deaths at 15 days in the tocilizumab group.

- Perez *et al.* **Reported adverse drug reactions associated with the use of hydroxychloroquine and chloroquine during the COVID-19 pandemic.** Annals of Internal Medicine (January 26, 2021). Using the FDA Adverse Event Reporting System database, the authors determined that adverse drug reactions (ADRs) with hydroxychloroquine and chloroquine doubled in 2020 compared with 2018 and 2019; reported ADRs seemed to coincide with positive endorsements in the media.

Prevention, Mitigation, and Intervention Strategies

- Shimabukuro *et al.* **Allergic reactions including anaphylaxis after receipt of the first dose of Pfizer-BioNTech COVID-19 vaccine**. JAMA (January 21, 2021). Based on case reports submitted to the Vaccine Adverse Event Reporting System during December 14-23, 2020, anaphylaxis after the first dose of the Pfizer-BioNTech COVID-19 vaccine occurred at an estimated rate of 11.1 cases per million doses administered. The reports of anaphylaxis may lead to vaccine hesitancy but it is important to note that a history of severe allergies is not a contraindication to vaccination unless the allergy is to the vaccine or one of its components (Glover *et al.* **Vaccinating against COVID-19 in people who report allergies.** BMJ).

Protection in Healthcare and Non-Healthcare Work Settings

- Quilty *et al.* **Quarantine and testing strategies in contact tracing for SARS-CoV-2: A modelling study.** The Lancet Public Health (January 20, 2021). Modelling showed that testing can allow for reduced quarantine duration without substantial increases in transmission risk. Results support current CDC guidance.

Disclaimer: The purpose of the CDC COVID-19 Science Update is to share public health articles with public health agencies and departments for informational and educational purposes. Materials listed in this Science Update are selected to provide awareness of relevant public health literature. A material's inclusion and the material itself provided here in full or in part, does not necessarily represent the views of the U.S. Department of Health and Human Services or the CDC, nor does it necessarily imply endorsement of methods or findings. While much of the COVID-19 literature is open access or otherwise freely available, it is the responsibility of the third-party user to determine whether any intellectual property rights govern the use of materials in this Science Update prior to use or distribution. Findings are based on research available at the time of this publication and may be subject to change.

TOPLINE MESSAGES FOR THE WEEK (January 25)

- The current COVID-19 vaccines are safe and effective.
  - Many people don't have any side effects after COVID-19 vaccines, but some people will have pain or swelling at the injection site or fever, chills, or a headache.
  - These typically don't last long and are signs that your body is building protection.
  - As of Tuesday, January 19, there have been 15 confirmed cases of anaphylaxis after receipt of Moderna COVID-19 vaccine and 45 confirmed cases of anaphylaxis after receipt of Pfizer-BioNTech COVID-19 vaccine. Per 1 million doses administered, that's a rate of 2.1 cases for Moderna and 6.2 cases for Pfizer.
  - The observed rates of anaphylaxis are comparable to other vaccines.
  - These estimated rates may change as additional doses of COVID-19 vaccine are administered and CDC continues to collect more information.
- We know that there will be bumps in the road as the COVID-19 vaccination program is rolled out – that is to be expected. However, public health experts have extensive experience with vaccine distribution and administration and will work to quickly overcome obstacles.
- While ACIP and CDC make national recommendations, we understand that there will be a level of local adaptation.
  - The phased vaccine recommendations are meant to be fluid and not restrictive for jurisdictions.
  - It is not necessary to vaccinate all individuals in one phase before initiating the next phase; phases may overlap.
- Vaccination is a critical tool in bringing this unprecedented pandemic to an end. But until every person in the U.S. is able to get a COVID-19 vaccine, we continue to ask Americans to embrace proven public health strategies including social distancing, good hand hygiene, and wearing a mask in public to reduce the risk of transmission and protect our communities.

CDC COVID-19 VACCINE MESSAGES

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UPDATEDS (IN BLUE BELOW IN THE SECTIONS)

mRNA clinical considerations guidance

- CDC still recommends that people get their 2nd dose of COVID-19 vaccine as close to the recommended interval as possible (3 weeks for Pfizer-BioNTech, one month for Moderna).
- After posting initial guidance, we received feedback that some flexibility in our language might be helpful to reduce barriers to vaccination, especially if there are challenges around returning on a specific date or if someone's circumstances had changed (like being discharged or entering a long-term care facility).
- As always, CDC encourages people to follow our guidance around intervals and interchangeability, but we also don't want our guidance to be so rigid that it creates unintended barriers.
- CDC's updated guidance says that if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose.
    - The Pfizer efficacy analyses included people who received the 2nd dose up to 42 days after the first, and the majority of Moderna trial participants received their 2nd dose within this time frame as well.
    - This is also in line with the time frame endorsed by WHO as well as a few other countries, but in contrast we are not recommending this as a strategy to allow more people to get 1st doses, but rather to address feasibility issues.
- Additionally, we note that "in exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series."
- This guidance is intended for situations where someone received the 1st dose but does not know what product, and despite efforts, including using resources outlined in the guidance (e.g. vaccination cards, Immunization Information Systems), it still cannot be determined what product they used, we are saying that they can get the 2nd dose with either product.
    - Another example we have been hearing about is someone who got vaccinated in a LTCF and then was discharged to the community, or vice versa, and the same vaccine product not being available and there would be significant barriers to getting the right vaccine product resulting in the person only getting one dose.

IMPLEMENTATION – JURISDICTIONS

- CDC is working through existing U.S. jurisdiction programs to coordinate the distribution and administration of COVID-19 vaccines.
- After that initial distribution of vaccine, jurisdictions will order from their weekly allocations:
    - A second dose will automatically be set aside for each first dose a jurisdiction orders.
    - Jurisdictions will be prompted to order the second dose through VTrckS.
    - New allocation numbers will be posted each Tuesday in Tiberius and will be updated in VTrckS every Thursday.
    - Under the regular ordering and delivery cadence, deliveries of vaccine doses will be made Monday through Friday for all COVID-19 vaccine products.
- Jurisdictions and commercial or federal partners will place orders on behalf of providers.
- Jurisdictions must ensure that providers report vaccine administration data so that the jurisdiction can then send data to the CDC's IZ Gateway.

Background

- On September 16, CDC released the first iteration of the *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* that provides general interim guidance on how to plan and operationalize a vaccination response to COVID-19 within jurisdictions.
    - This playbook was updated on October 29.
    - Executive summaries of each plan may be found on the CDC website.

IMPLEMENTATION – FEDERAL ENTITY PLANNING

General

- Five federal entities receive direct allocation of COVID-19 vaccines:
  - Federal Bureau of Prisons
  - Department of Defense
  - Department of State
  - Department of Veterans Affairs
  - Indian Health Service
- Federal agencies are encouraged to implement ACIP and CDC recommendations when vaccinating staff and populations they serve.
- Federal agencies involved in the COVID-19 response but not one of the five agencies receiving direct allocations should work with immunization programs in their jurisdictions to ensure their staff is included in vaccination plans.
- Federal entities will be allocated vaccine doses on a pro rata basis according to the adult population they serve and their number of employees.
  - The allocations for federal entities are separate from the state/jurisdictional allocation and federal entities are treated as a separate jurisdiction.
  - Federal entity populations are not deducted from the state population.
  - Federal entity populations are added to the total U.S. adult population, which is used as the denominator for determining allocations, and pro-rata distribution is then determined for each jurisdiction.

Tribes

- To ensure equitable access to COVID-19 vaccines, Tribal Nations have decided on their allocation preferences—whether to receive vaccine through their jurisdiction or through the Indian Health Service (IHS).
- Tribal Health Programs and Urban Indian Health Organizations that selected to receive vaccine through the state/jurisdiction should already be included in state/jurisdiction vaccine distribution plans and will receive vaccine based on those plans.
  - The supplement is not intended to disrupt or replace existing plans, but to support vaccine distribution across the jurisdiction, including to Tribal Health Programs and Urban Indian Health Organizations.
  - Not all states/jurisdictions will receive a supplemental allocation each week because of vaccine availability.
  - However, all states/jurisdictions should continue to provide COVID-19 vaccine to Tribal Health Programs and Urban Indian Health Organizations in keeping with existing vaccine distribution plans, even in the absence of a specific supplemental allocation.

VACCINE DISTRIBUTION

- COVID-19 vaccines are being allocated pro rata by population to ensure fair and equitable distribution across the U.S.
- The latest data on vaccine distribution and administration is posted on CDC's COVID Data Tracker Monday through Friday. This includes jurisdictional data as well as data on the Federal Pharmacy Partnership for Long-Term Care Program.

Background

- In August, CDC exercised a contract option with McKesson Corporation, which will serve as the central distributor for COVID-19 vaccines and ancillary kits.
  - Pfizer vaccine is being shipped directly from the manufacture.

- Initially, jurisdictions should anticipate that allocations will be less than demand until supply can catch up. Over time, distribution strategies will change as more vaccine becomes available and more people are recommended for vaccination.
- CDC's Vaccine Tracking System (VTrckS) will be used for vaccine ordering.
    - VTrckS is a secure, web-based IT system that integrates the entire publicly funded vaccine supply chain from purchasing and ordering through distribution to participating state, local, and territorial health departments and healthcare providers.
- Pfizer vaccine doses are distributed as part of 975-dose trays. Pfizer does not recommend partial tray redistribution.
- Moderna vaccine doses are distributed as part of 100-dose trays.

PHARMACY – LONG-TERM CARE FACILITIES

- The U.S. Department of Health and Human Services has partnered with CVS, Walgreens, and Managed Health Care Associates, Inc. to offer on-site COVID-19 vaccination services for nursing homes and assisted living facilities residents.
- Long-term care settings, in particular, are high-risk locations for COVID-19 exposure and spread of the virus.
- The Pharmacy Partnership for Long-term Care (LTC) Program provides end-to-end management of the COVID-19 vaccination process, including cold-chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments.
- This program is available for residents in all LTCF settings, including skilled nursing facilities, nursing homes, assisted living facilities, residential care homes, and adult family homes.

Background

- The allocation of vaccine for Long-Term Care Facilities as part of the Pharmacy Partnership for Long-Term Care Program is included in the pro rata population-based allocation for each jurisdiction. This is not an additional number of doses that will be allocated.
- Jurisdictions have control over when the LTC program will launch within their jurisdictions.
- This program is free of charge to LTCFs. This service will also be available in rural areas that may not have an easily accessible pharmacy.
- LTCF staff members who have not been previously vaccinated for COVID-19 will also be eligible for these services.
- CDC expects the program services to continue on-site at participating LTCFs for approximately two months. After the initial phase of vaccinations, the facility can choose to continue working with the CVS, Walgreens, or MHA partner that provided its initial on-site clinics or can choose to work with a pharmacy provider of its choice.
- Jurisdictions need to provide at least a two-week notice to begin the LTCF program.
    - This period allows federal pharmacy partners to prepare for vaccine administration and coordinate with LTCF facilities.
    - To begin the program, a jurisdiction must have an allocation of at least 50% of the required doses to cover the program within one week of providing notice.
- Jurisdictions need to select which authorized vaccine will be used to support the program in their jurisdiction. Once activated, vaccine to support the program will come from jurisdictional allocations.
- The LTCF program is split into two components:
    - In Part A, the program will perform vaccinations at skilled nursing facilities.
    - In Part B, the program will provide vaccinations at other facilities enrolled in the program such as assisted living facilities, continuing care residential facilities, etc.
- Jurisdictions can choose to start with Part A alone when activating the program or can opt to activate both Parts A and B simultaneously.

- CDC provided jurisdictions with an estimated number of doses needed to cover Part A and Part B. Allocations that are not used as part of the program will be returned to the rest of the jurisdiction's allocation.
- The official launch date of the Federal Pharmacy Partnership for Long-term Care (LTC) Program was December 21, 2020, for jurisdictions that opted to use Pfizer vaccine for the program and December 28, 2020, for jurisdictions that chose to use Moderna vaccine.
    - These launch dates were chosen to account for the time needed to ensure adequate vaccine supply is available and the time pharmacy partners will need to schedule and coordinate clinics at each facility.
    - The timing allowed pharmacies and facilities to work with residents and their families to understand the vaccines and agree to participate before the clinics begin.
- Pharmacy partners who are administering COVID-19 vaccine at long-term care facilities may require written consent from recipients before vaccination.
    - This is at the discretion of the pharmacy; written consent is not required by federal law for COVID-19 vaccination in the United States.
    - Long-term care facility administrators can request pharmacy partners email consent forms to residents' families in advance when they are serving as medical proxies. Individual providers should consult with their own legal counsel for state requirements regarding consent.

PHARMACY – RETAIL AND COMMUNITY

- The Federal Retail Pharmacy Program for COVID-19 Vaccination is a public-private partnership that involves 21 national pharmacy partners and networks of independent pharmacies representing over 40,000 retail and long-term care pharmacy locations nationwide.
- Coordination for the program is at the federal level, with the goal of increasing access to vaccine, improving vaccine uptake, and decreasing the logistical and operational burden on public health.
- Through the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination, select pharmacy partners will receive a direct allocation of COVID-19 vaccine.
- Almost 90% of people live within five miles of a community pharmacy, pharmacies have unique reach and ability to provide access to COVID-19 vaccine and support broad vaccination efforts.
    - This program will provide critical vaccination services for the U.S. population, with vaccine administered at retail locations at no cost to recipients.
- The federal allocation to pharmacies will not cover every pharmacy in the United States.
- Based on their (1) size and reach, (2) capability to store vaccines and ensure cold chain management, (3) ability to meet data reporting requirements to jurisdictions and CDC, and (4) estimated daily number of doses each facility is able to administer, these partners stand ready to assist jurisdictions in COVID-19 vaccination efforts.
- Program Benefits:
    - Once we have an adequate supply of COVID-19 vaccine to support broader vaccination efforts, it will be important to swiftly increase access to COVID-19 vaccine for the general population.
    - Partnerships with retail chain pharmacies and networks of community pharmacists in the United States will increase the general population's access to COVID-19 vaccine.
    - Pharmacists can be crucial public health partners to increase access and convenience of COVID-19 vaccines.
    - Pharmacists are trained to provide vaccinations and are important immunizers in their communities.
    - Pharmacists are a trusted health resource in their communities and play a vital role in the public health response to COVID-19 by counseling patients and administering tests.
    - Pharmacies have the capability to quickly surge and meet demand nationwide because of existing infrastructure and the large number of pharmacists who can administer vaccines.

- CDC has worked extensively with pharmacy chains to improve pandemic preparedness, conduct vaccine throughput exercises, and assess store and organizational response capabilities.

VACCINE SAFETY

Vaccine Safety Monitoring

- For COVID-19 vaccines, CDC and federal partners will use a toolbox of existing and new monitoring systems for COVID-19 vaccine safety.
  - CDC will rely on existing systems that monitor the safety of vaccines every day, the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), and the Clinical Immunization Safety Assessment (CISA) Project.
  - CDC has also developed a new, voluntary smartphone-based tool, v-safe, that uses text messaging and web surveys to provide personalized health check-ins after patients receive a COVID-19 vaccination.
  - CDC has also expanded its collaboration with the Advisory Committee on Immunization Practices (ACIP) to include a special ACIP COVID-19 Vaccine Safety Technical Sub-Group to review available vaccine safety data.
- If potential safety issues with any COVID-19 vaccine are discovered, CDC will take the following steps:
  - Work with the Food and Drug Administration (FDA) and other vaccine safety partners to rapidly assess the potential safety issue.
  - Provide up-to-date vaccine safety information to ACIP. CDC routinely shares this kind of information for all vaccines. ACIP may recommend additional assessment and analysis, advise CDC on the balance between the benefit of COVID-19 vaccination and the risk of adverse events, or make changes to its recommendations.
  - Communicate vaccine safety information to the public in a timely and transparent manner.

Anaphylaxis

- Early monitoring of both the Moderna and the Pfizer-BioNTech COVID-19 vaccines indicate that anaphylaxis following vaccination is a rare event, and though anaphylaxis is serious, it occurs shortly after vaccination (usually within minutes), is readily diagnosed, and effective treatments are available.
  - Patients experiencing anaphylaxis after vaccination do well and recover.
- Many people don't have any side effects after COVID-19 vaccines, but some people will have pain or swelling at the injection site or fever, chills, or a headache. These typically don't last long and are signs that your body is building protection.
- As of Tuesday, January 19, there have been 15 confirmed cases of anaphylaxis after receipt of Moderna COVID-19 vaccine and 45 confirmed cases of anaphylaxis after receipt of Pfizer-BioNTech COVID-19 vaccine.
  - Per 1 million doses administered, that's a rate of 2.1 cases for Moderna and 6.2 cases for Pfizer.
  - The observed rates of anaphylaxis are comparable to other vaccines.
  - These estimated rates may change as additional doses of COVID-19 vaccine are administered and CDC continues to collect more information.
- Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 vaccine.
- CDC considers a history of severe allergic reaction to another vaccine (any other vaccine besides the Pfizer-BioNTech COVID-19 vaccine) or to any injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution, but not a reason to forgo, receiving the vaccine.
- CDC currently recommends that persons who receive Pfizer-BioNTech COVID-19 vaccine be observed following vaccination:
  - Persons with a history of anaphylaxis (due to any cause): 30 minutes
  - All other persons: 15 minutes

Vaccine safety response to significant reports of adverse events or clusters of adverse events
As COVID-19 vaccine is administered in the U.S., there may be significant adverse events or clusters of adverse events reported. We anticipate that these clusters could fall in one of the following categories:

- Adverse events of special interest that CDC vaccine safety monitoring systems are following,
- Adverse events that are unexpected and for which background rates are not available,
- Adverse events that are hard to define and for which background rates are not available, or
- Adverse events which may be similar to symptoms or outcomes from COVID-19 disease.

In the event that significant adverse events or clusters of adverse events following COVID-19 vaccination are identified, CDC will do the following:

1. Review the VAERS database for any similar reports following COVID-19 vaccines or other vaccines to determine counts, reporting rates, and demographics.
2. Engage the Vaccine Safety Datalink (VSD) to determine if these adverse events are occurring in VSD following COVID-19 vaccines or any other vaccine, and to quickly determine the background rates and conduct chart review, if needed.
3. Conduct CISA consults/evaluations which would include medical experts and medical record review, if needed.
4. Work with our federal partners to determine if their surveillance systems are observing adverse events following COVID-19 vaccination.
5. Initiate any investigations needed to further evaluate this adverse event or cluster of adverse events following COVID-19 vaccination.

VACCINE EFFECTIVENESS

- Two COVID-19 vaccines are currently authorized by the FDA for emergency use. CDC is studying how well the vaccines protect people against COVID-19 in real-world conditions. This is called “vaccine effectiveness.”
- Vaccine effectiveness data are important to understand the real-world impact of vaccination and is used to help inform policy decisions by public health officials
- Vaccine effectiveness differs from vaccine efficacy. Vaccine efficacy refers to vaccine protection measured in randomized control trials, usually under optimal conditions where vaccine storage and delivery are monitored. Vaccine effectiveness refers to vaccine protection measured in observational studies that include people who have been administered vaccines by different healthcare providers under real-world conditions.
- CDC has launched several vaccine effectiveness studies that will evaluate how well COVID-19 vaccines are working. Additional studies will begin as vaccines are administered across the United States among different groups.
    - These studies will use different study designs and measure protection against different outcomes. For example, some studies will examine how much vaccination reduces the risk of infection (including infection without symptoms) or of milder COVID-19 illness.
    - Others will evaluate how much vaccination protects against more serious outcomes, like how much vaccination reduces the risk of being hospitalized for COVID-19
- These real-world vaccine effectiveness studies will include a diverse set of people, like health care and other essential workers, older adults, and people living in nursing homes, as well as people with certain underlying medical conditions and people in disproportionately affected racial and ethnic minority groups.
- These studies will use both CDC systems that were already in place to study how well vaccines work and new systems developed specifically for COVID-19.
- CDC will also study the impact vaccination has on spread. For example, whether people who have been vaccinated can still spread COVID-19 to others.

- Since vaccination of priority groups with COVID-19 vaccines has only recently begun, data to determine vaccine effectiveness are being collected but are not yet available. As data on vaccine effectiveness become available, CDC will provide regular updates with that information.
- CDC will continue to conduct vaccine effectiveness studies until we have a good understanding of how vaccines are working across different populations and different outcomes.

ACIP

- While ACIP and CDC make national recommendations, we understand that there will be a level of local adaptation.
    - The phased vaccine recommendations are meant to be fluid and not restrictive for jurisdictions.
    - It is not necessary to vaccinate all individuals in one phase before initiating the next phase; phases may overlap.
- Decisions regarding transition from one phase to the next should be made at the local, state, or territorial level, and may be based on factors such as demographic and workforce characteristics, COVID-19 epidemiology within the jurisdiction, and vaccine supply and demand within the jurisdiction.
- Decisions about transitioning to subsequent phases should also depend on supply, demand, equitable vaccine distribution, and local, state, or territorial context.

Background

- The Advisory Committee on Immunization Practices (ACIP) is an independent federal advisory committee of medical and public health experts that provides advice and guidance to the CDC director on the most effective means to prevent vaccine-preventable diseases in the United States.
- ACIP develops written recommendations—subject to the CDC director's approval—for the routine administration of vaccines to both pediatric and adult populations.
- ACIP and CDC's recommendations include:
    - On December 1, ACIP voted to recommend that vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) health care personnel (HCP) and 2) residents of long-term care facilities (LTCF).
        - It is estimated there are 21 million people working in the healthcare industry and approximately 3 million people living in long-term care facilities.
        - To date, more than 378,000 healthcare workers have contracted COVID-19 and more than 1,200 have died.
        - According to estimates, deaths in long-term care facilities account for 40% of all COVID-19 deaths nationwide.
        - These factors contributed to the committee's recommendation to prevent spread by protecting those on the front lines, healthcare workers treating COVID-19 patients, and protect the most vulnerable, those elderly persons living in long-term care facilities.
    - On December 12, ACIP voted to recommend Pfizer's COVID-19 vaccine for people 16 and older for the prevention of COVID-19.
    - On December 19, ACIP voted to recommend Moderna's COVID-19 vaccine for individuals 18 years of age and older.
    - On December 20, ACIP voted to recommend prioritizing individuals 75 and older and frontline essential workers for Phase 1b. Phase 1b includes approximately 49 million individuals who were not included in Phase 1a.
        - There are approximately 21 million people in the U.S. who are 75 and older. Approximately 2 million of these individuals were recommended for vaccination in Phase 1a (e.g. residents of long-term care facilities).
        - There are approximately 30 million frontline essential workers in the U.S. A frontline essential worker is someone in a sector essential to the functioning of society who is at substantially higher risk of exposure to SARS-CoV-2. This includes first responders, teachers,

grocery store workers, USPS employees, corrections workers, public transit employees, manufacturing workers, and employees in food and agriculture industries.
    - For Phase 1c, the committee voted to prioritize people aged 65-74 years, people aged 16-64 years with high-risk medical conditions, and other essential workers. Phase 1c adds 129 million new individuals to the groups recommended in Phases 1a and 1b.
    - About 32 million people in the U.S. are in the 65-74-year age bracket, 28 million of whom are not part of Phases 1a or 1b.
    - More than 110 million people are between the ages of 16-64 and have high-risk medical conditions, including 81 million people who are not part of the Phase 1a or 1b recommendations. There are fewer than 86 million individuals in this age group without such conditions.
    - There are approximately 57 million other essential workers, including individuals who work in transportation and logistics, food service, construction, water, and other sectors. 20 million of these essential workers were not accounted for in the Phase 1a and 1b recommendations.

Sub-Prioritization of Phase 1A Priority Groups

- Considerations for sub-prioritization of HCPs, of equal importance, include:
    - HCP with direct patient contact and thus who are unable to telework, including those who work in inpatient, outpatient, or community settings, who provide services to patients or patients' family members, or who handle infectious materials.
    - HCP working in residential care or long-term care facilities.
    - HCP with documented acute SARS-CoV-2 infection in the preceding 90 days may choose to delay vaccination until near the end of the 90 day period in order to facilitate vaccination of those HCP who remain susceptible to infection, as current evidence suggests reinfection is uncommon during this period after initial infection. Of note, previous SARS-CoV-2 infection, whether symptomatic or asymptomatic, is not considered a contraindication to vaccination and serologic testing for SARS-CoV-2 antibodies is not recommended prior to vaccination.
- Considerations for sub-prioritization among LTCF residents include:
    - Skilled nursing facilities should be prioritized among LTCFs as they provide care to the most medically vulnerable residents.
    - After skilled nursing facilities, consider broadening to LTCFs.

Post-vaccination symptoms in HCP

- Based on available data, COVID-19 vaccination is expected to elicit systemic post-vaccination symptoms, such as fever, headache, and myalgias.
- While the incidence and timing of post-vaccination symptoms will be further informed by phase III clinical trial data, strategies are needed to mitigate possible HCP absenteeism and resulting personnel shortages due to the occurrence of these symptoms. Considerations might include:
    - Staggering delivery of vaccine to HCP in the facility so that personnel from a single department or unit are not all vaccinated at the same time. Based on greater reactogenicity observed following the second vaccine dose in phase I/II clinical trials, staggering considerations may be more important following the second dose.
    - Planning for personnel to have time away from work if they develop systemic symptoms following COVID-19 vaccination.

Sub-Prioritization of Phase 1b Priority Groups

- Sub-prioritization considerations for frontline essential workers include:
    - Workers in locations where high rates of transmission and/or outbreaks have occurred
    - Workers who are at increased risk for severe illness based on age or underlying medical conditions
    - Workers who do not have a history of documented acute SARS-CoV-2 infection in the prior 90 days

ADMINISTRATION, STORAGE, AND HANDLING

- Proper COVID-19 vaccine administration is critical to ensure that vaccination is safe and effective.
    - COVID-19 vaccine specific education and training materials to facilitate storage and handling of ultra-cold vaccine based on guidance from the vaccine's manufacturer is available from the manufacture.
    - Additionally, CDC has added a COVID-19 Addendum to the *Vaccine Storage and Handling Toolkit*.
- A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures.
    - It begins with vaccine manufacturing and ends with vaccine administration.
    - Vaccines must be stored properly from the time they are manufactured until they are administered.
    - Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.
- Any temperature reading outside the range recommended by the manufacturer is considered a temperature excursion and requires immediate action.
    - To determine whether a vaccine is likely to still be viable, COVID-19 vaccine manufacturers will analyze information about the magnitude of the temperature excursion, including the total amount of time that temperatures were out of range.
- Expired vaccines and diluents should be removed immediately from storage units to avoid inadvertently administering them. Manufacturers may have specific guidance on how to handle expired or compromised vaccines.
- Medical waste disposal requirements are set by state environmental agencies and may vary from state to state.
- As part of the COVID-19 Vaccination Program, a minimum order size of COVID-19 vaccine, diluent, and ancillary supplies will be shipped directly to enrolled COVID-19 vaccination providers.
    - In most instances, vaccine will be delivered directly to the facility where it will be administered to maintain the vaccine cold chain.

mRNA clinical considerations guidance

- CDC still recommends that people get their 2nd dose of COVID-19 vaccine as close to the recommended interval as possible (3 weeks for Pfizer-BioNTech, one month for Moderna).
- After posting initial guidance, we received feedback that some flexibility in our language might be helpful to reduce barriers to vaccination, especially if there are challenges around returning on a specific date or if someone's circumstances had changed (like being discharged or entering a long-term care facility).
- As always, CDC encourages people to follow our guidance around intervals and interchangeability, but we also don't want our guidance to be so rigid that it creates unintended barriers.
- CDC's updated guidance says that if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose.
    - The Pfizer efficacy analyses included people who received the 2nd dose up to 42 days after the first, and the majority of Moderna trial participants received their 2nd dose within this time frame as well.
    - This is also in line with the time frame endorsed by WHO as well as a few other countries, but in contrast we are not recommending this as a strategy to allow more people to get 1st doses, but rather to address feasibility issues.

- Additionally, we note that "in exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series."
- This guidance is intended for situations where someone received the 1st dose but does not know what product, and despite efforts, including using resources outlined in the guidance (e.g. vaccination cards, Immunization Information Systems), it still cannot be determined what product they used, we are saying that they can get the 2nd dose with either product.
    - Another example we have been hearing about is someone who got vaccinated in a LTCF and then was discharged to the community, or vice versa, and the same vaccine product not being available and there would be significant barriers to getting the right vaccine product resulting in the person only getting one dose.

DATA AND MONITORING

- Integrated IT systems —both public and private, as well as new and existing—are needed to ensure successful vaccine allocation, distribution, administration, monitoring, and reporting.
- HHS and CDC have agreed to maintain the confidentiality of data received from state immunization information systems (IISs) to the fullest extent required by federal law.
- Jurisdictions who may have legal or regulatory restrictions around submitting identifiable data to CDC may submit redacted data sets and implement Privacy Preserving Record Linkage (PPRL) technology as indicated by their Data Use Agreements.

Vaccine Logistics and Administration

- Three systems support vaccine logistics and administration: the Vaccine Tracking System, Immunization Information Systems, and VaccineFinder.
- (1) The Vaccine Tracking System (VTrckS) is CDC's vaccine order management system, which supports routine vaccination with almost 80 million doses of vaccine annually.
    - CDC will use VTrckS as its platform for ordering all COVID-19 vaccines.
    - VTrckS users—the 64 state, local, and territorial public health jurisdictions and enrolled national provider organizations will use VTrckS to:
        - View vaccine allocations for each program
        - Place and manage vaccine orders for their providers
        - Generate reports throughout the vaccine distribution process, from vaccine order placement through distribution
        - Track vaccine shipments
- (2) IISs, formerly known as "immunization registries," vary by jurisdiction in their capacity to automate processes, handle large volumes of data, and capture high-quality data.
    - Vaccine recipients and enrolled providers use IISs to access people's vaccination records.
    - In addition, IISs collect data from public and private healthcare provider organizations (e.g., electronic health records), health information systems (e.g., vital statistics, state Medicaid agencies), and pharmacies. IISs share these data with the IZ Gateway, CDC, and other jurisdictions if an agreement is in place. IISs also share vaccination records with healthcare providers and individuals.
    - As part of the overall IT infrastructure to support COVID-19 vaccination IISs connect with VTrckS, VAMS (see below for details), and federal data and reporting systems.
- (3) The VaccineFinder website helps people find providers who offer select vaccines. VaccineFinder also allows healthcare providers to list their vaccination locations in a centralized, searchable database and to track vaccine supply. VaccineFinder will serve two roles in the COVID-19 vaccination program:
    - Inventory reporting (required for all COVID-19 vaccine providers): Providers will report on-hand COVID-19 vaccine inventory each day through VaccineFinder.

- Increase access to COVID-19 vaccines (optional for COVID-19 vaccine providers): Once there is enough supply, COVID-19 vaccination providers may choose to make their location visible on VaccineFinder, making it easier for the public to find provider locations that have doses available. CDC will direct the public to use VaccineFinder to find locations offering COVID-19 vaccine.
- As part of the overall IT infrastructure to support COVID-19 vaccination, VaccineFinder sends data to and receives data from the IZ Data Lake.

Vaccine Data Collection and Reporting

- The IZ Gateway is a cloud-based message routing service intended to enable data exchange between IISs, other provider systems, and the IZ Data Lake. The IZ Gateway allows:
  - IISs to report data to the CDC Data Clearinghouse
  - Cross-jurisdictional queries and data exchange
  - Multijurisdictional providers to share data with multiple IISs via a central connection
  - VAMS data to be routed to the IIS where applicable

New Systems to Support COVID-19 Vaccination Clinics and Vaccine Administration

- Vaccine Administration Management System (VAMS) is an optional web-based application that supports planning and execution for temporary, mobile, or satellite COVID-19 vaccination clinics. VAMS has modules to support four specific user groups: public health jurisdictions, healthcare providers, employers/organizations, and vaccine recipients.
- VAMS connects with IISs via federal and data reporting systems and sends data to IISs through the IZ Gateway or IZ Data Clearinghouse.

New Systems Developed for COVID-19 Vaccination Data Collection and Reporting

- (1) The IZ Data Clearinghouse is a cloud-hosted data repository that receives, deduplicates, and deidentifies COVID-19 vaccination data that are then used to populate the IZ Data Lake with deidentified data for analytics. It allows healthcare providers to search for a patient, see what brand of COVID-19 vaccine they received, and see when they received their first dose of COVID-19 vaccine to ensure dose matching and appropriate vaccination intervals to complete the vaccine series.
- (2) The IZ Data Lake is a cloud-hosted data repository to receive, store, manage, and analyze deidentified COVID-19 vaccination data. CDC, jurisdictions, federal agencies, and pharmacy partners will use the IZ Data Lake to store and process administration, coverage, logistics, inventory, ordering, distribution, and provider data. VAMS, IISs, pharmacies, VTrckS, and VaccineFinder will provide data for the IZ Data Lake.

National Healthcare Safety Network COVID-19 Vaccination Modules for Healthcare Facilities

- The National Healthcare Safety Network (NHSN) is a web-based system for monitoring healthcare-associated adverse events, healthcare worker vaccinations, and other prevention practices. It has been in operation since 2005.
- NHSN captures data from 37,000 participating facilities in all 50 states. Data that are entered into the system are available in real time. Data are used for facility-level clinical performance measurement, state- and national-level health surveillance and prevention, and public reporting of facility-specific data and Medicare reimbursement.
- NHSN's COVID-19 Vaccination Modules will allow healthcare facilities to report weekly facility-level vaccination coverage among initial priority groups.
- NHSN COVID-19 modules are optional for healthcare facilities. Reporting via these modules does not replace CDC's IIS reporting requirements.
- These modules provide the only data source for monitoring facility-level vaccination of initial priority groups. Data will not be reported at the individual level. Facilities will report cumulative vaccination numbers and can calculate coverage rates.
- NHSN can also capture data on adverse events and provide a link to VAERS.

COVID-19 VACCINE STATUS

Currently authorized vaccines

- On December 11, FDA issued an EUA for Pfizer's mRNA vaccine candidate, BNT162b2.
    - Earlier Pfizer and its partner BioNTech announced that its first interim efficacy analysis has found its vaccine candidate is more than 90% effective. The study enrolled over 43,000 participants and has not uncovered any serious safety concerns.
- On December 18, FDA issued an EUA for Moderna's mRNA vaccine candidate.
    - Per a statement from Moderna, "Out of an abundance of caution and leveraging the flexibility of our mRNA platform, we are advancing an emerging variant booster candidate against the variant first identified in the Republic of South Africa into the clinic to determine if it will be more effective to boost titers against this and potentially future variants."
    - On December 2, Moderna announced that it would soon begin testing its coronavirus vaccine in children ages 12 through 17. In a post on clinicaltrials.gov, the study plans to include 3,000 children, with half receiving two shots of vaccine four weeks apart, and half getting placebo shots of salt water.
    - Moderna announced that its first interim efficacy analysis has found its vaccine candidate is 94.5% effective. The study enrolled over 43,000 participants and has not uncovered any serious safety concerns. Moderna's trial includes 30,000 participants.
    - By the end of 2020, Moderna expected to have approximately 20 million doses ready to ship in the U.S. and remains on track to manufacture 500 million to 1 billion doses globally in 2021, including 100 million to 125 million doses in the first quarter of the year.

AstraZeneca

- AstraZeneca issued a press release reporting results from its Phase III clinical trial in Brazil and the United Kingdom indicating strong vaccine effectiveness among participants.

Janssen/Johnson & Johnson

- Janssen's ENSEMBLE COVID-19 vaccine clinical trial has fully enrolled 45,000 participants and hopes to be able to consider applying for an Emergency Use Authorization (EUA) of our vaccine FDA in February.

mRNA vaccines

- mRNA vaccines are being held to the same rigorous safety and effectiveness standards as all other types of vaccines in the United States. The only COVID-19 vaccines the Food and Drug Administration (FDA) will make available for use in the United States (by approval or emergency use authorization) are those that meet these standards. mRNA vaccines do not use the live virus that causes COVID-19. They cannot give someone COVID-19.
- mRNA never enters the nucleus of the cell, which is where our genetic material (DNA) is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.
- This means the mRNA vaccines do not affect or interact with our DNA in any way.

MISCELLANEOUS

Cost

- COVID-19 vaccine will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers.
- Providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient's plan.
- Vaccine providers will be able to charge an administration fee. However, participating vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees or coverage status, as stated in the CDC Provider Agreement.

    - Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient.
    - For uninsured patients, the vaccine provider can seek reimbursement for an administration fee from the HRSA Provider Relief Fund.
- Immunization cooperative agreement funds may be used by the awardee to pay for redistributing vaccines. However, provider organizations cannot purchase equipment or contract with a vendor for redistribution and then bill the immunization program or federal government for those costs.
- To help providers, states, and insurers prepare for vaccine administration, the Centers for Medicare & Medicaid Services (CMS) has released a set of toolkits that are designed to increase the number of vaccine-administering providers and ensure adequate Medicare reimbursement. These toolkits also make clear to private insurers and Medicaid programs that they must cover the vaccine at no charge to beneficiaries.

COVID-19 Vaccination, Pregnancy, and Breastfeeding

- People who are pregnant and part of a group recommended to receive COVID-19 vaccine, such as healthcare personnel, may choose to be vaccinated.
    - A conversation between pregnant patients and their clinicians may help them decide whether to get vaccinated with a vaccine that has been authorized for use under Emergency Use Authorization (EUA).
    - While a conversation with a healthcare provider may be helpful, it is not required prior to vaccination.
- Until findings are available from clinical trials and additional studies, only limited data are available on the safety of COVID-19 vaccines, including mRNA vaccines, administered during pregnancy:
    - Limited data are currently available from animal developmental and reproductive toxicity studies. No safety concerns were demonstrated in rats that received Moderna COVID-19 vaccine before or during pregnancy; studies of the Pfizer-BioNTech vaccine are ongoing.
    - Studies in people who are pregnant are planned.
    - Both vaccine manufacturers are monitoring people in the clinical trials who became pregnant.
- CDC and the FDA have safety monitoring systems in place to capture information about vaccination during pregnancy and will closely monitor reports.
- Based on how mRNA vaccines work, experts believe they are unlikely to pose a specific risk for people who are pregnant. However, the actual risks of mRNA vaccines to the pregnant person and her fetus are unknown because these vaccines have not been studied in pregnant women.
- There are no data on the safety of COVID-19 vaccines in lactating women or on the effects of mRNA vaccines on the breastfed infant or on milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. People who are breastfeeding and are part of a group recommended to receive a COVID-19 vaccine, such as healthcare personnel, may choose to be vaccinated.

Vaccines and COVID-19 variants

- CDC is closely monitoring reports out of the United Kingdom of a new variant of the virus that causes COVID-19.
- Viruses constantly change through mutation, and new variants of a virus are expected to occur over time.
    - In this particular case, genetic analysis show changes to the spikes on the virus and to other parts of the virus.
    - Scientists in the UK have reported that the number of mutations detected are more than what we normally see in a virus now.
- However, based on available data to date, we do not believe the new variant will impact the effectiveness of the COVID-19 vaccines.

CDC Resources for Case Investigations and Contact Tracing

This resource is an inventory of case investigation and contact tracing resources available on the CDC COVID-19 website. The goal of this resource is to capture all case investigation and contact tracing resources in one place. Resources include guidance documents, checklists, case investigator and contact tracer scripts, training plans, fact sheets, infographics, and other communication resources.

Newly added resources will be highlighted in the gray boxes.

Table of Contents

- Case Investigations and Contact Tracing Guidance Documents
- Contact Tracing Implementation Guides and Tools for the Public Health Workforce
- Training Resources
- Contact Tracing Resources for the Public or Persons with and/or Exposed to COVID-19
- Digital Tools: Exposure Notification and Patient Monitoring Resources

If assistance is needed, please email the Contact Tracing Program Support functional mailbox: eocevent348@cdc.gov

Case Investigations and Contact Tracing Guidance Documents

Date Released/Updated	Name/Description	URL
January 7, 2021	**Improving Ventilation in Your Home** This CDC guidance gives information on how improving ventilation can help prevent virus particles from accumulating in the air in your home.	Improving Ventilation in Your Home
December 3, 2020	**Contact Tracing Webpage** CDC's information on contact tracing for consumer audiences.	Contact Tracing Webpage
December 2, 2020	**Options to Reduce Quarantine for Contacts of Persons with SARS-CoV-2 Infection Using Symptom Monitoring and Diagnostic Testing** CDC currently recommends a quarantine period of 14 days. However, based on local circumstances and resources, options to shorten quarantine are available as acceptable alternatives.	Options to Reduce Quarantine for Contacts of Persons with SARS-CoV-2 Infection Using Symptom Monitoring and Diagnostic Testing
December 1, 2020	**CDC Guidance for Expanded Screening Testing to Reduce Silent Spread of SARS-CoV-2** The updated guidance is meant to assist health departments in decision making and considerations for groups to be considered for expanded screening testing with the aim of slowing asymptomatic and presymptomatic community transmission.	CDC Guidance for Expanded Screening Testing to Reduce Silent Spread of SARS-CoV-2

Date Released/Updated	Name/Description	URL
November 23, 2020	**Prioritizing Case Investigations and Contact Tracing for COVID-19 in High Burden Jurisdictions** This new guidance further refines prioritization recommendations and presents emerging modeling data regarding timeframes for effectiveness.	Prioritizing Case Investigations and Contact Tracing for COVID-19 in High Burden Jurisdictions
November 23, 2020	**Prioritizing COVID-19 Contact Tracing – Mathematical Modeling Methods and Findings** This document presents emerging modeling data regarding timeframes for case investigation and contact tracing effectiveness.	Prioritizing COVID-19 Contact Tracing – Mathematical Modeling Methods and Findings
November 19, 2020	**Training, Evaluation, and Monitoring Guidance for Health Departments Supervisors and Leads** This document will help supervisors and training leads to effectively develop and assess case investigators' interviewing skills.	Training, Evaluation, and Monitoring Guidance for Health Departments
November 18, 2020	**Interim Guidance for Case Investigation and Contact Tracing in K-12 Schools** This guidance is intended to help administrators of K-12 schools plan for the development and implementation of COVID-19 case investigation and contact tracing efforts in their schools. This guidance highlights potential collaboration between health officials and K-12 school administrators to facilitate effective case investigation and contact tracing.	Interim Guidance for Case Investigation and Contact Tracing in K-12 Schools

Date Released/Updated	Name/Description	URL
October 22, 2020	**Case Investigation and Contact Tracing in Non-healthcare Workplaces: Information for Employers** This document provides tips and considerations for how employers can partner with state, tribal, local, or territorial (STLT) health departments and work with their employees in COVID-19 response efforts.	Case Investigation and Contact Tracing in Non-healthcare Workplaces: Information for Employers
October 22, 2020	**COVID-19 Case Investigation and Contact Tracing among Refugee, Immigrant, and Migrant (RIM) Populations: Important Considerations for Health Departments** Important considerations for health departments conducting case investigation and contact tracing among Refugee, Immigrant, and Migrant populations (RIM).	COVID-19 Case Investigation and Contact Tracing among Refugee, Immigrant, and Migrant (RIM) Populations: Important Considerations for Health Departments
October 21, 2020	**Interim Guidance for Case Investigation and Contact Tracing in Institutions of Higher Education (IHEs)** This guidance is intended to help administrators of IHEs plan for the development and implementation of COVID-19 case investigation and contact tracing efforts in their schools. This guidance highlights potential collaboration between health officials and IHE administrators to facilitate effective case investigation and contact tracing.	Interim Guidance for Case Investigation and Contact Tracing in Institutions of Higher Education (IHEs)
October 21, 2020	**Overview of Testing for SARS-CoV-2 (COVID-19)** This document provides a summary of considerations and current Centers for Disease Control and Prevention (CDC) recommendations regarding SARS-CoV-2 testing strategy. The CDC recommendations for SARS-CoV-2 testing have been developed based on what is currently known about COVID-19 and are subject to change as additional information becomes available.	Overview of Testing for SARS-CoV-2 (COVID-19)

Date Released/Updated	Name/Description	URL
May 26, 2020	**Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan** This CDC interim guidance document is intended to assist state, local, territorial, and tribal health departments develop jurisdictional plans for the implementation and enhancement of COVID-19 case investigation and contact tracing efforts.	Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan
April 8, 2020	**Handling Non-COVID-19 Public Health Activities that Require Face-to-Face Interaction with Clients in the Clinic and Field in the Current COVID-19 Pandemic** CDC guidance for the management of public health workers engaged in public health activities that require face-to-face interaction with clients in clinic and field settings.	Handling Non-COVID-19 Public Health Activities that Require Face-to-Face Interaction with Clients in the Clinic and Field in the Current COVID-19 Pandemic

Contact Tracing Implementation Guides and Tools for the Public Health Workforce

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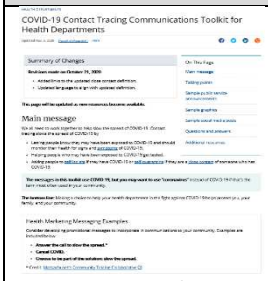
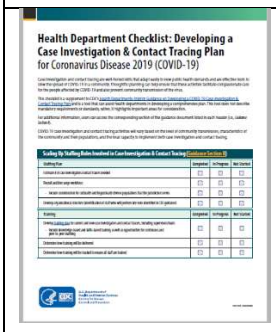
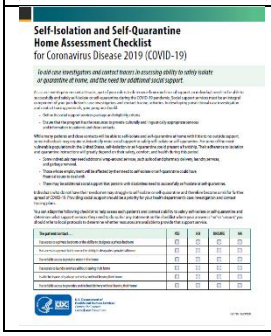
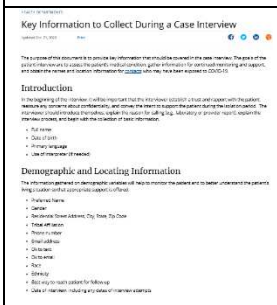
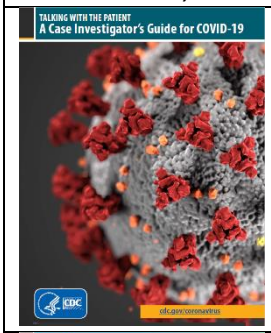
 *HTML only*	**COVID-19 Contact Tracing Communications Toolkit for Health Departments** This toolkit provides health departments with sample talking points, public service announcements, graphics, social media posts, and more for communicating about contact tracing for COVID-19. Also available in Spanish.	COVID-19 Contact Tracing Communications Toolkit for Health Departments
	**Health Department Checklist: Developing a Case Investigation & Contact Tracing Plan for COVID-19** This checklist is a supplement to CDC's Health Departments: Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan and is a tool that can assist health departments in developing a comprehensive plan.	Health Department Checklist: Developing a Case Investigation & Contact Tracing Plan for COVID-19
	Contact Tracing: A Community Engagement Checklist for Health Departments Keep these tips in mind when working with community organizations on contact tracing.	Contact Tracing: A Community Engagement Checklist for Health Departments
	**Self-Isolation and Self-Quarantine Home Assessment Checklist** This checklist is to help case investigators and contact tracers in assessing a person's ability to safely isolate or quarantine at home, and the need for additional social support.	Self-Isolation and Self-Quarantine Home Assessment Checklist

Image of Material	Name/Description	URL
	Example COVID-19 prioritization questions for non-health care worksite assessments by state, tribal, local, and territorial health departments This is a questionnaire to help prioritize worksite assessments. Information sources might include one or more employees at the company; such as human resources, occupational health staff, or a safety professional.	Example COVID-19 prioritization questions for non-health care worksite assessments by state, tribal, local, and territorial health departments
 *HTML only*	**Key Information to Collect During a Case Interview** The purpose of this document is to provide key information that should be covered in the case interview.	Key Information to Collect During a Case Interview
	**Talking with the Patient: A Case Investigator's Guide for COVID-19** The intent of this document is to provide suggested communication strategies for COVID-19 case interviews.	Talking with the Patient: A Case Investigator's Guide for COVID-19
	COVIDTracer COVIDTracer is a spreadsheet-based tool that allows state and local-level public health officials and policy makers to compare three different contact tracing/monitoring strategies. The COVIDTracer Manual accompanies the software tool COVIDTracer, beta version 1.0, released by CDC.	COVIDTracer Spreadsheet Tool Access the manual here: COVIDTracer Manual
	COVIDTracer Advanced COVIDTracer Advanced extends on the capability of COVIDTracer by allowing users to distinguish the impact of interventions by three age groups in terms of changes in the numbers of COVID-19 cases and hospitalizations, as well as changes in direct medical costs.	COVIDTracer Advanced Spreadsheet Tool Access the manual here: COVIDTracer Advanced Manual

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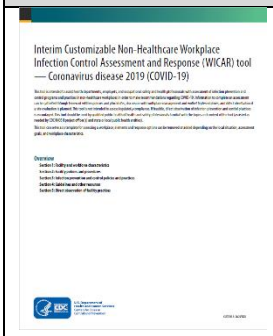
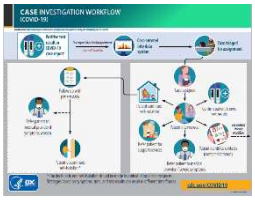
	**Interim Customizable Non-Healthcare Workplace Infection Control Assessment and Response (WICAR) tool – Coronavirus Disease 2019 (COVID-19)** This tool is intended to assist health departments, employers, and occupational safety and health professionals with assessment of infection prevention and control programs and practices in non-healthcare workplaces in order to make recommendations regarding COVID-19.	Interim Customizable Non-Healthcare Workplace Infection Control Assessment and Response (WICAR) tool – Coronavirus Disease 2019 (COVID-19)
 HTML only	**Notification of Exposure: A Contact Tracer's Guide for COVID-19** This guide provides suggested communication approaches and steps for public health staff to create a script for contact tracers to tell people that they may have been exposed to COVID-19.	Notification of Exposure: A Contact Tracer's Guide for COVID-19
	Contact Tracing – CDC's Role and Approach This document provides an overview of CDC's role and approach to contact tracing for COVID-19.	Contact Tracing – CDC's Role and Approach
	**Case Investigation Workflow** This document is an infographic of the case investigation workflow for COVID-19.	Case Investigation Workflow
	Contact Tracing Workflow This document is an infographic of the contact tracing workflow for COVID-19.	Contact Tracing Workflow

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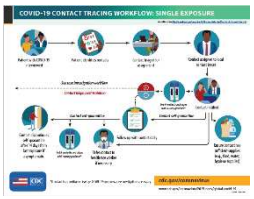
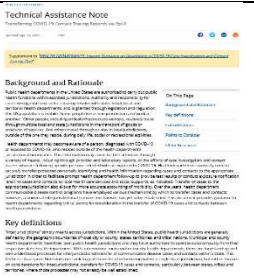
	**COVID-19 Contact Tracing Workflow: Single Exposure** This document is an infographic of the contact tracing workflow for COVID-19 for single exposure.	COVID-19 Contact Tracing Workflow: Single Exposure
	Daily Temperature/Symptom Log for Close Contacts This document is a daily temperature/symptom log for people who are considered close contacts to monitor their health.	Daily Temperature/Symptom Log for Close Contacts
 *HTML only*	**Technical Assistant Note: Transferring COVID-19 Contact Tracing Records via Epi-X** The document is a supplement to CDC's Health Departments: Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan. The resource provides information on transferring COVID-19 cases and contacts between health jurisdictions.	Technical Assistant Note: Transferring COVID-19 Contact Tracing Records via Epi-X
	Case Investigation and Contact Tracing: Part of a Multipronged Approach to Fight the COVID-19 Pandemic This resource highlights basic principles of case investigation and contact tracing to stop COVID-19 transmission; detailed guidance for health departments is available.	Case Investigation and Contact Tracing: Part of a Multipronged Approach to Fight the COVID-19 Pandemic
	Operational Considerations for Adapting a Contact Tracing Program to Respond to the COVID-19 Pandemic This document is for CDC country offices, ministries of health, sub-national public health authorities, and other implementing partners in non-US settings. While select adaptations may be relevant for any jurisdiction, the document focuses on adaptations that might be especially useful in low- and middle-income countries.	Operational Considerations for Adapting a Contact Tracing Program to Respond to the COVID-19 Pandemic

Training Resources

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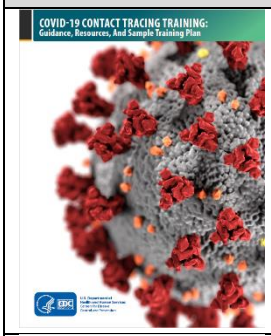
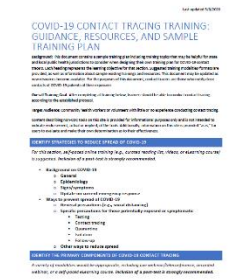
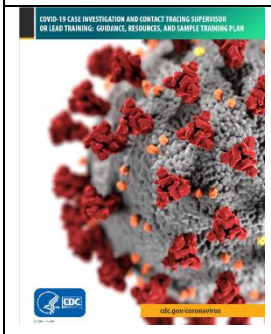
	**COVID-19 Contact Tracing Training: Guidance, Resources, and Sample Training Plans** These sample training plans include training topics that may be helpful for state and local public health jurisdictions to consider when designing their own training plan for COVID-19 contact tracers, case investigators, and team leads.	COVID-19 Contact Tracing Training: Guidance, Resources, and Sample Training Plan
	**Sample COVID-19 Contact Tracing Training: Guidance, Resources, and Sample Training Plan** This document contains a sample training plan and gives training goals for contact tracers. After completing the training, participants should be able to conduct contact tracing according to the established protocol.	Sample COVID-19 Contact Tracing Training: Guidance, Resources, and Sample Training Plan
	CDC-funded Training for the COVID-19 Contact Tracing Workforce The CDC COVID-19 Response and the CDC Division of STD Prevention are supporting two cooperative agreements to train the COVID-19 contact tracing workforce.	CDC-funded Training for the COVID-19 Contact Tracing Workforce
	**COVID-19 Case Investigation and Contact Tracing Supervisor or Lead Training: Guidance, Resources, and Sample Training Plan** This document contains a sample training plan and includes training topics that may be helpful for state and local public health jurisdictions when designing their own training plan for leads or contact tracing supervisors for COVID-19 case investigations. Suggested training modalities/formats are provided, as well as information about sample existing trainings and resources.	COVID-19 Case Investigation and Contact Tracing Supervisor or Lead Training: Guidance, Resources, and Training Plan

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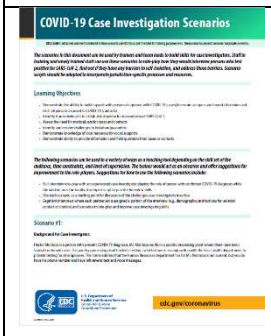
	COVID-19 Case Investigator Training: Guidance, Resources, and Sample Training Plans These sample training plans include training topics that may be helpful for state and local public health jurisdictions to consider when designing their own training plan for COVID-19 case investigators.	COVID-19 Case Investigator Training: Guidance, Resources, and Sample Training Plan
	COVID-19 Contact Tracing Scenarios The scenarios in this document can be used by trainers and team leads to build skills for contact tracers. Staff in training and newly trained staff can use these scenarios to role-play how they would interview contacts, find out if they have any barriers to self-quarantine, and address those barriers. Specific scripts based on these scenarios can incorporate jurisdiction-specific processes and resources.	COVID-19 Contact Tracing Scenarios
	COVID-19 Contact Tracing Scenarios: Disaster Shelters The scenarios in this document can be used by trainers and team leads to build skills for contact tracers. Staff in training and newly trained staff can use these scenarios to role-play how they would interview contacts, find out if they have any barriers to self-quarantine, and address those barriers. Specific scripts based on these scenarios should incorporate jurisdiction-specific processes and resources.	COVID-19 Contact Tracing Scenarios: Disaster Shelters
	**COVID-19 Case Investigation Scenarios** The scenarios in this document can be used by trainers and team leads to build skills for case investigators. Staff in training and newly trained staff can use these scenarios to role-play how they would interview persons who test positive for SARS-CoV-2, find out if they have any barriers to self-isolation, and address those barriers. Scenario scripts should be adapted to incorporate jurisdiction-specific processes and resources.	COVID-19 Case Investigation Scenarios

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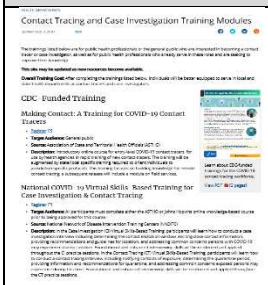
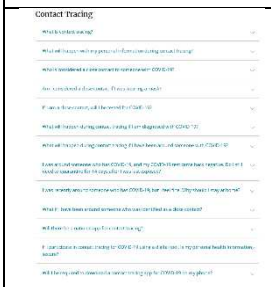
 *HTML only*	**General Contact Tracing and Case Investigation Training Modules** The training modules in this resource are for public health professionals interested in becoming a contact tracer or case investigator, as well as those who already serve in these roles and are seeking to improve their knowledge.	General Contact Tracing and Case Investigation Training Modules

Contact Tracing Resources for the Public or Persons with and/or Exposed to COVID-19

Image of Material	Name/Description	URL
	Contact Tracing: Do your part to keep your family, friends, and community safe. This document is an infographic that explains the steps of contact tracing for people who are diagnosed with COVID-19 and people who may have been around someone with COVID-19. Also available in Spanish, Chinese, Vietnamese, Korean, and Marshallese.	Contact Tracing: Do your part to keep your family, friends, and community safe.
 *HTML only*	**Contact Tracing: Frequently Asked Questions and Answers** Check out CDC's answers to commonly asked questions about COVID-19 for the general public. Also available in Spanish, Chinese, Vietnamese, and Korean.	Contact Tracing Frequently Asked Questions and Answers
	3 Key Steps to Take While Waiting for Your COVID-19 Test Results This resource will help explain what people should do while they are waiting for a COVID-19 test result to help them prepare for contact tracing. Also available in Spanish, Chinese, Korean, Marshallese, and Vietnamese.	3 Key Steps to Take While Waiting for Your COVID-19 Test Results
	Answer the Call: Contact Tracing Video This 1-minute long animation video with voiceover informs the public about contact tracing and why they should answer and respond to a call from a contact tracer. Also available in Spanish.	Answer the Call – Contact Tracing Video Answer the Call – Contact Tracing Video (Español)

Digital Tools: Exposure Notification and Patient Monitoring Resources

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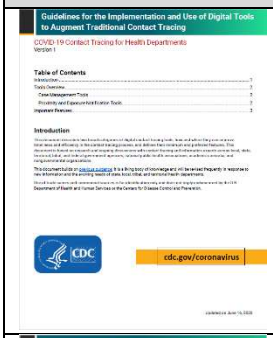
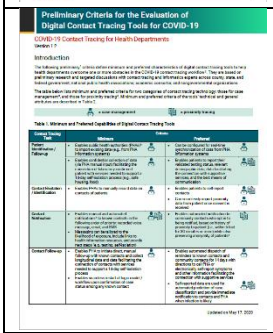
	**Guidelines for the Implementation and Use of Digital Tools to Augment Traditional Contact Tracing** This document is an update and expansion on previously published evaluation criteria.	Guidelines for the Implementation and Use of Digital Tools to Augment Traditional Contact Tracing
	Contact Tracing: Using Digital Tools This technology guide serves as a companion to the case investigation and contact tracing workflows and describes how and where technology can assist in the processes.	Contact Tracing: Using Digital Tools
	**Preliminary Criteria for the Evaluation of Digital Contact Tracing Tools for COVID-19** This document contains preliminary criteria that define minimum and preferred characteristics of digital contact tracing tools to help health departments overcome one or more obstacles in the COVID-19 contact tracing workflow.	Preliminary Criteria for the Evaluation of Digital Contact Tracing Tools for COVID-19
	Sara Alert CDC provides funding to MITRE, a Federally Funded Research and Development Center through a Project Work Statement through June 2022, to support Sara Alert™, an open-source, standards based, web-based tool that supports automated monitoring and reporting of COVID-19 close-contacts.	Sara Alert

FEMA

COVID-19

ESF 15 - EXTERNAL AFFAIRS

SOCIAL LISTENING REPORT

WEDNESDAY, JANUARY 27, 2021

SUMMARY

- There are reports of increased skepticism regarding the vaccine among Latinx communities. There is a lack of trust in the guidance and policies being shared by the federal government and some state and local officials. This is causing some to feel more hesitant about receiving the vaccine.
- Many individuals who have received the first round of the vaccine are growing more concerned that supplies will run out before they can receive their second dose, or that they will not be able to obtain appointments for their second dose.
- There is a small amount of local news coverage regarding FEMA funeral assistance. Members of the National Funeral Directors Association report they are anxiously awaiting additional guidance from FEMA about how the program will be implemented. There has also been steady coverage in local media regarding the recent allocation of funds to bolster state vaccine administration capacity.
- There is some debate and disagreement among state lawmakers regarding what populations should be prioritized for the vaccine.
- This afternoon, traditional media has focused on the White House COVID-19 Response Team's press brief. Popular topics covered in the brief included overall action plans, infection risk following detection of new virus strains within U.S. borders, and ongoing concerns about vaccine supplies and accessibility. Today's newspaper front-page headlines covered new vaccination sites, concerns regarding new strains of the virus, and mixed public reaction to the pace of vaccine distribution and administration.

PUBLIC PERCEPTION/SENTIMENT

- Reports of inequitable vaccine distribution is becoming an increasingly hot topic among Latinx communities. (example 1, example 2)
    - Some members of these communities claim there is hesitation to get vaccinated due to a lack of official information available in Spanish and a large circulation of myths/rumors causing an overall lack of trust towards government messaging regarding the vaccine.

  - Many feel reports of inequitable vaccine are intended to be polarizing, claiming that the states being analyzed in the news reports are predominantly white anyways.
- Debate over double masking has grown significantly due to increased coverage from local news outlets. (example 1, example 2) There continue to be a large number of people who say they do not plan to wear multiple masks. These individuals often cite concern for breathing or a lack of trust in federal guidance.
- The anti-vaccine sentiment remains strong on social media. Content encouraging people to get vaccines is frequently overwhelmed by comments from accounts sharing false or negative information related to vaccines.
- A number of people are anxious and confused over how to schedule their second doses within the vaccine manufacturers recommended time frames.

RUMORS/MISINFORMATION

- Henry County, Tennessee Sheriff's Office is warning residents of a scam in which callers are requesting personal information and payment to schedule an appointment for COVID-19 vaccination. The public is advised the public not to give personal details nor payment over the phone.
- One Pennsylvania news outlet reports that 'experts' warn not to take pain relievers before getting vaccinated. However, the news article does not specify what kind of experts issued the warning.
- Following news that baseball Hall of Famer Hank Aaron died a few a weeks after taking the vaccine, those who are skeptical or against the vaccine have falsely linked his death to the COVID-19 vaccine.

FEMA

- Many news stations and elected officials are sharing the news of FEMA's allocation of funds for vaccine storage and distribution in various states and territories. (example 1, example 2, example 3)
- Elected officials in Virginia are urging the governor and FEMA to establish a mass vaccination site in Northern Virginia.
  - Officials are also are pushing for streamlining the process and developing a more transparent and equitable system for distribution.
- A few people are relieved and grateful to FEMA staff who are helping at state vaccination sites. (example 1, example 2, example 3)
- There is a low volume of local news coverage on the implementation of funeral reimbursements. A spokesperson for the National Funeral Directors Association said they are eagerly awaiting additional guidance from FEMA.

Federal Response

- There is a high volume of discussion about President Biden's press conference yesterday with many people focusing on the desire to have 300 million Americans vaccinated by the end of summer. (example 1, example 2)
    - Some people are questioning if children will be included in the 300 million.
- There continues to be a push from elected officials to speed up vaccine delivery and distribution. Many place blame on the federal government saying it is delaying the process. (example 1, example 2)
- National media outlets report the White House will reopen HealthCare.gov marketplaces, currently operating in 36 states, to give those affected by the pandemic an opportunity to sign-up. (example 1, example 2, example 3)

Vulnerable Populations

- The World Health Organization does not recommended the Moderna COVID-19 vaccine for pregnant women, unless they are at risk of high exposure.
- CDC Director vows to follow the White House's executive order to bring equality to those disproportionally burdened by the pandemic.
    - Responses to her post ask the Director to not to forget disabled people, people of color, high risk and chronically ill people living independently, homeless, immunocompromised, and intellectually disabled among others.

Public Health

- CDC issued more detailed recommendations for COVID-19 vaccine distribution to include veterinary services in Phase 1-b.
- According to CNN, a survey published by the Kaiser Family Foundation of more than 1,500 adults found that 41% want the vaccine and at least 6% have already received at least the first dose.
    - Comments under the post are mixed. Several people shared that they want the vaccine or have already received it, while just as many express adverse feelings about the vaccine.

Transportation

- International airports across the country began to implement new policies yesterday requiring all passengers entering the US to provide proof of a negative COVID-19 test.
    - Reports that the government is considering expanding this policy to domestic travel have been met with mixed emotion. Some are saying it feels unconstitutional others are pleased at the idea of additional precautions being put in place.

Community Mitigation

- CDC Morbidity and Mortality Weekly Report (MMWR) reports NFL use of wearable devices for contact tracing and strict COVID-19 mitigation protocols for high-risk contacts limited the spread of infection.

Private Sector

- Darden Restaurants, the parent company of Olive Garden and Red Lobster, will offer their employees paid time off to get the COVID-19 vaccine.

REGION ONE

Supply Chain

- In New Hampshire, people are experiencing issues scheduling their second shots within the CDC's updated recommended time frame of 4-6 weeks due limited appointments and lack of supply.
    - Some appointments are having to be set as much as almost 8 weeks after the initial dose. The state advises that appointments will be made available when more vaccines are received.

Vaccine Administration

- Starting Wednesday, January 27, in Massachusetts, residents 75 and older may schedule appointments beginning in February for a COVID-19 vaccine for the start of Phase 2.
- Some Stop and Shop locations have been approved to give the Moderna vaccine based on the state's COVID-19 vaccination plan. These locations will begin accepting appointments on February 1.
- In Massachusetts, Eastfield Mall in Springfield is preparing the old Macy's location to serve as a vaccination site. Scheduling started today, January 27 for 500 appointments.

Vulnerable Populations

- In New Hampshire, for the first time in months there are no new outbreaks to report at long term care facilities. The governor attributes this, in part, to the implementation of vaccines.
- In Massachusetts, Boston homeless shelters are encountering a high level of vaccine hesitancy, as high as 50% at one location. Health care providers also have concerns about reaching people without cell phones for their second dose.

Public Health

- Maine CDC reported two new COVID-19 outbreaks at Lisbon Public Works and the Oxford Casino, while investigating 25 cases at Maine Veterans' Home.
- In Massachusetts, the town of Ossipee commissioners (selectmen) temporarily closed their administration building due to a COVID-19 outbreak in their campus-adjoining jail.

- The Ossipee commissioners also reversed their decision to mandate masks in the town hall, despite 21 people related to town hall business contracting the virus.

Community Mitigation

- The Appalachian Trail Conservancy have asked hikers to postpone plans to cover the Appalachian Trail, which runs through 14 states from Maine to Georgia, this year due to COVID-19.
  - Hikers usually stay at shelters in close quarters along the trail which don't allow for the CDC's recommended guidelines for social distancing and washing hands often.
  - The suggestion was made because of concern that thousands of travelers entering many small towns along the trail may overwhelm local hospital systems.
- Chicago, Illinois teachers are threatening to defy a Chicago Public School's order to return to classrooms on January 27. The Chicago Teachers Union alleges the school system has failed to put in place agreed upon COVID-19 protocols necessary for in-person learning. Teachers are expected to receive their shots in mid-February.

REGION TWO

Vaccination Administration

- People in the Tri-state area are having trouble getting their second vaccine dose appointment on time, local media reported.
  - In a Twitter poll hosted by the same local media outlet: 49.5% of people who filled it out claimed to have difficulty getting an appointment for their second dose.
- In Hudson County, New Jersey, the county's executive has expressed frustration saying the county has infrastructure ready for mass vaccination but not enough doses. The county's Health Officer informed that to deal with the problem, they are not registering individuals unless they have doses available.
- New Jersey will receive about 130 thousand vaccine doses for each of the next 3 weeks, announced the governor today.
- A New Jersey hospital in Hunterdon County reportedly vaccinated wealthy donors and their relatives in December before vaccine eligibility was expanded in the state.

Vulnerable Populations

- In Long Island, New York, local leaders said that they're facing an "uphill battle" in convincing minorities to get vaccinated. They're launching new efforts to make sure the minorities have equal access to the vaccines.
- In New York City, local media reported that early vaccination data from December showed that white people received about five times as many vaccinations while making up 42% of the population. The report also showed that about 40% of recipients didn't mark down their race or ethnicity.

REGION THREE

Vaccination Administration

- The Governor of Maryland announced the state will open at least six mass vaccination sites by early February.
    - Yesterday, January 26 he also announced that Six Flags America and Baltimore Convention Center will be converted into mass vaccination sites. Six Flags is expected to be converted February 5.
- In Lehigh County, Pennsylvania a drive-thru COVID-19 vaccination clinic opened today. The clinic opened at Dorney Park and they plan to vaccinate individuals 75 and older.
- In Chesterfield County, Virginia unregistered residents showed up at a Chesterfield appointment-only vaccine clinic. The county's official government page posted a message informing residents of the issue and asking them to be patient.

Vulnerable Populations

- The Pennsylvania State Troopers Association is speaking out against the state's decision to include smokers in the high priority category, urging the state to reject the CDC's recommendation.

Community Mitigation

- In Portsmouth, Virginia the health department launched a hot line to assist those without reliable internet. The hot line helps residents navigate the COVID-19 vaccination process. They've had over 2,000 call this week alone.

REGION FOUR

Supply Chain

- Mississippi is expecting to receive around 37,000 doses of COVID-19 vaccine this week from the federal government. According to the state's Department of Health, it is the same allocation the state has received the past few weeks. While the state would like to receive an increase in their allotted vaccines, they share that they are receiving what they expect.

Vaccination Administration

- Local news in North Carolina reports that there is a discrepancy between the reported amount of administered vaccines versus actual state data. The North Carolina Department of Health and Human Services (NCDHHS) reports that it has administered 95% of all first-round doses but data shows hundreds of thousands doses have not been administered.
    - The state Association of Health Directors is critical of NCDHHS' decision to prioritize two mass vaccination events at the expense of local health departments.
    - Health directors are also upset that the rerouting of vaccines from local providers triggered thousands of cancelled appointments, which they feel is slowing down vaccine distribution.

- Alabama Department of Public Health announced a new no-reservation, first come, first serve drive-thru site for COVID-19 vaccination clinics in Baldwin County to begin on February 2.
- Alabama State University announced this week that it will serve as a COVID-19 vaccine administration site.

Public Health

- Georgia's public health commissioner expressed to state lawmakers the pandemic is a strain on the Department of Public Health, but there will not be an increase in the their budget plan, published by the Governor's office, to account for COVID-19 expenses.
    - Some officials feel that public health should be more of a priority and that more funding is needed.
- CDC highlights the need for health depts and schools to weigh the benefits of allowing high contact sports against risk for spread of virus after COVID-19 outbreak linked to two wrestling tournaments in Florida.
- A Georgia state representative was removed from Georgia's House chamber for refusing to be tested for COVID-19, which is mandatory. His refusal was due to his frustration that state lawmakers have access to regular testing while many other Americans do not.

REGION FIVE

Supply Chain

- In Wisconsin, a pharmacist charged with intentionally tampering with dozens of vials of COVID-19 vaccine in attempt to spoil them is facing 20 years in prison after pleading guilty.
    - His actions allegedly caused more than 50 people to be vaccinated with improperly stored doses.

Vaccination Administration

- In Indiana, teachers are protesting the change in vaccination priorities to people who are high risk due to age over teachers, despite CDC guidelines to treat teachers and grocery store workers as essential workers.
- The Minnesota Department of Health opened a 24-hour vaccine lottery to choose approximately 11,700 residents who are 65 and older to receive the COVID-19 vaccine.
- The Ohio Funeral Directors Association asked the Governor of Ohio to add funeral directors, embalmers and their staff in a list with group 1B.

Community Mitigation

- Wisconsin Senate has voted to repeal their governor's statewide mask mandate. Both legislative chambers have to pass the resolution, scheduled for a vote on January 28.

REGION SIX

Vaccination Administration

- In Texas, local media reported that some individuals who received their first dose, are seeing conflicting information on how to obtain an appointment for their second dose and are worried about not getting their second dose in time.
- The governor of Texas announced that the state set a new record for COVID-19 vaccinations in a single day with 114,000 shots were administered yesterday (1/26).
- The vaccine registration website from Harris County, Texas, which had technical problems earlier in the week, was fixed and over 49,000 people have registered despite the site crashing a couple times. Many residents have also been receiving busy signals when calling the county's vaccine registration phoneline.
- New Mexico Governor announced that the state has the 3rd highest rate of COVID-19 vaccine administration in the country.

Vulnerable Populations

- The Texas National Guard teams are scheduled to begin COVID-19 vaccination on Thursday (1/28) in a new State mobile vaccine pilot program that aims to reach and immunize underserved areas like Starr County and others.
- The city of Corpus Christi, Texas, is deploying its firefighters to help vaccinate homebound senior residents.

Public Health

- In Amarillo, Texas, COVID-19 hospitalizations are decreasing. Area health experts believe vaccinations and masking precautions along with a high number of recoveries are contributing to the decrease in positive cases.

Community Mitigation

- An Oklahoma lawmaker filed a bill that would require people to wear a mask in public and face fines if one fails to do so.
- In Oklahoma, students in Rector Johnson Middle School and Broken Bow High School who forget their masks will have to buy one or call their parents. The schools say that giving students masks have depleted their supplies.

REGION SEVEN

Supply Chain

- Missouri Governor Mike Parson plans to divert unused COVID-19 vaccine doses from pharmacies, designated for long-term care facilities, to mass vaccination sites operated by the National Guard to increase the vaccine distribution rate.
    - This action will not prevent CVS and Walgreens from finishing their work providing vaccinations at nursing homes.

Vaccination Administration

- Missouri launched a new COVID-19 vaccine dashboard to track administered doses. The site shows the total vaccine shots administered and the number of individuals who have received single or double doses, county and demographic information of recipient.
- University of Iowa Hospitals and Clinics (UIHC) will begin their next phase of COVID-19 vaccinations next week to include emergency responders, teachers and people 65 and older.
    - The Governor and UIHC health officials share while vaccine supply is low, they will be able to administer a steady flow of vaccinations and can handle the administration of the vaccines. Officials want residents to remain hopeful.

Staffing

- Iowa lawmakers are considering a bill that will allow dentists to administer the COVID-19 vaccine and flu shots. It would require dentists to take four hours of training and prohibit them from allowing dental hygienists or dental assistants from vaccine administration.
    - Legislatures who disapprove feel that there are enough healthcare personnel to distribute the vaccine and that the real issue is the limited supply.

Vulnerable Populations

- In Kansas, local news reports that on January 26, the first day that residents 80 and up were allowed to get the vaccine in Johnson County, they were waiting in long lines in the cold. This was due to people showing up ahead of their scheduled appointments and healthcare workers in need of their second dose. The county said it won't happen again with more staff on site today.
- Kansas state lawmakers disagree on the state's vaccine administration plan on prioritizing healthcare workers over residents who are 65 and older. Some officials feel the governor's plan makes it harder for older residents to get vaccinated.

REGION EIGHT

Vaccination Administration

- In Sioux Falls, South Dakota law enforcement and health care professionals were able to receive their second COVID-19 vaccine yesterday. Many essential workers expressed gratitude to receive a second dose and were glad to do their part in protecting themselves and others.
- Utah chose the grocery chains Smith's and Walmart to help vaccinate the general public when allowed. This is a switch from CVS and Walgreens, which are currently helping vaccinate long-term care facility staff and residents.

Vulnerable Populations

- In Denver, Colorado state and local leaders asked SCL health to work on a mass vaccination event geared toward communities of color and underserved populations. Their goal is to vaccinate at least 5,000 people on Saturday, February 6th.

Public Health

- The Governor of North Dakota announced this morning that the statewide COVID-19 risk level will be adjusted from moderate to low beginning at 8 a.m. Friday, January 29th.
- A Washington State resident was arrested last week after prosecutors say he used social media to peddle untested, injectable COVID-19 "vaccines" on social media. He sold the "vaccines" on Facebook for $400-$1,000 and now faces misdemeanor federal charges of introducing misbranded drugs into interstate commerce.

REGION NINE

Vaccination Administration

- In California, Santa Clara County health officials are withholding COVID-19 vaccines from Good Samaritan Hospital after it broke vaccination eligibility rules.
    - Los Gatos Union School District teachers were instructed, in an email from their Superintendent, to impersonate health care workers to obtain vaccine appointments, displacing eligible people over 65 and health care workers.
- In California, San Diego County is planning for two new COVID-19 mass vaccination sites in the North and East Counties, and at least five more community sites.
- In California, Riverside Convention Center is preparing to open as a mass vaccination site.

Staffing

- Local news reports that FEMA has deployed 66 personnel to Tucson, Glendale, Kingman and Prescott Valley to help accelerate their efforts at vaccine sites.

Public Health

- Nevada officials announced the COVID-19 UK variant was detected in a specimen from a Las Vegas woman. Some local officials suggest that the state should increase their prevention efforts.

Private Sector

- In California, a group of tech workers created VaccinateCA.com, a database with a map of COVID-19 vaccination sites in the state, since there was not statewide site. It is verified by a group of 200 volunteers who phone bank for information.
- In California, the annual California Strawberry Festival in Oxnard, scheduled for mid-May, is now cancelled due to the uncertainty surrounding the pandemic.

REGION TEN

Vaccination Administration

- A new pop-up drive-thru clinic opened yesterday in Piece County, Washington. Washington residents were able to fill out their paperwork and receive the vaccine without leaving their car.
- Health officials in Oregon provided drivers who were stuck on the road during a snowstorm COVID-19 vaccines. The vaccines would have been spoiled if not used.
- In Olympia, Washington a mass vaccination site opens today at the Spokane Arena. The site will be open by appointment only and the goal is to provide about 500 vaccinations every day.

Vulnerable Populations

- In Washington, the Washington Black Lives Matter Alliance is urging state legislators to take action to address inequity, including declaring racism a public health crisis.
- Local organizations in Idaho are relaying important information about COVID-19 and the vaccination process to Latinx Americans.

Public Health

- In Washington, a biologic entrepreneur was arrested last week after prosecutors say he used social media to sell untested COVID-19 "vaccines" on social media. It is unclear how many were injected.
- In Akutan, Alaska there was a coronavirus outbreak. Numerous employees tested positive for coronavirus at the Trident Seafoods processing plant.

Community Mitigation

- Local media breaks down how Idaho residents 65 and older that aren't living in long-term care facilities can get the COVID-19 vaccine. On February 1, individuals eligible for the vaccine will be able to find appointments in their area from the state website.

TRADITIONAL MEDIA

Federal Response

- National media has frequently reported on vaccine distribution plan developments shared during today's White House COVID-19 Response Team's virtual press brief.
    - Two national outlets emphasized the CDC director's estimation of 479,000 to 514,000 pandemic-related fatalities by mid-February, adding that despite virus variants present in 26 states, approved vaccines appear to successfully provide protection.
- Multiple national and local outlets highlight several federal agencies warning about vaccine fraud schemes, urging members of the public to not communicate their personal information over the phone. (example 1, example 2, example 3)
- This morning, one national news outlet highlighted FEMA's recent $216 million grant to pay for vaccine storage, transport, distribution and administration services. Congressional representatives had previously stated these areas created a 'supply-demand imbalance.'

Supply Chain

- Since Monday, coverage regarding state and local governments complaints of insufficient amount of vaccine doses remains high.
    - In response to community concerns, California's governor has announced changes to the states' current system for receiving the COVID-19 vaccination. The new plan will "simplify eligibility." The system prioritizes healthcare workers, residents aged 65 and older, teachers, childcare workers, emergency responders, and food and agriculture workers. Afterward, the state will reportedly prioritize eligible vaccine recipients by age.
    - Pennsylvania's governor is reportedly attributing vaccine accessibility difficulties to supply overpromises from the prior White House administration. The governor also states that a decentralized vaccine signup system should serve more efficiently.
- This morning, one U.S. Virgin Islands news outlet reported FEMA will reimburse the island government for costs related to storing, handling, and distributing the vaccine. The article proceeds to highlight U.S. Virgin Islands currently operates 32 territorial facilities and receives just under 3,000 vaccine doses per week.
- One national radio outlet's online platform reported N95 masks remain in short supply due to limited retailers. This report has been widely reposted by various local television outlets. The original story references the White House's invocation of Defense Production Act to boost critical medical supplies as well as urging the general public to wear masks. (example 1, example 2, example 3)

Vulnerable Populations

- In Dallas, Texas, one outlet reported Tuesday night that caretakers and family members confined to their homes remained worried about the lack of access to a vaccine. An associate medical director of Prospero Health said there has yet to be formalized plans on how to vaccinate the thousands of homebound Texans.
- In Washington state, cities and county governments are organizing vaccination teams to help those who cannot access a medical clinic for treatment. Vulnerable communities referenced include Rainier Valley, Kent, SeaTac, Covington, Maple Valley and South King counties.

Healthcare System Stress

- Ahead of North Carolina governor's press conference update this afternoon, the state's healthcare systems and county health departments are reportedly fighting to acquire limited doses. The state is also expected to receive its first federal shipment of vaccines today.
- In Washington state, Overlake Medical Center and Clinics' chief development officer, emailed donors who gave more than $10,000 to the Eastside Hospital System that they will receive 'special access' to coveted vaccine slots. The email gave the donors an access

code to register for appointments 'by invite' only. Overlake reportedly shut down online access to the invite-only clinic after getting a call from Governor Jay Inslee's staff.

Public Health

- This morning, Palm Beach County, Florida's commissioner has strongly criticized the state governor for deciding to designate Publix grocer's pharmacies as sole distributors in the county. The county's commissioners also expressed discontent of enabling the private sector instead of public health officials to vaccinate residents as well as the fear of a dose shortage after February 5th.
- This afternoon, one local outlet references CDC's recently released analysis on allergies to both Pfizer and Moderna vaccines, which concludes low anaphylaxis risk.

Private Sector

- Late this morning, Moderna has confirmed the company is discussing the possibility of delivering another 100 million vaccine doses later this year. This would bring the total commitment of vaccine dose purchases from Moderna to 300 million.
- At least one national outlet reports CVS pharmacy will start offering in-store vaccinations in "New York, Indiana and Massachusetts," expecting to deliver 25 million each month. The article references the federal government previously tapping CVS and Walgreens to help vaccinate nursing home residents.

THE SPOKESMAN-REVIEW

WEDNESDAY, January 27, 2021

CORONAVIRUS VACCINATION

VACCINATIONS BEGIN TODAY AT THE ARENA

Online appointments – up to 500 a day – required through CHAS Health; only 3,000 shots on site for those eligible

"Why not prioritize those who are teaching in person?"

Jeremy Shay

Teachers worry about going back to school without shot

SPS chief says

The Dallas Morning News

Dallas, Texas, Wednesday, January 27, 2021

DallasNews.com

HEALTH CARE

Biden to reopen ACA marketplace

If harmed by pandemic, anyone eligible for coverage can sign up

DALLAS CITY COUNCIL

Vaccination frustration

Leaders struggle to get on the same page about giving shots quickly

EAST BAY TIMES

WEDNESDAY, JANUARY 27, 2021

POWER OUTAGES EXPECTED

Atmospheric river storm 'an all-hands-on-deck situation'

Help on the way: PG&E

CENTRALIZED DISTRIBUTION

State to handle vaccine rollout

System includes network of providers, inoculation sites and new website

THE NEWS-TIMES

Conn. to get more vaccine

Biden sending federal staff to state to help set up clinics

Connecticut nears 7,000 coronavirus-related deaths

President Joe Biden delivers remarks on COVID-19 Tuesday in the State Dining Room of the White House, in Washington.

one dollar

WEDNESDAY, JANUARY 27, 2021

newsminer.com

FAIRBANKS

Daily News-Miner

THE VOICE OF INTERIOR ALASKA

Inside Today Denali Junior Nordic Ski program gets kids outdoors. » A3

COVID UK variant detected in Alaska

• More than 101,000 doses of COVID-19 vaccine have been administered

• Alaska continues to see decline in cases, deaths but new strain spreads easier

The Boston Globe

WEDNESDAY, JANUARY 27, 2021

A quieter White House. Discipline. COVID tests. A daily press briefing. But the deep partisan division remains

MONDAY, JANUARY 25 — Making his mark

Mass. vaccine program expands

75 and older can sign up; shots will start Monday

FEMA

The Seattle Times

WINNER OF 11 PULITZER PRIZES

INDEPENDENT AND LOCALLY OWNED FOR MORE THAN 120 YEARS

Washington will soon get more COVID-19 vaccines, Inslee says

Open schools as soon as possible, say CDC officials

PRECAUTIONS

Emphasize masks, social distancing to limit transmission.

The Modesto Bee

Stanislaus County remains hard-pressed by COVID-19

Napa Valley Register

Making a gutsy move

Habituate opens at First Street Napa

Flash flood watch

Napa warns of flood risk

Napa grad on Lasorda

Neidlinger pitched for Dodgers

WINDS SUBSIDING WITH RAIN 54 • 46 FORECAST, B4 | WEDNESDAY, JANUARY 27, 2021 | napavalleyregister.com | $1

PUBLIC HEALTH

County is stuck in 'deep purple'

Challenges are daunting for Napa in move to less restrictive red tier

The Atlanta Journal-Constitution

Credible. Compelling. Complete.

METRO, 5B

AIRPORT TOPS GUN LIST

220 WEAPONS CONFISCATED BY SECURITY LAST YEAR

METRO, 3B

COVID-19 AND SCHOOLS: WHAT DISTRICTS WANT

AJC CONTINUING COVERAGE CORONAVIRUS OUTBREAK

Ga. won't say where virus strain found

CORONAVIRUS IN GA.

As of Tuesday evening

727,752 CONFIRMED CASES

11,995 CONFIRMED DEATHS

4,828 CURRENT HOSPITALIZATIONS

AJC.com

VACCINES UPDATE

9 THINGS to know to receive your COVID-19 vaccine in metro Atlanta and the surrounding area, W2

U.K. mutation believed to be 30% more deadly than common virus

Dr. Jeremy Edwards

Palladium-Item

WEDNESDAY, JANUARY 27, 2021 | RICHMOND, IND.

PART OF THE USA TODAY NETWORK

Northeastern admin charged

Green accused of giving alcohol to minors after 8 month investigation

Mike Emery

WINCHESTER — A Northeastern Wayne Schools administrator is accused of providing alcohol to minors.

Eric Green, 44, is charged in Randolph County with two counts of furnishing alcohol to a minor. If convicted, the class A misdemeanor charges are punishable by up to 180 days in jail and/or a fine up to $5,000.

Green is an administrative assistant for the Northeastern Wayne School Corporation. Superintendent Lance Hinshaw confirmed Green was on leave after the district learned of an Indiana State Police investigation into Green. The investigation began last Feb. 12.

Hinshaw has since left the theaters after being issued an expungement by Muncie Circuit Court Judge Matthew Hinkle at the request made by the prosecutor's office.

"Mr. Hicks's predecessor took the only steps available at the time by swiftly placing Mr. Green on administrative leave to prevent his having any in-person contact with students based on the initial and ongoing allegations," said a statement issued Tuesday by Northeastern Wayne Schools.

"The statement indicates that an internal investigation continues and "appropriate action will be taken as a result" of the investigation.

SEE GREEN, Page 2A

'Ready, willing, able' to increase vaccinations

The Wayne County Health Department has been administering 500 coronavirus vaccine doses per week at the former Elder-Beerman building, and is claiming to the state that it has the ability to deliver twice that amount if it receives more doses.

Wayne County asks state to double doses

Mike Emery

Couple accused of robbing 2 men at gunpoint

Mike Emery

RICHMOND — A Richmond couple now has been charged with felonies after two men were accused of gunpoint robbery.

Tabitha Lee Hall, 31, is charged by the Wayne County Prosecutor's Office with armed robbery and aggravated armed robbery as Level 3 felonies and with Level 4 felony possession of narcotics. He remains in the Wayne County Jail on a $50,000 bond that was set when probable cause was found for his charges.

Hall's fiancé, Mikala Dunaway, 21, is charged with Level 3 felony armed robbery. She also remains in jail on a $30,000 bond.

A Level 3 felony conviction carries a standard nine year sentence with a sentencing range of three to six years as established by the Indiana legislature. A Level 4 felony conviction has only one standard

Voice of the Rocky Mountain Empire

THE DENVER POST

WEDNESDAY, JANUARY 27, 2021

COVID-19 VACCINE

Frustrations grow in state

Limited supply, confusion hurting rollout for residents 70 and older

By Jessica Seaman
The Denver Post

Latest modeling: 4,000 lives could be saved if Coloradans can continue social distancing through the end of spring. >5A

HOUSTON CHRONICLE

WEDNESDAY, JANUARY 27, 2021 • HOUSTONCHRONICLE.COM • VOL. 130, NO. 106 • $2.00 ★★

Biden pledges surge in vaccine to states

Push to inoculate 300M by early fall does little to lessen frustration of Texas leaders

By Jonathan Drew and Zeke Miller

President Joe Biden likened his push to boost dosage deliveries to hard-hit states such as Texas to a "wartime effort."

THE PRESS OF ATLANTIC CITY

Phillies re-sign catcher Realmuto

Philadelphia and the two-time All-Star agree on a $115.5 million, five-year contract. B1

IMPEACHMENT DISMISSAL DEFEATED

But the Senate vote shows the trial of former President Donald Trump will not be an easy test C1

ShopRite shifts drug business to CVS

JOSEPH S. BISTEFANO
The Philadelphia Inquirer

Pharmacies in 32 ShopRite stores from Connecticut to Maryland are closing over the next month and sending customers to nearby CVS pharmacies as the drugstore business continues to consolidate into a few giant chains.

ShopRite owner Wakefern Foods Corp., based in Woodbridge Township, Middlesex County, has sold its customer files to the Rhode Island-based CVS Pharmacy drugstore chain and reassigned them to CVS locations.

For example, patients who picked up prescriptions from the ShopRite at 52nd and Parkside in West Philadelphia are being sent to the CVS at 40th and Market streets, nearly two miles away. Customers at an East Falls ShopRite are being sent to a CVS in Manayunk.

The closings include 22 in the Philadelphia area and parts of South Jersey and Delaware, according to a list provided by CVS. An additional 147 ShopRites will still have pharmacists, spokesman Daniel Emmer said.

For years, food markets aggressively added pharmacies to their stores, seeing them as drivers for customers. But the stores have badly been losing them, lacking

'We need supply'

First Lady Tammy Murphy, left, watches AtlantiCare nurse Elnora Ky vaccinate Miriam Ramos, of Pleasantville, on Tuesday at the Atlantic City Convention Center.

N.J. first lady tours Atlantic City mega vaccination site

JEANNELLE BRUNETTI
PRESS
Staff Writer

ATLANTIC CITY — A long, snaking path is roped out on the floor of the exhibit hall in the Atlantic City Convention Center, ready to

and will be there when the supply becomes more available.

One of those mega centers, The Meadowlands Arena site in East Rutherford, Bergen County, closed for a day Tuesday due to a lack of vaccine, officials

SERVING ASHEVILLE SINCE 1870

CITIZEN TIMES

WEDNESDAY, JANUARY 27, 2021 | CITIZEN-TIMES.COM

PART OF THE USA TODAY NE

NC transitioning to mass vaccination sites

North Carolina Gov. Roy Cooper and Donald Spenderprass of Carrboro talk after Spenderprass received a coronavirus vaccine as Gov. Cooper tours a large-scale vaccination site at UNC's Friday Center in Chapel Hill Jan. 13. UNC Hospitals hope to administer 1,500 first COVID-19 vaccine doses at the Friday Center by the end of this week. AP

Move forcing NC health systems to cancel or delay appointments

Bryan Anderson
ASSOCIATED PRESS/REPORTER FOR AMERICA

where nearly 10,000 people were vaccinated over the weekend. Other mass vaccination sites also are opening.

But UNC Health on Monday said the 10,000 doses it will now receive this week is less than half of what it expected, and the less than the 30,000 doses it

Department of Health and Human Services, said in a statement on Monday that supply shortages are fueling the problem.

"So long as we are getting such a small amount of vaccine as a state, there are going to be challenges and

Study reveals PTSD in firefighte

Data: More than 20
likely have disorder

Joel Burgess
USA TODAY NETWORK

ASHEVILLE – More than Asheville firefighters likely ha incalculable number, a st that is causing the emergency to double the crew on all rides and raise job burnout, a recent stu

Presented Jan. 22 to the pa study said barriers to firefight ting treatment for the potenti billating condition range fa concerns to fear of negative co parts, according to data gath 2018. That was seven years a death of Asheville Fire Dep Captain Jeff Brower in a 2013 ho Mission Hospital, an event tha the department.

"It is still hard to have to ta ideally between my health, my and chemical health, rather tha with a job that I fell in love with job that I am passionate ab good at," said former Asheville fighter Bentley Andrews, wh during a comment session of th al presentation.

Andrews said she particip the study then two years la granted unclassified remorse fo for experiencing "severe sleep sation and debilitating anxiety.

The study's recommendat time were decreasing stigm other barriers to treatment creasing supports and resourc

Knoxville NEWS SENTINEL

WEDNESDAY, JANUARY 27, 2021 | KNOXNEWS.COM

PART OF THE USA TODAY NETWORK

Vaccines promised, never delivered

Tenn. leaders say Trump's failure to supply pledged doses slowing down state's progress

Brett Kelman for the Knoxville News Sentinel
USA TODAY NETWORK - TENNESSEE

The Tennessee government at one point reported to get as many as 400,000 coronavirus vaccine doses from the Trump administration's supposed vaccine reserve, which would've been a windfall for a state with untapped distribution capacity and limited supply. Tennessee's top health official confirmed.

Instead, state leaders were stunned earlier this month when it was revealed the federal reserve was empty. Tennessee got no surge of doses from the release of the reserve and, separately, is still waiting for increased vaccine supplies that federal officials promised would start this week, said Health Commissioner Dr. Lisa Piercey.

"We were all under the impression there was this big reserve and they were going to flood the market with it," Piercey told USA TODAY NETWORK - Tennessee. "We had calculated internally, [not informal estimations, that we could get up to 400,000 – like this big [inflat

Inside
Delivered, Walmart and Nissan Stadium may become vaccination sites. 5A

See VACCINES, Page 8A

SunHerald

State 'unconquerable' amid virus, disasters says Reeves

BY EMILY WAGSTER PETTUS
Associated Press

JACKSON

Mississippi is "unconquerable" after a year dominated by the coronavirus pandemic and natural disasters including tornadoes that cut wide paths of destruction last Easter Sunday, Republican Gov. Tate Reeves said in his State

Tate Reeves

of the State speech Tuesday.

Speaking on the south steps of the Capitol, Reeves made a few policy proposals. He renewed his call for eliminating the state's personal income tax and said he would sign a bill to increase teachers' pay. He called on legislators to make "wise investments" in workforce training, although he did not offer specific proposals.

And he vowed that Mississippi will vaccinate people against the coronavirus as quickly as possible.

"We need to crush this virus and get back to our way of life," Reeves said, according to a prepared text of his speech. "The virus is still here, and it cannot be solved by ignoring it. We have to defeat it, because Mississippians are done. We're done burying loved ones who were lost to this virus. We're done with stressed hospitals. We're done with the fearful talk of lockdowns and shutdowns. We're ready for economic again."

Reeves served eight years as state treasurer and eight as lieu-

Brent Myers, a CVS pharmacist, second from left, spoke with residents at the Mississippi State Veterans Home in Jackson on Jan. 9 about receiving the Pfizer COVID-19 vaccination.

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Weekly vaccine allocation remains consistent

Health's

Mississippi has a population of around 2 million.

The department reported Tuesday that Mississippi had 1,452 new confirmed cases of the virus as of Monday evening. The department also reported

Akron Beacon Journal

INFORMING. ENGAGING. ESSENTIAL.

WEDNESDAY, JANUARY 27, 2021 | BEACONJOURNAL.COM

PART OF THE USA TODAY NETWOR

SCHOOLS HOPE TO BEGIN TEACHER VACCINATIONS

Sndre Szentmiklyi teaches a German language class Tuesday at Hardenia High School. The district is working with Summit County Public Health to vaccinate teachers when possible. PHOTOS BY AARON JOSEFCZYK/BEACON JOURNAL

Later curfew could be just ahead

From Staff Reports
Akron Beacon Journal
USA TODAY NETWORK

Ohio's overnight COVID-19 curfe could be eased later or lifted in th coming weeks if hospitalizations co tinue to decline.

The coronavirus patient count h eased significantly in recent weeks i Summit County hospitals and schoo across the state, boosting official hopes that bars and restaurants ca resume longer hours as long as infec tions aren't surging.

Ohio's current curfew, which e tends from 10 p.m. to 5 a.m., ends t weekend. Gov. Mike DeWine could m it back to 11 p.m. to 5 a.m. as soon a Thursday.

DeWine announced that if th

See CURFEW, Page 6A

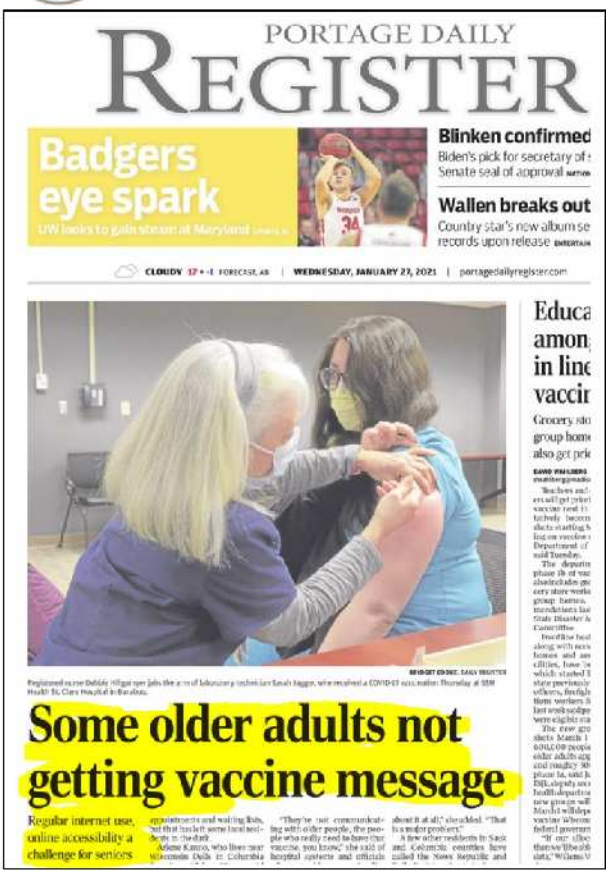
Shortage of doses may delay the vaccine in Summit County districts

Alan Ashworth, Jennifer Pignolet and Krista S. Kano
Akron Beacon Journal

All school employees in Summit County were slated to be first in line in

US to increase vaccine supply

Jonathan Drew and Zeke Miller
ASSOCIATED PRESS



PORTAGE DAILY
REGISTER

Badgers eye spark
UW looks to gain steam at Maryland

Blinken confirmed
Biden's pick for secretary of
Senate seal of approval

Wallen breaks out
Country star's new album se
records upon release

CLOUDY 17 • -1 FORECAST, AB | WEDNESDAY, JANUARY 27, 2021 | portagedailyregister.com

Some older adults not getting vaccine message

Regular internet use, online accessibility a challenge for seniors

The News Leader

SDAY, JANUARY 27, 2021 | NEWSLEADER.COM

PART OF THE USA TODAY NETWORK

THE BUZZ

Quick move

COVID-19 variant found in Virginia

First case of UK B.1.1.7 reported in northern part of state

Monique Calello

From:	Green, Jamilla (CDC/DDID/NCEZID/DPEI)
To:	Byers, Paul; Craig, Jim; Jefferson, Randy (CDC/DDID/NCHHSTP/DSTDP); Ware, Daphne; Vaughn, Wayne
Cc:	CDC IMS 2019 NCOV Response HDTF 4/6 Regional Support TM
Subject:	CDC COVID-19 Weekly Digest of Resources: 1/30 - 2/5
Date:	Monday, February 8, 2021 5:02:45 PM
Attachments:	2021-02-05-Science-Update_Final_Public.pdf ELC_EnhancingDetectionExpansion_FAQs_2Feb2021.pdf Fact Sheet_12-things-jurisdictions-need-to-know-about-vaers_Feb2021.pdf

Good afternoon Mississippi Colleagues,

Here is your weekly digest of CDC resources.

CDC COVID-19 Science Update: See the latest science update, released on 2/5/2021, attached to this email. Previous science updates can be viewed at ***https://www.cdc.gov/library/covid19*.**

MMWR Articles: Below are links to recent COVID MMWR articles

- **February 5, 2021 (Early Release)** Observed Face Mask Use at Six Universities — United States, September–November 2020
- **February 5, 2021 (Early Release)** Decline in COVID-19 Hospitalization Growth Rates Associated with Statewide Mask Mandates — 10 States, March–October 2020
- **February 5, 2021** Sexual Orientation Disparities in Risk Factors for Adverse COVID-19–Related Outcomes, by Race/Ethnicity — Behavioral Risk Factor Surveillance System, United States, 2017–2019
- **February 5, 2021** Decreases in Young Children Who Received Blood Lead Level Testing During COVID-19—34 Jurisdictions, January–May 2020
- **February 5, 2021** Racial and Ethnic Disparities in the Prevalence of Stress and Worry, Mental Health Conditions, and Increased Substance Use Among Adults During the COVID-19 Pandemic — United States, April and May 2020
- **February 5, 2021** Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program — United States, December 14, 2020–January 14, 2021
- **February 5, 2021** Early COVID-19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program — United States, December 2020–January 2021

*Older MMWR COVID-19 Reports can be viewed at
https://www.cdc.gov/mmwr/Novel_Coronavirus_Reports.html

CDC Website Updates: Please find updated CDC website pages for 1/30-2/5

Response Website Updates (1/30/21-2/5/21)
• Cases in the U.S. Friday, February 05, 2021 • Overall US COVID-19 Vaccine Distribution and Administration Update as of Fri, 05 Feb 2021 06:00:00 EST Friday, February 05, 2021 • COVID-19 Science Update released: February 5, 2021 Edition 75 Friday, February 05, 2021 • Vaccination Considerations for Persons with Disabilities Friday, February 05, 2021 • COVID-19 Vaccination for Communities Friday, February 05, 2021 • Requirement for Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States Friday, February 05, 2021

Information for School Nurses and Other Healthcare Personnel (HCP) Working in Schools and Child Care Settings Friday, February 05, 2021

- Guidance for SARS-CoV-2 Point-of-Care Testing Friday, February 05, 2021
- Toolkit for Correctional and Detention Facilities Friday, February 05, 2021
- eCR Now: COVID-19 Electronic Case Reporting Friday, February 05, 2021
- COVID-19 Questions and Answers: For People Who Use Drugs or Have Substance Use Disorder Friday, February 05, 2021
- More Resources about COVID-19 Friday, February 05, 2021
- Protecting Seafood Processing Workers from COVID-19 Friday, February 05, 2021
- Communication Toolkit Friday, February 05, 2021
- Manufacturing Workers and Employers Friday, February 05, 2021
- Meat and Poultry Processing Workers and Employers Friday, February 05, 2021
- COVIDView Weekly Summary Friday, February 05, 2021
- COVID-19 Travel Recommendations by Country Friday, February 05, 2021
- Cases, Data, and Surveillance Friday, February 05, 2021
- Community, Work, and School Friday, February 05, 2021
- CDC Readiness and Planning Tool: To Prevent the Spread of COVID-19 in Primary and Secondary Schools in Low Resource Non-U.S. Settings Thursday, February 04, 2021
- COVID-19 Vaccine Information for Specific Groups Thursday, February 04, 2021
- US COVID-19 Cases Caused by Variants Thursday, February 04, 2021
- Workplaces and Businesses Thursday, February 04, 2021
- Wear Face Masks on Public Transportation Conveyances and at Transportation Hubs Thursday, February 04, 2021
- Federal Register Notice: Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19 Thursday, February 04, 2021
- Investigating the Impact of COVID-19 during Pregnancy Thursday, February 04, 2021
- Toolkit for People with Disabilities Thursday, February 04, 2021
- Print Resources Thursday, February 04, 2021
- How to Protect Yourself & Others Thursday, February 04, 2021
- ACIP Live Meeting Archive - January 27, 2021 Wednesday, February 03, 2021
- Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination Wednesday, February 03, 2021
- Federal Retail Pharmacy Partnership Program for COVID-19 Vaccination FAQs Wednesday, February 03, 2021
- Pharmacies Participating in the Federal Retail Pharmacy Program Wednesday, February 03, 2021
- Global Clinical Mitigation Wednesday, February 03, 2021
- Science Briefs Wednesday, February 03, 2021
- When Vaccine is Limited, Who Gets Vaccinated First? Wednesday, February 03, 2021
- Vaccines Wednesday, February 03, 2021
- Previous COVID-19 Forecasts: Cases Wednesday, February 03, 2021
- COVID-19 Forecasts: Cases Wednesday, February 03, 2021
- COVID-19 One-Stop Shop Toolkits Wednesday, February 03, 2021
- People with Certain Medical Conditions Wednesday, February 03, 2021
- Considerations for Public Beaches Wednesday, February 03, 2021
- Crew Disembarkations through Commercial Travel Wednesday, February 03, 2021
- Previous COVID-19 Forecasts: Hospitalizations Wednesday, February 03, 2021
- COVID-19 Forecasts: Hospitalizations Wednesday, February 03, 2021
- Daily Activities and Going Out Wednesday, February 03, 2021

Operating schools during COVID-19: CDC's Considerations Wednesday, February 03, 2021

- Previous Forecasts of Total Deaths Wednesday, February 03, 2021
- COVID-19 Forecasts: Deaths Wednesday, February 03, 2021
- Community Mitigation Wednesday, February 03, 2021
- Staffing Resources Wednesday, February 03, 2021
- Coronavirus Disease 2019 (COVID-19) Wednesday, February 03, 2021
- What Aircraft Maintenance Workers Need to Know about COVID-19 Wednesday, February 03, 2021
- Information for Health Departments on Reporting Cases of COVID-19 Wednesday, February 03, 2021
- Interim Guidance for Health Departments: COVID-19 Vaccination Implementation for People Experiencing Homelessness Tuesday, February 02, 2021
- Global Community Mitigation Tuesday, February 02, 2021
- New Variant of Virus that Causes COVID-19 Detected Tuesday, February 02, 2021
- Testing and International Air Travel Tuesday, February 02, 2021
- Know Your Travel Risk Tuesday, February 02, 2021
- Know When to Delay your Travel to Avoid Spreading COVID-19 Tuesday, February 02, 2021
- Travel during the COVID-19 Pandemic Tuesday, February 02, 2021
- Returning to Work Tuesday, February 02, 2021
- Research Use Only CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay Real-Time RT-PCR Primers and Probes Tuesday, February 02, 2021
- CDC's Diagnostic Multiplex Assay for Flu *and* COVID-19 and Supplies Tuesday, February 02, 2021
- COVID-19 in Newly Resettled Refugee Populations Tuesday, February 02, 2021
- Agriculture Workers and Employers Tuesday, February 02, 2021
- Test for Past Infection Tuesday, February 02, 2021
- What Airline Catering Kitchen Workers Need to Know about COVID-19 Tuesday, February 02, 2021
- COVID-19 Employer Information for Transit Maintenance Workers Tuesday, February 02, 2021
- What Airline Customer Service Representatives and Gate Agents Need to Know about COVID-19 Tuesday, February 02, 2021
- Use of Masks to Help Slow the Spread of COVID-19 Tuesday, February 02, 2021
- K-12 Schools and Childcare Programs Tuesday, February 02, 2021
- Travelers Returning from Cruise Ship and River Cruise Voyages Tuesday, February 02, 2021
- After You Travel Tuesday, February 02, 2021
- Travel: Frequently Asked Questions and Answers Tuesday, February 02, 2021
- Frequently Asked Questions Tuesday, February 02, 2021
- Travel Tuesday, February 02, 2021
- COVID-19 Graphics and Buttons Monday, February 01, 2021
- Considerations for Public Pools, Hot Tubs, and Water Playgrounds During COVID-19 Monday, February 01, 2021
- Air Travel Toolkit for Airline Partners Monday, February 01, 2021
- Road Travel Toolkit for Transportation Partners Monday, February 01, 2021
- General Business Frequently Asked Questions Monday, February 01, 2021
- What to Know About HIV and COVID-19 Monday, February 01, 2021
- Information for Laboratories about Coronavirus (COVID-19) Monday, February 01, 2021
- Information for Healthcare Professionals about Coronavirus (COVID-19) Monday, February 01, 2021
- What Paratransit Operators Need to Know about COVID-19 Saturday, January 30, 2021
- What Transit Station Workers Need to Know about COVID-19 Saturday, January 30, 2021
- What Bus Transit Operators Need to Know about COVID-19 Saturday, January 30, 2021

What Rail Transit Operators Need to Know about COVID-19 Saturday, January 30, 2021

- Personal and Social Activities Saturday, January 30, 2021
- Protect Yourself When Using Transportation Saturday, January 30, 2021
- How to Select, Wear, and Clean Your Mask Saturday, January 30, 2021
- How to Wear Masks Saturday, January 30, 2021
- What Rideshare, Taxi, Limo, and other Passenger Drivers-for-Hire Need to Know about COVID-19 Saturday, January 30, 2021

*Daily website updates are now viewable at https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html

Updates on the Federal Retail Pharmacy Program for COVID-19 Vaccination

The initial phased implementation of the program will begin with select retail pharmacies administering COVID-19 vaccine across the country as early as Thursday, February 11. The program will be implemented incrementally, based on the available supply of COVID-19 vaccines. As the vaccine supply increases, the program aims to expand the number of participating pharmacy locations ultimately providing COVID-19 vaccines in all 40,000 retail pharmacy locations nationwide. Allocations to support the Federal Retail Pharmacy Program are separate from weekly allocations provided to jurisdictions. What jurisdictions see in their weekly allocation will remain stable.

Eligibility Criteria for Vaccination

The Federal pharmacy partners will administer vaccine to individuals according to state-selected eligibility criteria. Pharmacy partners have developed screening questionnaires specific to each jurisdiction's criteria and will finalize them based on the survey results to help ensure eligibility prior to vaccination. After launch, immunization program managers will be able to update eligibility criteria weekly using an application in Tiberius, the centralized system used by the federal government to support vaccine distribution efforts. Information about how to use this new Tiberius application will be sent to immunization programs this week.

Program Data and Monitoring

By Friday, CDC will provide a list of the retail locations that will be providing COVID-19 vaccine in each jurisdiction as part of the initial phased implementation of the program.

All pharmacy partners enrolled in the Federal Retail Pharmacy Program are required to report inventory daily to VaccineFinder and patient administration information to the jurisdiction's IIS as well as directly to CDC's Data Clearing House. Jurisdictions will have access to patient administration data submitted by all pharmacies in their jurisdiction. Jurisdictions will also have access to information in Tiberius-specific to pharmacy programs.

Information will include details on stores that will be receiving vaccine, store-level supply information, and administration/uptake information as it becomes available. Jurisdictions will also be provided points of contacts for pharmacy partners to facilitate coordination with partners.

Communications Support

CDC has developed a **toolkit of materials** to help jurisdictions and partners describe and

communicate about the implementation of the Federal Retail Pharmacy Program. We hope these materials will assist in providing clear and consistent information about the program goals and parameters.

The toolkit includes the attached materials for your use and reference:

- Frequently Asked Questions about the Program for Jurisdictions and Pharmacy Partners
- Key communication messages for jurisdictions and pharmacy partners
- A One-Page Fact Sheet on the Federal Retail Pharmacy Program (to share with partners or members of the community)

Upcoming Trainings/Webinars/Jurisdictional Calls

- Below is a link to a series of accredited education about COVID-19 vaccine in general, safety, and administration considerations.
    - Vaccine Courses, Broadcasts, Webcasts and Self Study Training | CDC
- Tiberius users can access the training video on submitting transfer requests at the following link: https://protect-ows.hhs.gov/workspace/compass/view/ri.compass.main.folder.c95b290c-2561-4cd1-85f7-e31dac51d34b [protect-ows.hhs.gov

Upcoming NACCHO Webinars:

Tuesday, February 9 at 12 pm ET: COVID-19 Action in the Biden Era: A Fireside Chat with Dr. Fauci

Upcoming CDC Foundation Webinar:

February 24 at 1:00-2:00 pm EST - Updates and Resources from CDC and Ad Council

During this session,

- Anne Schuchat, principal deputy director at the CDC, will provide an update on vaccine distribution.
- A representative from the Ad Council will present messaging content and guidance for local public health officials
- Judy Monroe, president, and CEO of the CDC Foundation, will moderate an audience Q&A.

Georgia Tech Center for Design and Inclusive Innovation Webinar:

February 10 at 2:00 pm EST

- Guidance for Businesses and Employers Considering the Needs of People with Disabilities during COVID-19

CDC COVID-19 Partner Update Webinar

- COVID-19 Information for Essential Workplaces
- February 8 at 3:00 PM ET

NEW Pharmacy/LTCF Office Hours

- Office Hours will now be held twice a week on Tuesdays and Fridays from 4 - 4:30 pm ET. Please find the call-in information below:

Microsoft Teams meeting

Join on your computer or mobile app

Click here to join the meeting

Or call in (audio only)

+1 404-718-3800,,561828018# United States, Atlanta
(888) 994-4478,,561828018# United States (Toll-free)
Phone Conference ID: 561 828 018#
Find a local number | Reset PIN
Learn More | Meeting options

Upcoming National Vaccine Advisory Committee (NVAC) Meeting

- February 4-5, 1:00-5:45 PM
- Live webcast link and agenda found here

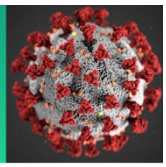
COVID-19 Resources

- Vaccine Confidence Consultations from Vaccine Task Force
  - This email serves as an entry point to many vaccine confidence consultation options offered by CDC. Vaccine confidence and communications experts will receive emails from providers and public health professionals and then set up brief calls to understand needs, tailor support, and provide further technical assistance in data collection, creation of communication products and more to promote community vaccine confidence for COVID-19 vaccines. They can be contacted at confidenceconsults@cdc.gov
- ELC Enhancing Detection Expansion FAQ (attached)
  - Developed by the ELC Team, this FAQ answers common questions about Enhancing Detection Expansion funding for jurisdictions. More information can be found on the ELC Website.
- Factsheet: 12 Things Jurisdictions Need to Know about VAERS (attached)
  - A factsheet developed by VTF on how to report adverse events following vaccination to the Vaccine Adverse Events Reporting System (VAERS)
- The COVID State-Profiles Report (aka Governors Report) is now posted publicly at COVID Data Tracker, and will be updated weekly. As a reminder, Community Profile Report has been posted publicly since December, and is updated daily. There is also a public facing version of the **T**herapeutics Distribution Location Tool**.**
- COVID-19 Vaccination Communication Toolkits for Community- Based Organizations and Essential Workers
  - COVID-19 vaccines will be available to essential workers and other community members soon. CDC has designed two toolkits to help build confidence in this new vaccine. The toolkits will help community-based organizations (CBOs) and employers to educate community members and workers about COVID-19 vaccines, raise awareness about the benefits of vaccination, and address common questions and concerns.

Thank you,

Jamilla Green, DrPH, MPH, CPH
Health Department Liaison (Region 4: KY, MS)
Health Department Section
State, Tribal, Local, and Territorial Support Task Force
COVID-19 Emergency Response
Centers for Disease Control and Prevention
qwq7@cdc.gov

COVID-19 Science Update



From the Office of the Chief Medical Officer, CDC COVID-19 Response, and the CDC Library, Atlanta, GA.
Intended for use by public health professionals responding to the COVID-19 pandemic.

***** Available on-line at https://www.cdc.gov/library/covid19 *****

Section headings in the COVID-19 Science Update align with the CDC Science Agenda for COVID-19.

Detection, Burden, and Impact

PEER-REVIEWED

Antigen-based testing but not real-time polymerase chain reaction correlates with severe acute respiratory syndrome coronavirus 2 viral culture. Pekosz *et al.* Clinical Infectious Diseases (January 20, 2021).

Key findings:

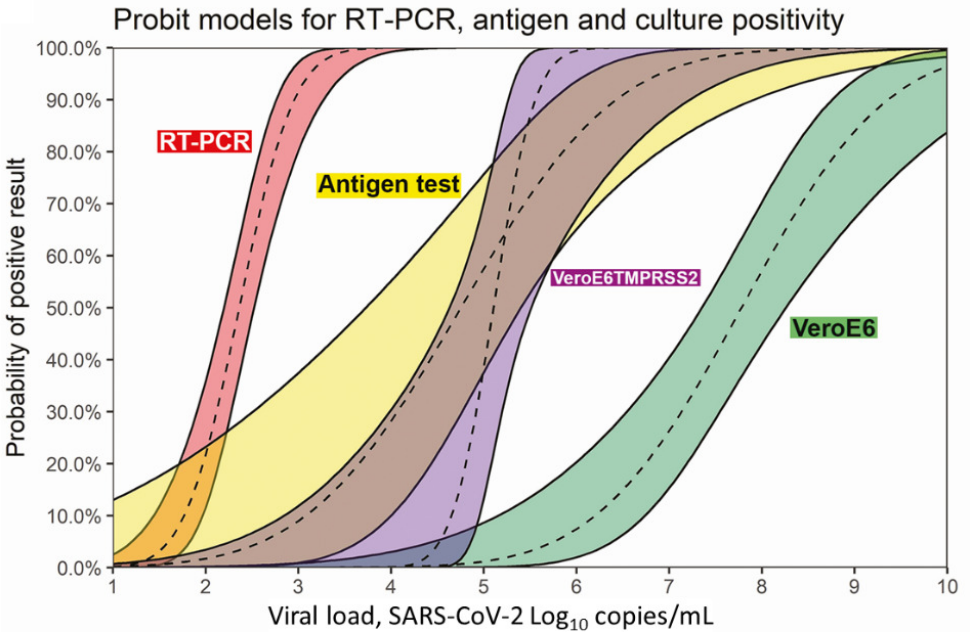
- The BD Veritor antigen test had a higher positive predictive value (PPV) (90.0%, 95% CI 76.3%-97.6%) than the Quidel Lyra RT-PCR SARS-CoV-2 test (73.7%, 95% CI 60.8%-85.3%) relative to positive viral culture.
- Viral culture using VeroE6TMPRSS2 cells, which are susceptible to infection by influenza and coronaviruses, correlated better with antigen tests compared with VeroE6 cells (Figure).

Methods: RT-PCR and antigen tests were compared with SARS-CoV-2 viral cultures from 38 adult patients sampled within 7 days of symptom onset across 21 US localities in June 2020. Probability of positivity and viral loads were fit with probit models for each testing method. *Limitations*: Correlations may be valid only for samples taken within 7 days from symptom onset; small sample of symptomatic adults.

Implications: Point-of-care antigen tests might minimize the spread of SARS-CoV-2 by identifying infectious adults in areas of high community transmission.

MS-DOH-21-1816-A-001578

Figure.



Note: Adapted from Pekosz *et al.* Modelled probability distributions of each SARS-CoV-2 test type, **RT-PCR**, **antigen**, and viral cultures (**VeroE6TMPRSS2** and **VeroE6**), across log-transformed viral load. As viral load increases, the probability of any test producing a positive result increases. Licensed under CC BY-NC-ND 4.0.

PREPRINT (NOT PEER-REVIEWED)

Predictive power of SARS-CoV-2 wastewater surveillance for diverse populations across a large geographical range. Melvin *et al.* medRxiv (January 25, 2021).

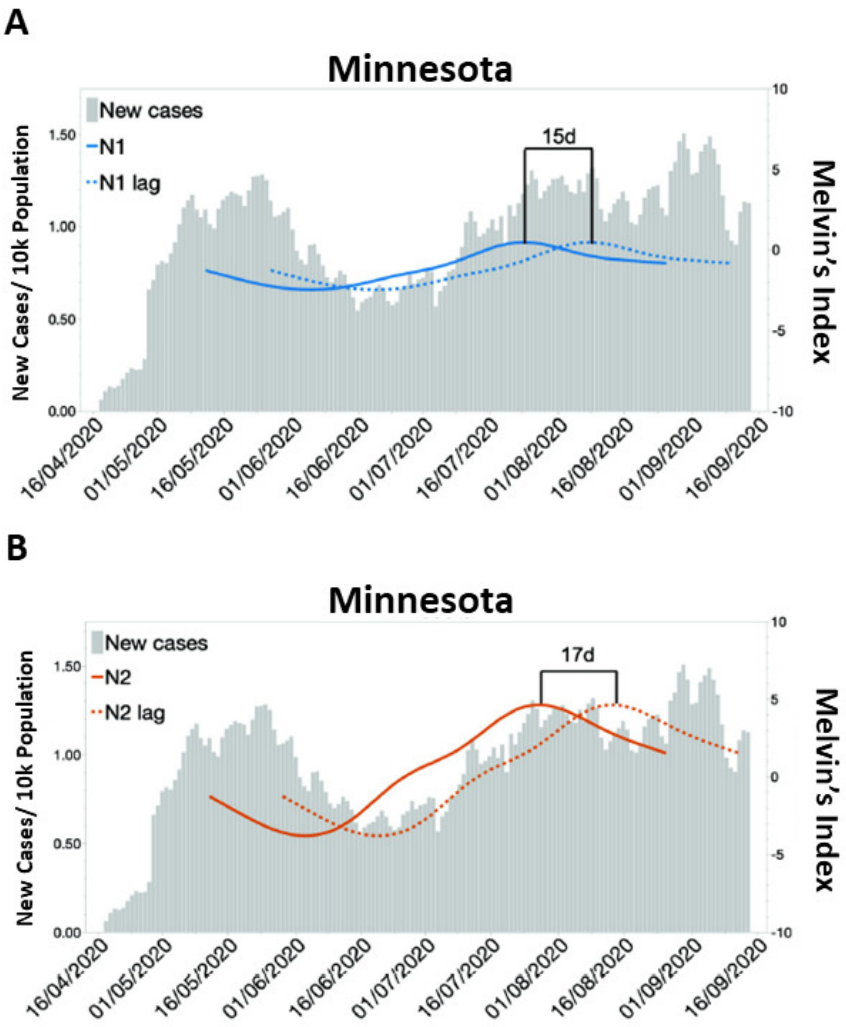
Key findings:

- In Minnesota, wastewater SARS-CoV-2 RNA levels, using RT-PCR to amplify 2 nucleocapsid gene targets (N1 and N2), predicted new clinical cases with a lag of 15 days for N1 ($r = 0.73$, $p < 0.001$) and 17 days for N2 ($r = 0.77$, $p < 0.001$) (Figure).

Methods: Compared Minnesota Department of Health COVID-19 case data with indexed SARS-CoV-2 RNA levels in municipal wastewater from 19 Minnesota cities in summer 2020. Developed a novel index (Melvin's Index) of wastewater SARS-CoV-2 viral load, standardized based on a plant virus that is abundant in human feces, to control for factors such as treatment facility capacity, flow rate, and population size. Successively lagged Melvin's Index values in 1-day increments to find the lag time (between observing an increase in SARS-CoV-2 RNA in wastewater and the appearance of confirmed new COVID-19 positive tests) that maximized correlation (r) between Melvin's Index and new confirmed cases. *Limitations*: Variations in clinical SARS-CoV-2 testing might affect correlation with population wastewater viral load.

Implications: Wastewater surveillance for SARS-CoV-2 might allow early detection of local outbreaks, especially where access to healthcare services is limited. A study in Barcelona found SARS-CoV-2 was detected in sewage collected 41 days before the first COVID-19 case.

Figure.



Note: Adapted from Melvin *et al*. Correlation and lag analysis of wastewater SARS-CoV-2 levels with new COVID-19 clinical cases in Minnesota. **A)** Indexed **N1 levels in real time** and **transposed (dotted line)** to show lag (15 days) to clinical case reports **B)** **N2 levels in real time** and **transposed (dotted line)** to show lag (17 days) to clinical case reports. Licensed under CC BY-ND 4.0.

Transmission

PEER-REVIEWED

Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence. Sabino *et al.* Lancet (January 27, 2021).

Key findings:

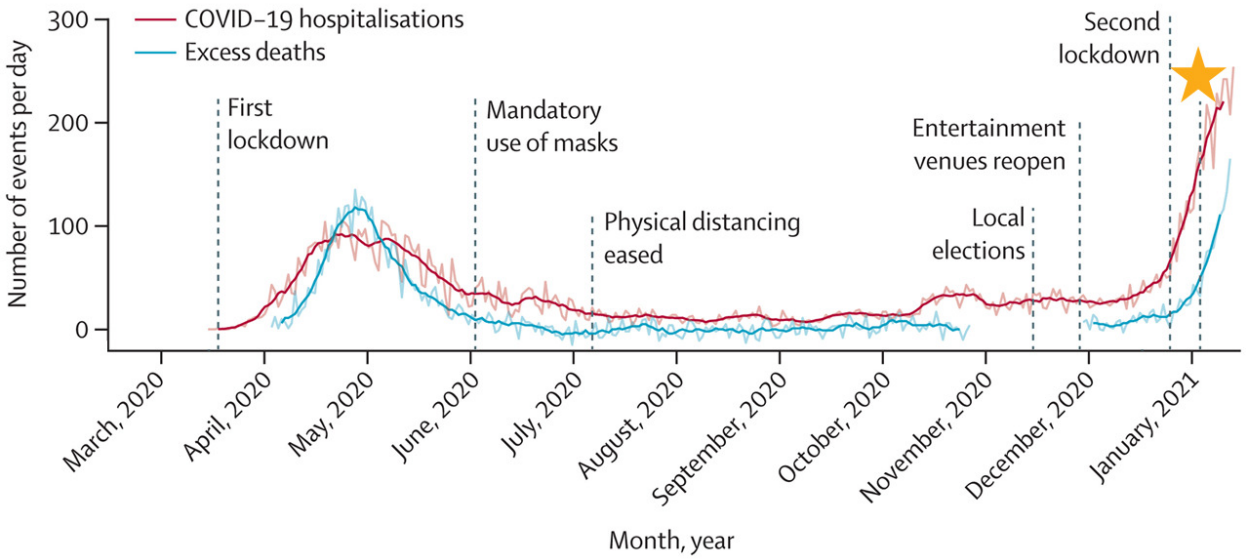
- Manaus, Brazil experienced a sharp rise in COVID-19 hospitalizations in January 2021 despite extensive transmission earlier in the pandemic and rates that had been stable and low for 7 months during relaxed COVID-19 mitigation (Figure).
- There are 4 possible explanations for the surge.
    - Greater mixing of susceptible and infected persons in December 2020.

- Waning immunity in the population.
- Circulating variants, specifically B.1.1.7 (501Y.V1) and P.1 with the E484K mutation, evading immunity.
- New variants being more transmissible.

Methods: COVID-19 hospitalizations, excess deaths, and real-time effective reproductive numbers were assessed from the literature and qualitatively compared monthly from March 2020 to January 2021 in Manaus, Brazil. *Limitations*: Associations were not directly estimated.

Implications: New variants of SARS-CoV-2 might demonstrate changes in transmissibility and/or virulence and could lead to a resurgence of COVID-19 despite high reported seroprevalence. In Rio Grande do Sul, another state in Brazil, da Silva Francisco *et al.* found wide circulation of the B.1.1.28 variant, with the E484K mutation, co-infection of variants, and new emerging variants. These findings stress the importance of tracking circulating viruses and of reaffirming COVID-19 mitigation measures.

Figure.



Note: Adapted from Sabino *et al.* Smoothed COVID-19 **hospitalizations** and **excess deaths** since March 2020 in Manaus, Brazil. Key mitigation events are marked with dotted lines. The gold star indicates the first detection of P.1 variant. Reprinted from The Lancet, Vol. 397 number 10273, Sabino *et al*, Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence., Pages 452– 455, Copyright (2021), with permission from Elsevier.

Natural History of SARS-CoV-2 Infection

PREPRINTS (NOT PEER-REVIEWED)

SARS-CoV-2 seropositivity and subsequent infection risk in healthy young adults: a prospective cohort study. Letizia *et al.* medRxiv (January 29, 2021).

Key findings:

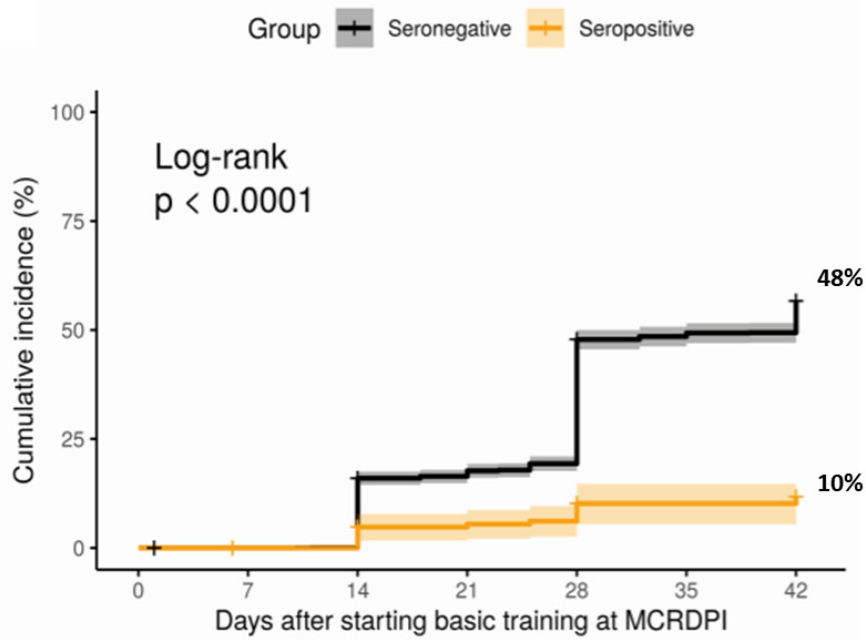
- Although seropositivity conferred an 82% reduced incidence rate, 10.1% of 189 seropositive participants had ≥1 positive RT-PCR test for SARS-CoV-2 (compared with 48.0% of 2,247 seronegative participants) (Figure).

  - Among those infected, seropositive participants had only a modest, approximately 10-fold decrease in nares virus load compared with seronegative participants.
- Among seropositive participants
  - New infection was associated with significantly lower baseline full-length spike protein IgG titers.
  - Baseline neutralizing titers were detected in 83.3% of the first 54 participants who never became PCR positive compared with 31.6% of the 19 infected participants.

Methods: Prospective 6-week observational study of 3,249 predominantly male, 18–20-year-old Marine recruits, who underwent baseline 2-week supervised quarantine and SARS-CoV-2 RT-PCR and IgG antibody testing. Serial RT-PCR testing was conducted and questionnaires on development of symptoms were completed during and after quarantine. *Limitations*: Overall high attack rate might not be generalizable to other populations and settings; unknown when seropositive participants were initially infected.

Implications: Although persons with SARS-CoV-2 antibodies are largely protected, subsequent infection is possible for some persons due to lack of sterilizing immunity. Some re-infected individuals could have a similar capacity to transmit virus as those infected for the first time.

Figure.



Note: Adapted from Letizia *et al*. SARS-CoV-2 PCR positive incidence curves during the six-week follow-up period among baseline **seropositive** and **seronegative** groups. Licensed under CC BY 4.0.

Kinetics and correlates of the neutralizing antibody response to SARS-CoV-2. Vanshylla *et al.* bioRxiv (January 26, 2021).

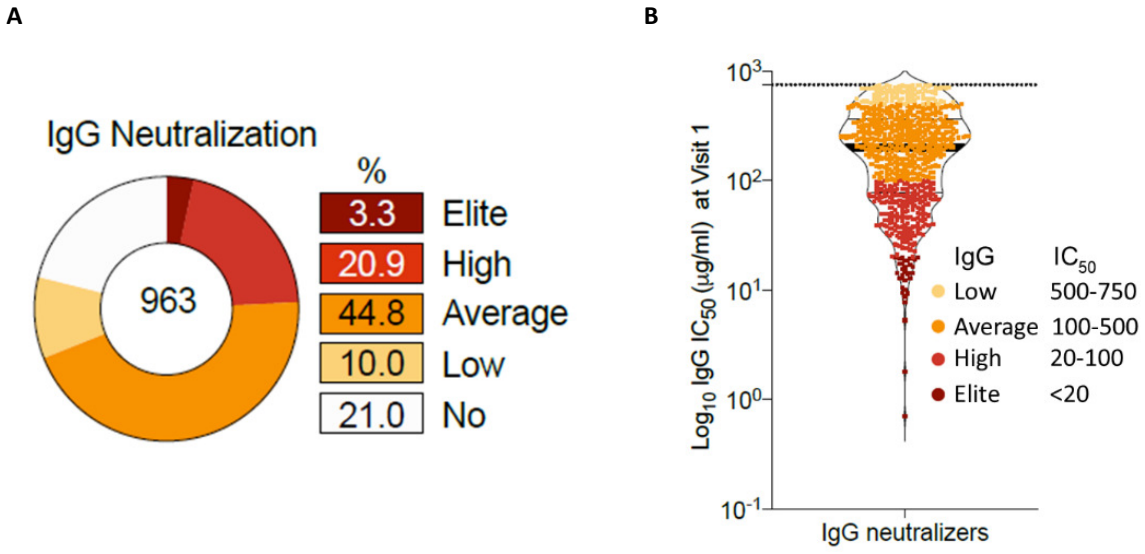
Key findings:

- 82% of individuals developed serum, and 79% IgG, neutralizing antibodies (NAb) to SARS-CoV-2.
- Neutralizing activity was highly variable, ranging from 3% who were initially 'elite' neutralizers, with a 50% Inhibitory Concentration [IC_{50}] of <20 µg/ml of IgG, to 21% who had no neutralizing activity (Figure).
- Higher anti-spike IgG levels, older age, time since disease onset, and fever during acute infection were predictors of SARS-CoV-2 neutralizing activity in mild courses of COVID-19.
- NAb had an initial half-life of 7 weeks in serum and 31 weeks in IgG titer samples.

Methods: NAb responses to SARS-CoV-2 were examined in 963 persons recently recovered from (mostly) mild COVID-19, during up to 4 follow-up visits between April 6 and December 17, 2020. Statistical modeling was used to infer antibody decay rates and to build a prediction model to evaluate how clinical features correlate with NAb titers. *Limitations:* Loss to follow up may bias results.

Implications: Although NAb can persist for up to 10 months after infection, persons who recover from mild COVID-19 illness have a broad spectrum of neutralizing activity which might affect protective immunity at a population level.

Figure.



Note: Adapted from Vanshylla *et al*. **(A)** Donut chart depicts the initial fraction of persons who developed NAb at study visit 1. **(B)** Violin plot depicts IgG IC_{50} values for the persons who developed neutralizing antibodies (n=760), categorized by IgG IC_{50}: **low** (IC_{50} >500-750 µg/ml), **average** (IC_{50} >100-500 µg/ml), **high** (IC_{50} 20-100 µg/ml), **and elite** (IC_{50} <20 µg/ml). Dotted line represents the limit of detection of the assay. Used by permission of authors.

Protection in Healthcare and Non-Healthcare Work Settings

PREPRINT (NOT PEER-REVIEWED)

Strategies to minimize SARS-CoV-2 transmission in classroom settings: combined impacts of ventilation and mask effective filtration efficiency. Rothamer *et al.* medRxiv. (January 4, 2021).

Key findings:

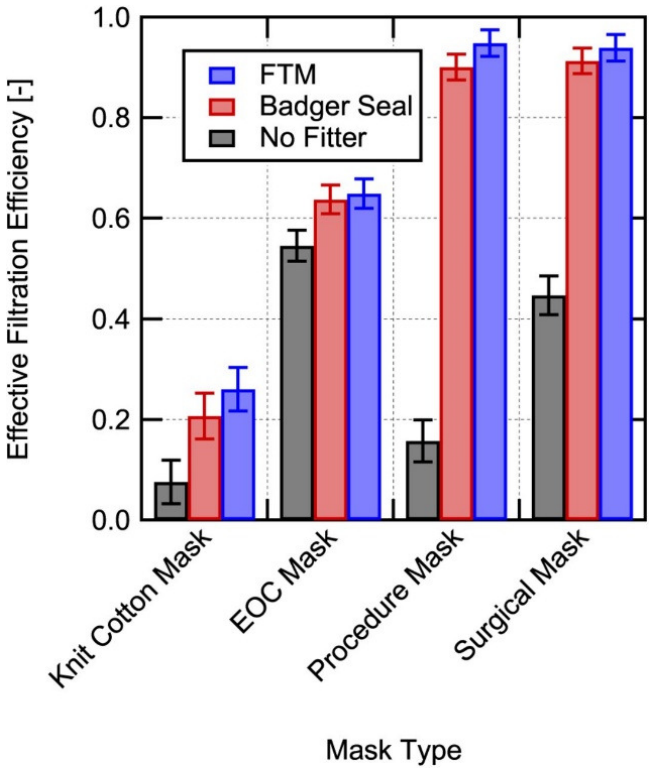
- Filtration efficiencies of four masks tested ranged from 7.5% to 54.5%.
- The addition of mask fitters, devices to improve the seal of a mask, increased filtration efficiency from 20.6% to 91.3% (Figure).
- Ventilation alone did not substantially reduce infection risk.

Methods: A simulation study to evaluate ventilation and mask filtration efficiency of non-medical grade masks, with and without mask fitters, on aerosol transmission in a classroom setting using CPR manikins fitted with aerosol-releasing tubing. Two mask fitters were tested, Badger Seal and Fit the Mask (FTM), using 4 masks: 1) a commercial 4-ply knit cotton mask, 2) a 3-ply polypropylene mask, 3) a 3-ply disposable procedure mask, and 4) a

surgical mask. *Limitations*: Potential overestimation of mask efficacy because manikins were fitted to minimize leakage; simulation might not represent real-world settings.

Implications: All non-medical grade masks are prone to leakage; however, the use of mask fitters can significantly reduce aerosol transmission of SARS-CoV-2 in a classroom setting. Gandhi *et al.* hypothesized that the use of multi-layered, well-fitting masks could achieve >90% efficiency at reducing aerosol transmission.

Figure.



Note: Adapted from Rothamer *et al*. Overall effective filtration efficiency for inhalation for 4 masks by fitter status (with **no mask fitter**, with the **Badger Seal mask fitter**, with the **Fit the Mask (FTM) mask brace**). Licensed under CC BY-ND 4.0.

Prevention, Mitigation and Intervention Strategies

PEER-REVIEWED

Model-informed COVID-19 vaccine prioritization strategies by age and serostatus. Bubar *et al.* Science (January 21, 2021).

Key findings:

- Prioritizing adults ≥60 years old shows the greatest reduction in mortality and years of life lost (YLL) after accounting for country-specific age structure, age-contact structure, infection fatality rates, seroprevalence, and age-varying efficacy of vaccine.
- Prioritizing adults aged 20–49 years old minimizes cumulative incidence but is only superior at minimizing deaths when R_0 = 1.15 and vaccine efficacy is ≥80% or vaccine rollout is ≤0.2%, or when vaccine efficacy is lower in older adults (≥60 years old) compared to individuals <60 years.
- Prioritizing seronegative individuals provides the greatest benefit where seroprevalence is high.

Methods: A mathematical model quantified the impact of five age-stratified COVID-19 vaccine prioritization strategies on cumulative incidence, mortality and YLL. *Limitations*: Model assumptions limit generalizability; disease severity is considered by age only.

Implications: Pairing vaccination with serological testing of individuals may be a useful strategy for prioritization of limited vaccine supplies and to reach vulnerable populations.

PREPRINTS (NOT PEER-REVIEWED)

mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. Wu *et al.* bioRxiv (January 25, 2021).

Key findings:

- Moderna mRNA-1273 vaccine was able to neutralize all known strains of SARS-CoV-2.
    - Full neutralization was still achieved despite diminished neutralizing responses against the B.1.351 (South Africa) variant, with the E484K mutation, because neutralizing titers remained relatively high (1:290).
    - No significant differences in neutralizing antibody titers against B.1.1.7 (UK), 20E, 20A.EU2, DG614-N439K, or mink cluster 5, variants were detected.

Methods: Neutralization assays using pseudovirus expressing SARS-CoV-2 spike protein mutations found in major current variants were used to determine the neutralizing capacity of sera from 8 human subjects and 12 non-human primates vaccinated with the Moderna mRNA-1273 vaccine. Neutralization was compared to the neutralization observed against D614G, the dominant strain of 2020. *Limitations*: Small sample size; P.1 variant was not included.

Implications: Moderna mRNA-1273 vaccine appears to be effective against both the UK and South African SARS CoV-2 variants. However, further studies are warranted to substantiate these findings.

The effectiveness of the first dose of BNT162b2 vaccine in reducing SARS-CoV-2 infection 13-24 days after immunization: real-world evidence. Chodick *et al.* medRxiv (January 29, 2021).

Key findings:

- The cumulative incidence of SARS-CoV-2 infection was 0.57% (n=2,484) during days 1-12 and 0.27% (n=614) during days 13-24 following the first dose of the BNT162b2 mRNA COVID-19 vaccine.
- There was a 51.4% reduction in the weighted average daily incidence of SARS-CoV-2 infection at days 13–24 after the first dose (21.8 per 100,000 population), compared to days 1–12 (43.41 per 100,000 population).

Methods: A retrospective cohort study of 503,875 individuals aged ≥16 years old in Israel estimated the effectiveness of the first dose of the BNT162b2 vaccine administered from December 19, 2020 to January 15, 2021. Daily and cumulative infection rates during days 13-14 were compared to days 1-12 after the first dose using generalized linear models. *Limitations*: Unreported vaccinations might bias results.

Implications: Based upon temporal incidence, the BNT162b2 vaccine (Pfizer-BioNTech) is approximately 51% effective at reducing the risk of SARS-CoV-2 infection at 13 to 24 days following the first dose.

In Brief

Detection, Burden, and Impact

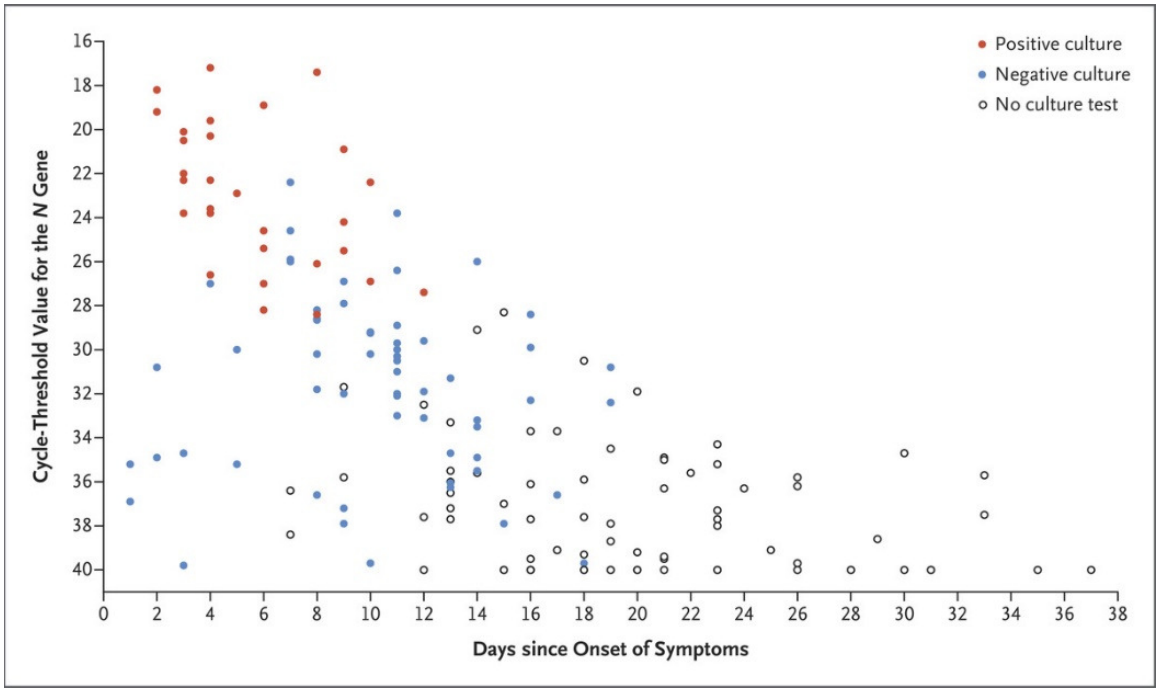
- Lowe *et al.* **Association of smoking and cumulative pack-year exposure with COVID-19 outcomes in the Cleveland Clinic COVID-19 registry.** JAMA Internal Medicine. (January 25, 2021). Of 7,102 adults with COVID-19 in the Cleveland Clinic COVID-19 registry between March 8 and August 25, 2020, 341 persons who smoked >30 pack-years had higher odds of hospitalization and death, although the odds were attenuated with inclusion of comorbidities; these data demonstrate an apparent dose-dependent relationship between smoking and adverse COVID-19 outcomes.

- Ehrenberg *et al.* **Launching a saliva-based SARS-CoV-2 surveillance testing program on a university campus.** medRxiv (Preprint, January 26, 2021). Describes a successful university-based surveillance system using saliva-based testing for SARS-CoV-2 among 3,653 persons to identify asymptomatic and pre-symptomatic cases and prevent outbreaks.

Natural History of SARS-CoV-2 Infection

- Kim *et al.* **Duration of culturable SARS-CoV-2 in hospitalized patients with COVID-19.** NEJM (January 27, 2021). Based on all 2-day RT-PCRs and viral cultures among 21 hospitalized patients with COVID-19, the median duration of shedding of viable virus was approximately 7 days (95% CI 5-10).

Figure.



Adapted from Kim *et al.* Timing of presence or absence of viable SARS-CoV-2 on viral culture and Ct values for 165 serial samples. Viral loads were determined with the Ct value for the *N* gene of SARS-CoV-2. Each circle represents a sample obtained on the specified day. Viral culture was either **positive** or **negative**. DOI: 10.1056/NEJMc2027040. Copyright © (2021) Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

- Al-Samkari et al. **Thrombosis, bleeding, and the observational effect of early therapeutic anticoagulation on survival in critically ill patients with COVID-19.** Annals of Internal Medicine (January 26, 2021). In a multi-center, observational cohort study of 3,239 critically ill patients admitted between March 4 and April 11, 2020, early therapeutic anticoagulation did not affect in-hospital survival.

- Starr *et al.* **Prospective mapping of viral mutations that escape antibodies used to treat COVID-19.** Science (January 25, 2021). Mapping of viral mutations to SARS-CoV-2 receptor binding domain showed that a single amino acid mutation (E406W) escapes the two monoclonal antibody REGN-CoV2 cocktail.

- Rappazzo *et al.* **Broad and potent activity against SARS-like viruses by an engineered human monoclonal antibody.** Science (January 25, 2021). An engineered human monoclonal antibody demonstrated neutralization potency similar to neutralizing antibodies currently in clinical use providing significant protection against COVID-19 in mouse models.

- Nemani *et al.* **Association of psychiatric disorders with mortality among patients with COVID-19.** JAMA (January 27, 2021). In a retrospective cohort study of 7,348 patients with confirmed COVID-19 at 4 acute care hospitals in New York City from March 3 to May 31, 2020, persons with schizophrenia had significantly increased odds of 45-day mortality.

- Alam *et al.* **An interactive COVID-19 virus mutation tracker (CovMT) with a particular focus on critical mutations in the receptor binding domain (RBD) region of the spike protein.** medRxiv (Preprint, January 25, 2021). As new SARS-CoV-2 variants emerge with increased transmissibility and potential immune escape, it is important to monitor sequencing efforts and evolution of mutations. These authors developed a global mutation tracker that is updated daily and includes clinical data.

Protection in Healthcare and Non-Healthcare Work Settings

- Moghadas *et al.* **Evaluation of COVID-19 vaccination strategies with a delayed second dose.** medRxiv (Preprint, January 29, 2021). Based on an assumed 80% efficacy after the first dose, modelling showed that delaying the second dose of the Moderna vaccine by 9-12 weeks could reduce infections, hospitalizations, and deaths. However, for the Pfizer-BioNTech COVID-19 vaccine, with an assumed 52% efficacy after the first dose, there was no clear advantage to delaying the second dose due to waning immunity.

Prevention, Mitigation, and Intervention Strategies

- Crane *et al.* **Change in reported adherence to nonpharmaceutical interventions during the COVID-19 pandemic, April-November 2020.** JAMA (January 22, 2021). National survey responses from 7,705 participants between April 1 and November 24, 2020, showed a decrease in adherence to nonpharmacological interventions indicating "pandemic fatigue; however, there was in increase in self-reported mask-wearing which may reflect improved public health messaging.

Social, Behavioral, and Communication Science

- Ayers *et al.* **Suicide-related internet searches during the early stages of the COVID-19 pandemic in the US.** JAMA Network Open (January 21, 2021). Google searches related to suicide between January 1 and July 5, 2020, showed a decline after a national emergency was declared in March 2020. This decline was likely due to increased social support, called the "pulling together" phenomenon, often associated with catastrophes.

Disclaimer: The purpose of the CDC COVID-19 Science Update is to share public health articles with public health agencies and departments for informational and educational purposes. Materials listed in this Science Update are selected to provide awareness of relevant public health literature. A material's inclusion and the material itself provided here in full or in part, does not necessarily represent the views of the U.S. Department of Health and Human Services or the CDC, nor does it necessarily imply endorsement of methods or findings. While much of the COVID-19 literature is open access or otherwise freely available, it is the responsibility of the third-party user to determine whether any intellectual property rights govern the use of materials in this Science Update prior to use or distribution. Findings are based on research available at the time of this publication and may be subject to change.

cdc.gov/coronavirus

ELC Enhancing Detection Expansion

Questions & Answers

As of February 2, 2021

All questions are hyperlinked to their respective answers below; click on a question to be brought to its answer. Click on 'ELC Enhancing Detection Expansion' at the bottom of each page to be brought back to the start of the document. Appendices available at the end which include allowable expense comparisons between ELC Enhancing Detection Expansion and Immunization VFC Supplemental Funding.

Budget and Allowable Costs

1. Is there a budget template?
2. What are examples of some costs not allowed in Enhancing Detection (ED) Expansion?
3. Can we use the funds to pay for activities done in months before the grant was awarded?
4. Can funding be used to support providers with Electronic Laboratory Reporting (ELR) or telemedicine technology to enhance testing?
5. Can funding be used to purchase vaccines?
6. When submitting a revised budget as an amendment, do you have to submit other forms?
7. Can resources be used for quarantine/isolation-related costs?
8. When setting up and operating pop-up testing sites, what types of expenses are allowable through ED Expansion?
9. If a recipient's partners and community providers meet the testing goal and need to provide additional supplies/resources for expanded testing, what costs are allowable through ELC Enhancing Detection Expansion?
10. Are funds intended to support activities for the duration of the 30-month period? For example, if a jurisdiction liquidates all their funds prior to the end of the 30 months, are they still required to continue activities in the guidance until the end of the 30 months?
11. If a jurisdiction liquidates most or all funds towards supporting a few activities in the workplan, are they still required to complete the remaining activities?
12. Can ELC ED Expansion funds be used to cover the costs of COVID-19 testing?
13. When reporting the monthly expenses in the REDCap Financial Reporting page, what are 'unliquidated obligations' and how do they differ from expenses?
14. Am I required to have prior approval (redirection/contract approval) before I can use the funds that were placed in the "Other" cost category of my ELC ED Expansion Notice of Award (NOA) for COVID-19 response activities?
15. The Notice of Award for ELC ED Expansion has a budget period from August 1, 2020, to July 31, 2023; does this mean that contracts and other acquisitions using ELC ED Expansion funds cannot go past July 31, 2021?
16. How does expanded authority work for the supplemental COVID-19 funds?
17. May social services be supported with ED Expansion funds?
18. Can ELC ED Expansion funding be used to purchase vehicles, including mobile testing vans?
19. Can ELC ED Expansion funding be used for renovations and minor construction costs?
20. Can recipients request more than the recommended "1 program manager, 1 budget staff" in the budget?
21. With this new funding opportunity, and the allowance of covering existing core staff's percent of work redirected to COVID-19 activities, what happens to our (base) core ELC funding?
22. Are recipients able to start spending funds, before revised budgets are approved?
23. Now that workplans are being combined into ED Expansion for ELC CARES and Enhancing Detection, will financial reporting be bundled as well?

Workforce Capacity:

24. If the health department has previously reached the personnel/hiring cap in their jurisdiction, should this be addressed or acknowledged in the budget?

ELC Enhancing Detection Expansion Testing & Testing Plan Template:

25. Can you confirm that the target coverage for our testing projections is 2% of population each month?

26. What level of continued federal support can recipients expect for laboratory testing (e.g., provision of specimen collection and testing kits) as the COVID-19 response evolves?
27. Is the laboratory test order and reporting activity required?

Advance Electronic Data Exchange at Public Health Labs:

28. Is the laboratory test order and reporting activity required?
29. I cannot find the ED Expansion performance measures, where are they located?
30. What elements are needed in the line level testing data reporting to CDC?
31. Will these expectations for lab test reporting affect current reporting feeds from labs to health departments? If the state feed changes, does the originating reporting feed at the lab have to change?
32. Our jurisdiction is having difficulty with ensuring all laboratories are reporting line-level test data (including negatives); how important is this element to our ELC activities?
33. Can CDC provide additional clarity on what specific activities under "Improve Surveillance and Reporting of Electronic Health Data" are considered to "enable comprehensive, automated, daily reporting to the CDC and others in a machine-readable format"?

Activities:

34. Could you elaborate on what activities are allowable under contact tracing?
35. Are we able to obligate subcontracts before our revised budgets are submitted?
36. If ED Expansion is a copy of ED in REDCap, do we still report milestones and progress updates for ED?

Coordinate and Engage with Partners:

37. If a jurisdiction is largely de-centralized, to what extent is the State Health Department expected to partner at the local level?
38. What are examples of partners to consider funding when addressing health equity needs?

Other projects:

39. We attended the webinar presented by the United States Digital Service (USDS) and are interested in participating. Can the ELC facilitate this?
40. For ELC COVID performance measures, where are measures E23, E24 and E25 located in the REDCap portal?

Appendices

A: Basic Comparison & Examples of Allowable
B: Costs Allowable Expenses At-A-Glance

ELC Enhancing Detection Expansion Answers

Budget & Expenses:

1. Is there a budget template?
    - Yes, the ELC budget workbook (Excel) was provided in a Grant Note in GrantSolutions (GMM). You can also contact your ELC Project Officer. Recipients must complete the budget revision using the Excel budget workbook and adhere to the CDC guidelines (https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.pdf). The revised budget must then be sent back to CDC through a budget revision amendment in GrantSolutions, along with a cover letter signed by the Authorized Organizational Representative (AOR) of record in GrantSolutions.
2. What are examples of some costs not allowed in Enhancing Detection (ED) Expansion?
    - Research, lobbying, and clinical care (except as may be allowed by law) cannot be supported with funds awarded under ELC Enhancing Detection (ED) Expansion. However, all questions should be submitted as a Grant Note in GMM for review by your Grants Management Specialist (GMS) at CDC's Office of Grant Services (OGS) and your ELC Project Officer.
3. Can we use the funds to pay for activities done in months before the grant was awarded?
    - Legislative language was not included in this appropriation to permit retroactive charges; therefore, only costs associated with activities from time of award issuance are allowable.
4. Can funding be used to support providers with Electronic Laboratory Reporting (ELR) or telemedicine technology to enhance testing?
    - Certain costs not associated with the delivery of clinical care may be allowable. Please email your ELC Project Officer for a more individualized consult to discuss the specifics of your situation.
5. Can funding be used to purchase vaccines?
    - Per OGS, the purchase of vaccines is not permissible using ED Expansion funds. However, certain vaccine related costs may be allowable using ED Expansion funds. This includes storage and administration costs (i.e., injection cost if not covered in question #12). Recipients are encouraged to coordinate with PHEP and Immunization partners within the jurisdiction to effectively plan necessary activities and optimize use of resources.
6. When submitting a revised budget as an amendment, do you have to submit other forms?
    - The following must be part of the submission:
        i. The workplan completed in REDCap (and exported as a PDF);
        ii. The revised ELC budget workbook, using the Excel workbook provided at the time of award issuance;
        iii. A cover letter which is on agency/recipient stationary and signed by the Authorizing Official of record in GrantSolutions;
        iv. The State Testing and Case Investigation & Contact Tracing Plan completed in REDCap (and exported as a PDF); and
        v. The ELC Governance Team support letter.
7. Can resources be used for quarantine/isolation-related costs?
    - Costs associated with quarantine and isolation may be allowable as they relate to one or more activities in the workplan. For example, resources necessary to support testing and monitoring of individuals traveling from high-risk areas (within or outside of the U.S.) may be allowable and within scope of this project (this includes wrap- around services). Resources necessary for quarantine under a legal order (hotel, wraparound services, etc.) may also be allowable; recipients should simply tie these requests to their ELC workplan. ELC Project Officers should be contacted to discuss the specifics of such a request.
8. When setting up and operating pop-up testing sites, what types of expenses are allowable through ED Expansion?
    - Most costs associated with setting up and operating alternate testing sites are allowable under ED Expansion if the workplan reflects these sites in one or more of the activities. Please see question #12 for additional details pertaining to insurance.

9. If a recipient's partners and community providers meet the testing goal and need to provide additional supplies/resources for expanded testing, what costs are allowable through ELC Enhancing Detection Expansion?
    - Most costs, in particular supplies and resources, are allowable so long as they relate to one or more of the activities in the workplan. However, testing costs, even for the uninsured would not be allowable when any/all of the associated costs are being reimbursed in any fashion. Please see question #12 for additional details pertaining to insurance.
10. Are funds intended to support activities for the duration of the 30-month period? For example, if a jurisdiction liquidates all their funds prior to the end of the 30 months, are they still required to continue activities in the guidance until the end of the 30 months?
    - The expected timeframe for completion of all required activities under ELC ED Expansion is 30 ½ months. It is possible that certain activities may be completed in a shorter period (e.g., 24 months); however, the overall project period is 30 ½ months to allow sufficient time to conduct the range of activities. As this award builds on the ELC ED award, it is important to gauge progress based on the achievement of the required expansion of activities, not the spending of funds. Expenditures that are not aligned with the commensurate level of completion of the approved activities will be scrutinized. Should it be found that resources were not utilized in the manner consistent with grant regulations, the award terms and conditions and/or approved work plans and budget submissions, the jurisdiction may be found to be noncompliant and could be required to reimburse the federal government. Additionally, as indicated in the Guidance associated with this award (https://www.cdc.gov/ncezid/dpei/elc/resources.html), if required tasks and activities in the Guidance are not addressed, funds may be restricted in the Payment Management System (PMS). It is highly recommended that recipients continue to engage their ELC Project Officer and the OGS GMS as funds are activities are undertaken and funds are expended to ensure appropriate progress during the ED Expansion project period.
11. If a jurisdiction liquidates most or all funds towards supporting a few activities in the workplan, are they still required to complete the remaining activities?
    - The ELC ED Expansion Guidance sets out the required activities in furtherance of the purpose and use of the funds and the award. Budgets should align to the workplans and are intended to support the breadth of all required activities.
12. Can ELC ED Expansion funds be used to cover the costs of COVID-19 testing?
    - Yes, COVID-19 testing can be covered using ELC Enhancing Detection Expansion funds in the following ways:
        i. Uninsured: ELC Enhancing Detection Expansion funds can cover costs associated with COVID-19 testing for the uninsured.
        ii. Unable to bill: ELC Enhancing Detection Expansion funds can cover costs associated with COVID-19 testing when billing is not feasible. While not an exhaustive list, some examples are the following: mobile testing sites; non-traditional testing sites; state/local laboratories not having the authority or ability to bill insurance; etc.
        iii. Billing serves as a real or perceived barrier to timely test delivery: ELC Enhancing Detection Expansion funds can cover costs associated with COVID-19 testing when establishing billing services (directly or through a contractual agreement) would delay testing and/or reduce the jurisdiction's ability to rapidly increase testing capacity to meet needs.
        iv. Payor of last resort when billing insurance: In situations where COVID-19 testing is billed to insurance and is either not covered or partially covered by a third-party payor (e.g., private insurance, CMS, etc.), after the claim is rejected or partial reimbursement occurs, the outstanding balance can be covered by ELC Enhancing Detection Expansion funds.
13. When reporting the monthly expenses in the REDCap Financial Reporting page, what are 'unliquidated obligations' and how do they differ from expenses?
    - The funds awarded fall into one of three categories:
        i. Unobligated: Funds in a budget or spend plan that are available for use, but not yet encumbered or committed.

ii. Unliquidated obligations (ULOs): Funds that have been encumbered/committed but have not yet been paid out. Examples include: (1) executing a $100K contract and having to pay 10% upfront would result in $10K in 'expenditures' and $90K in 'unliquidated obligations'; (2) using a purchase order to acquire a piece of equipment for $50K would result in $50K in 'unliquidated obligations' until the equipment is delivered, the agency is invoiced, and the invoiced is paid.
iii. Expenditures: Funds that have been drawn down from the account and paid out.

- Note: It is important to remember that once an unliquidated obligation is paid, the following monthly reporting should transfer the amount paid from 'unliquidated obligations' to 'expenditures' as the obligation has now been liquidated.

14. Am I required to have prior approval (redirection/contract approval) before I can use the funds that were placed in the "Other" cost category of my ELC ED Expansion Notice of Award (NOA) for COVID-19 response activities?
    - All awarded funds were placed in the 'Other' cost category as an initial means to obligate and award funding. This action allowed CDC to expedite your award and facilitate your emergency response. Based on the emergency, you have been authorized to use these funds consistent with the issued Guidance and terms of the award set out therein, including entering into contracts as required to address the needs of COVID-19. Please ensure that such funds are expended in accordance with your organization's policies and procedures and are reasonable, allocable, allowable, and necessary as per 2 CFR Part 200 and 45 CFR Part 75. All costs must also be reflected in the budget and workplan you are preparing for submission by March 18, 2021. You are not required to wait until your budget is submitted and approved to execute any needed contracts or other obligations. We do however require that this information is incorporated in the budget and that the contract(s) are in alignment with the issued CDC Guidance, applicable terms and conditions, and your internal procurement policies. This ability to use the funds prior to the budget submission and approval is an exception that applies solely to COVID-19 awards within ELC.
15. The Notice of Award for ELC ED Expansion has a budget period from August 1, 2020, to July 31, 2023; does this mean that contracts and other acquisitions using ELC ED Expansion funds cannot go past July 31, 2021?
    - The ELC ED Expansion awards were issued in ELC Budget Period 2. There was specific guidance in the Terms and Conditions of the Notice of Award that provided an extended fiscal period (i.e., extending past the end of the budget period in which funds were awarded) for these special COVID-19 funds. The 30 ½ -month fiscal period for the ELC Enhancing Detection Expansion awards means that contracts can extend past the July 31, 2021, end of Budget Period 2, by exercising option years. Additionally, other costs (e.g., purchasing equipment, supplies, etc.) can also occur after July 31, 2021, in accordance with the terms and conditions of this award.
16. How does expanded authority work for the supplemental COVID-19 funds?
    - Unlike funding in ELC (base) core awards, the supplemental ELC ED Expansion COVID-19 awards are issued with an expanded budget period; therefore, expanded authority is not needed to extend use of COVID supplemental funds from one ELC budget period to the next.
    - During the regular ELC budget period closeout (i.e., October 30), when submitting the annual FFRs, one FFR will need to be submitted for each document number that ELC awards were made on. The special COVID-19 document numbers will be reported on separate FFRs from the (base) core ELC award for Budget Periods 1 & 2. For base (core) funding only, whatever funds remain unobligated at time of submitting the annual FFR should be noted in Section #12 along with the intended use of Expanded Authority.
    - Given the ELC ED Expansion award has an extended fiscal period, the account will continue to be active in the Payment Management System (PMS) and can have funds drawn down to cover expenses through the end of the ED Expansion award budget period.
17. May social services be supported with ED Expansion funds?
    - Social services that are critical to facilitating the detection, prevention, and control of COVID-19 may be allowable. For example, those services that help facilitate compliance with isolation and quarantine and/or case investigation and contact tracing efforts may be allowable expenses and may be a part of recipient workplans (e.g., health educators, counselors, etc.). ELC Project Officers should be contacted to

discuss the specifics of such a request. Recipients are reminded that funds are to be expended in accordance with your organization's policies and procedures and are reasonable, allocable, allowable, and necessary as per 2 CFR Part 200 and 45 CFR Part 75.

18. Can ELC ED Expansion funding be used to purchase vehicles, including mobile testing vans?
    - Yes, but recipients must include three (3) quotes and/or a blanket purchasing agreement along with a justification for leasing/purchasing in the revised budgets that are due by March 18, 2021. For situations where the acquisition needs to occur before the revised NOA is issued, please submit the request and associated quotes in GrantSolutions via Grant Note. This information must also be included in the revised budget once submitted.
    - For redirecting funds to purchase vehicles, including mobile testing vans, that were not in the approved budgets, please work with your ELC Project Officer to submit a redirection request. The request will need to include a cost analysis between lease versus purchase options and quote. For mobile testing vans, due to the nature of having to customize the vehicle, it is understood that a lease versus purchase analysis might not be applicable.
19. Can ELC ED Expansion funding be used for renovations and minor construction costs?
    - Yes, but recipients must include the quotes and justification for renovations and/or minor construction in the revised budgets that are due by March 18, 2021. For situations where the alterations need to occur before the revised NOA is issued, please submit the request and associated quotes in GrantSolutions via Grant Note.
    - For redirecting funds to conduct renovations and/or minor construction that were not in the approved budgets, please work with your ELC Project Officer to submit a redirection request. The request will need to include:
        i. A description of the renovation or minor construction,
        ii. The justification of how the renovations or minor construction will relate to activities in the approved workplan, and
        iii. A quote or bid justifying the cost that is being requested in the redirection.
20. Can recipients request more than the recommended "1 program manager, 1 budget staff" in the budget?
    - Yes, this is a minimum recommendation for basic management of this project. Recipients may also need to increase overall administrative staff support to accommodate the demands of managing their portfolio.
21. With this new funding opportunity, and the allowance of covering existing core staff's percent of work redirected to COVID-19 activities, what happens to our (base) core ELC funding?
    - Recipients' (base) core dollars should be reserved for non-COVID programmatic activities. As numerous health department staff are working on COVID-19 currently, it is understandable if (base) core funding spending is lower than usual. These programmatic activities can be extended into Budget Period 3.
    - ELC staff who are typically supported through (base) core funding but are working all or a portion of their time on the COVID-19 response should have their associated personnel costs charged to the ELC CARES, ELC Enhancing Detection, and/or ELC ED Expansion COVID accounts as appropriate.
22. Are recipients able to start spending funds, before revised budgets are approved?
    - Yes, funds are available for use now. In the interim (before revised budgets are accepted), make sure your expenses align with activities described in the ELC Guidance (https://www.cdc.gov/ncezid/dpei/elc/resources.html). Also, please see response to #14 above. Also, recipients are reminded that funds are to be expended in accordance with your organization's policies and procedures and are reasonable, allocable, allowable, and necessary as per 2 CFR Part 200 and 45 CFR Part 75.
23. Now that workplans are being combined into ED Expansion for ELC CARES and Enhancing Detection, will financial reporting be bundled as well?
    - No, each COVID-19 supplemental award requires its own, monthly financial report due to the nature of being awarded on separate accounts in the Payment Management System (PMS) and the need to track and account for spending by each separate supplemental appropriation.

Workforce Capacity:

24. If the health department has previously reached the personnel/hiring cap in their jurisdiction, should this be addressed or acknowledged in the budget?
    - Increased staffing (e.g., contractual, temporary, term staff, etc.) may be essential to achieve the targets and requirements of this award, but we understand expanding human resources in your jurisdictions may not be in your control. If you anticipate insurmountable challenges with hiring or starting new contracts, please let your ELC Project Officer know immediately. Direct assistance and technical assistance can be discussed on a case-by-case basis, and major challenges will also be proactively communicated to the Department of Health and Human Services (HHS).

ELC Enhancing Detection Expansion Testing & Testing Plan Template:

25. Can you confirm that the target coverage for our testing projections is 2% of population each month?
    - Yes, and 2% is the minimum threshold as recommended by HHS/Office of the Assistant Secretary for Health (OASH).
26. What level of continued federal support can recipients expect for laboratory testing (e.g., provision of specimen collection and testing kits) as the COVID-19 response evolves?
    - The ELC can only speak to the funding that CDC administers. Questions regarding the monthly allocations of Viral Transport Medium (VTM) and swabs should be directed to your regional HHS/OASH representative. Of note: the published Jurisdictional Testing Plans may be found at: https://www.hhs.gov/coronavirus/testing-plans/index.html. Any questions should be directed to your HHS/OASH representative.

Advance Electronic Data Exchange at Public Health Labs:

27. Can recipients accelerate previously on-going activities to improve laboratory informatics, for example, more rapid interfacing diagnostic equipment to improve the automation of reporting?
    - Yes, ELC expects all funded jurisdictions will make measurable progress in improving the efficiency of laboratory management and operations, as well as improving the analytic capacity within the laboratory settings. This may include improving automation of reporting with increased test volumes to efficiently manage throughput and staffing, or new analytic capacity to better inform the jurisdictional response efforts.
28. Is the laboratory test order and reporting activity required?
    - Yes, all activities included in the Guidance document (https://www.cdc.gov/ncezid/dpei/elc/resources.html) should be considered required with the ELC ED Expansion award.
29. I cannot find the ED Expansion performance measures, where are they located?
    - At the time the Guidance was published, the performance measures were not yet finalized. Recipients should anticipate their performance under the ED Expansion award will continue to be measured by and monitored as was done with the ELC Enhancing Detection award. Once changes are finalized for the ELC ED Expansion award, information will be shared via the ELC mailbox and a webinar will be held.
30. What elements are needed in the line level testing data reporting to CDC?
    - This includes all RT-PCR, antigen, and antibody tests and results (positives, negatives, and indeterminants), patient demographics, as well as reporting, performing and ordering facilities. For more detailed guidance please refer to standard CSV file, which ELC will share.
    - Critical data elements should be the primary focus for lab data reporting to CDC for COVID-19:
        i. Test ordered – use harmonized LOINC codes provided by CDC
        ii. Device Identifier – use if LOINC codes do not indicate device/test kit
        iii. Test result
        iv. Test Result date
        v. Accession #/Specimen ID
        vi. Age (or DOB)
        vii. Patient race

viii. Patient ethnicity
ix. Patient gender
x. Patient residence zip code
xi. Patient residence county
xii. Ordering provider name and NPI or CLIA (as applicable)
xiii. Ordering provider zip
xiv. Performing Lab name and CLIA number, if known
xv. Performing Lab zip code
xvi. Specimen Source - use appropriate LOINC, SNOMED-CT, SPM4 codes, or equivalently detailed alternative codes
xvii. Date test ordered (date format)
xviii. Date specimen collected (date format)

- "Ask On Order" questions that are highly desired are shown below. These are secondary in importance to the critical data elements above:
  i. First test (Y/N/U)
  ii. Employed in healthcare? (Y/N/U)
  iii. Symptomatic? Y/N/U and then Date of Symptom Onset (mm/dd/yy)
  iv. Hospitalized? (Y/N/U)
  v. ICU? (Y/N/U)
  vi. Resident in a long-term care facility (including skilled nursing facilities, nursing homes, long-term care for the developmentally disabled, and assisted living homes): (Y/N/U)
  vii. Pregnant? (Y/N/U)

31. Will these expectations for lab test reporting affect current reporting feeds from labs to health departments? If the state feed changes, does the originating reporting feed at the lab have to change?
    - It is possible reporting fields or feeds will be expanded to accommodate for this reporting, but please defer to your local and state health department guidance. It should result in laboratories collecting and sending more complete data, though laboratories should continue to report the most complete data they have to their jurisdictional health departments. States should include the more complete data they receive to CDC. Any changes with reporting to CDC will be handled and managed through the epidemiology and informatics sections of your health departments.
32. Our jurisdiction is having difficulty with ensuring all laboratories are reporting line-level test data (including negatives); how important is this element to our ELC activities?
    - The public health response to COVID-19 depends on having comprehensive laboratory testing data - at scale, in near real-time, and including critical geographic and demographic information, to the fullest extent as feasible and with sufficient granularity. These data will contribute to understanding disease incidence and testing coverage and may contribute to the identification of testing issues and/or supply shortages. Additionally, the ELC has several performance measures that rely on the reporting of these data. The ELC has elected to reduce the burden placed on recipients by utilizing data sources and elements where states/jurisdictions are already reporting. Without the successful line-level test data reported (see: https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html), the ELC would need to institute a separate reporting process for laboratory data.
33. Can CDC provide additional clarity on what specific activities under "Improve Surveillance and Reporting of Electronic Health Data" are considered to "enable comprehensive, automated, daily reporting to the CDC and others in a machine-readable format"?
    - This suite of activities is intended to improve the health department's access to and interoperability of many relevant data sources for visibility on the spread of disease and to increase the usefulness of all data sources. Health departments should be able to receive all data message types and have the systems, processing ability, and staffing to consume and analyze new feeds alongside existing data, such as: increased testing volumes from new sites, death registry reports, and ADT data feeds from emergency departments and urgent care clinics. Linked data should be accessible to local public health

(and the public, where possible), in a format that can be easily uploaded into commonly used analysis and visualization tools, such as ESRI, Tableau, and PowerBI.

Activities:

34. Could you elaborate on what activities are allowable under contact tracing?
    - Activities allowable under contact tracing may include:
        i. Temporary staff used for incremental tracing
        ii. Public education/awareness campaign
        iii. Contracted vendor for contact tracers and monitors
        iv. Management and supervision of trainers, as well as the conducting of training
        v. Data and software platforms needed to support the training programs
35. Are we able to obligate subcontracts before our revised budgets are submitted?
    - Yes, you are able to grant subawards at this time, so long as the activity is undertaken consistent with the Guidance and the terms of the award. Please see response to #14 above.
36. If ED Expansion is a copy of ED in REDCap, do we still report milestones and progress updates for ED?
    - We are in the midst of Quarter 2 workplan milestone progress reporting for ED. Once that ends, we will close the ED workplan monitoring portal. Starting with Quarter 3 reporting, the Community-based Surveillance, ELC CARES, and ELC Enhancing Detection workplan milestone progress reporting will cease. Recipients will only be required to report the workplan milestone progress for ELC ED Expansion as these activities cover the other prior COVID awards.

Coordinate and Engage with Partners:

37. If a jurisdiction is largely de-centralized, to what extent is the State Health Department expected to partner at the local level?
    - CDC encourages State Health Departments to continue working collaboratively with city, county, and local health departments, and other partners (e.g., academic, regional organizations) to improve capacity for addressing gaps in addressing COVID-19 within their communities (e.g., testing, outbreak investigation, infection prevention and control (IPC) practices, etc.). Providing financial resources to local health departments is strongly encouraged, where possible, to build local public health capacity.
38. What are examples of partners to consider funding when addressing health equity needs?
    - Examples of partners may include but are not limited to:
        i. Tribal affiliates and community-based organizations colleges and universities
        ii. Occupational health settings for large employers
        iii. Churches or religious or faith-based institutions
        iv. Federally Qualified Health Centers (FQHCs), including Community Health Centers (CHCs)
        v. Pharmacies
        vi. Long-term care facilities (LTCFs), including independent living facilities, assisted living centers, and nursing homes
        vii. Organizations and businesses that employ critical workforce
        viii. First responder organizations
        ix. Non-traditional providers and locations that serve high-risk populations
        x. Other partners that serve underserved populations

Other Projects:

39. We attended the webinar presented by the United States Digital Service (USDS) and are interested in participating. Can the ELC facilitate this?
    - The USDS webinar provided an overview of the three projects which will be piloted in interested jurisdictions to help with better, faster data to public health departments. The ELC is not directly involved with the projects or the decision-making process for pilot selection. It is ELC's understanding that any products developed through the pilots will be open source and available for all jurisdictions to

adopt. While you may utilize ELC resources to support a project, you will need to tie the project back to your workplan and ensure successful completion of all the required ELC Enhancing Detection Expansion activities. If you have any questions about USDS-CDC collaboration or any specific projects, please email USDS@cdc.gov.

40. For ELC COVID performance measures, where are measures E23, E24 and E25 located in the REDCap portal?
    - Measures E23, E24 and E25 are collected by the HAI/AR program via their performance measure REDCap site "HAI/AR Performance Measures 2019 - 2020 (BP1)". Recipients will be notified directly by the HAI/AR program when these measures are available on REDCap.

Appendices

A: Basic Comparison & Examples of Allowable
B: Costs Allowable Expenses At-A-Glance

ELC Enhancing Detection Expansion & Immunization CoAg COVID-19 Funding Supplementals

A: Basic Comparison & Examples of Allowable Costs

Please ensure that such funds are expended in accordance with your organization's policies and procedures and are reasonable, allocable, allowable, and necessary as per 2 CFR Part 200 and 45 CFR Part 75.

All costs must alignment to the workplan and the impact to the overall ability to complete required activities.

	ELC Enhancing Detection (ED) Expansion	Immunization & VFC Cooperative Agreement
Purpose	Provide critical resources to state, local, & territorial health departments in support of a broad range of COVID- 19/SARS-CoV-2 testing & epidemiologic surveillance related activities. Activities intended to complement activities covered through other ELC COVID resources and explicitly expand upon those strategies and activities in ELC Enhancing Detection Expansion.	Provide resources to support and strengthen critical COVID-19 immunization planning and implementation requirements and activities to ensure effective and efficient vaccination in phases 1 (a, b, and c), 2, and 3 for state, local, and territorial awardees.
Funding appropriation	Coronavirus Response and Relief Act, 2020 (P.L. 116-260)	Coronavirus Response and Relief Supplemental Appropriations Act of 2021 (P.L. 116-260)
Key Activities	All Activities are required: 1. Enhance Laboratory, Surveillance, Informatics, and other Workforce Capacity (5 Activities) 2. Strengthen Laboratory Testing (3 Activities) 3. Advance Electronic Data Exchange at Public Health Labs (1 Activity) 4. Improve Surveillance and Reporting of Electronic Health Data (6 Activities) 5. Use Laboratory Data to Enhance Investigation, Response, and Prevention (3 Activities) 6. Coordinate and Engage with Partners (2 Activities)	1. Increase COVID-19 vaccination capacity across the jurisdiction, including among high-risk and underserved populations 2. Ensure high-quality and safe administration of COVID-19 vaccines 3. Ensure equitable distribution and administration of COVID-19 vaccines 4. Increase vaccine confidence through education, outreach, and partnerships 5. Develop and implement community engagement strategies to promote COVID-19 vaccination efforts 6. Support high vaccination uptake in tribal nations 7. Use immunization information systems to support efficient COVID-19 vaccination
Amount	$19.11 billion	$3 billion
Previous COVID funding	Over $11 billion and 15 projects represented. Of this, $10.25 billion was for ELC Enhancing Detection—the guidance upon which ED Expansion builds	This is the 3rd IP19-1901 COVID supplement during budget year 2 (July 2020 - June 2021) and the 4th total IP19-1901 COVID supplement. In total between all the supplements, approximately $3.48 billion in COVID funding has been awarded to the 64 immunization jurisdictions.
Funding period	1/15/2021 - 7/31/2023	7/1/2020 - 6/30/2024
Number of recipients	64	64
Funding strategy	PHEP formula (per legislation)	PHEP formula (per legislation)
Project director	Project Directors largely from Epi and Lab	Immunization and VFC CoAg Principal Investigator which is largely the immunization program manager

	ELC Enhancing Detection (ED) Expansion	Immunization & VFC Cooperative Agreement
Engagement with local health departments	While no formula exists for the advisable level of funding to local health departments (LHD), LHD needs should be reflected within budgets. Workplans should indicate how LHD engagement will take place to successfully complete the activities. Recipients should also be able to estimate the resources provided to LHDs for quarterly reporting and highlight any barriers to relaying this support.	Allowable and encouraged. LHD needs should be reflected within budgets. Workplans should indicate how LHD engagement will take place to successfully complete the activities. Recipients should also be able to estimate the resources provided to LHDs for quarterly reporting and highlight any barriers to relaying this support.
Mandate to support local health departments at a specified level	No, however, budgets and workplans should reflect how LHD needs will be addressed through these resources. Recipients should also be able to estimate the resources provided to LHDs for quarterly reporting and highlight any barriers to relaying this support.	No, however, LHD and partners work plans must include activities and deliverables to meet vaccination needs of their community.
Financial reporting	Monthly reporting via REDCap & GrantSolutions	Monthly reporting via REDCap & GrantSolutions
Progress on activities reporting	Quarterly reporting via REDCap. Includes updates to Jurisdictional Testing and Contact Tracing/Case Investigation plans	Quarterly through REDCap
Performance measure reporting	Quarterly, through REDCap, but reporting frequency may be adjusted	Quarterly, through REDCap, but reporting frequency may be adjusted
Reimbursement of allowable costs	Officially allowable but activities supported would largely fall upon award/post-award. Prior incurred costs would need to be associated with activities in the workplan. Charges not related to the workplan activities may result in the health department having to pay the money back.	Allowable
Restrictions	Research as defined by CDC, clinical care (except as may be allowed by law), purchasing vaccines, and major construction (e.g., new building, modification of more than 50% of structure, etc.) are not allowed. Renovations and minor construction (e.g., modification of less than 50% of structure, concrete slabs for modular labs/generators, etc.) are allowable.	Research as defined by CDC, clinical care (except as may be allowed by law), purchasing vaccines, and major construction (e.g., new building, modification of more than 50% of structure, etc.) are not allowed. Renovations and minor construction (e.g., modification of less than 50% of structure, concrete slabs for modular labs/generators, etc.) are allowable.
Of note: Allowable, allocable, reasonable; and consistent with the appropriation, grant regulations, grant terms and conditions	Resources to complement, but not duplicate, other CDC vaccine delivery efforts (e.g., those activities covered under IP19-1901). Costs can include infrastructure needs (e.g. staff, contractors, call centers, storage, space, etc.) that support testing as well as vaccination operations.	Resources to complement, but not duplicate, other CDC vaccine delivery efforts (e.g., those activities covered under IP19-1901). Costs can include infrastructure needs (e.g., staff, contractors, call centers, storage, space, etc.) that support testing as well as vaccination operations.

ELC Enhancing Detection Expansion & Immunization CoAg COVID-19 Funding Supplementals

B: Allowable Expenses At-A-Glance

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
Personnel (term, temporary, students, overtime, contract staff, etc.)	**Laboratorians**	Yes	No
	Informaticians	Yes	Yes
	Epidemiologists	Yes	Yes
	Data Entry Clerks, managers/analysists	Yes	Yes
	Data Visualization Specialists	Yes	Yes
	Vaccine registry data manager	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
	Health Communicators (including those specializing in risk comms.)	Yes	Yes
	Health Educators	Yes	Yes
	Management, budget, & administrative support	Yes	Yes
	Infection Prevention & control staff	Yes	Yes, may be allowable if the position is responsible for vaccine-related work
	Community Health Workers & organizations working with populations at higher risk for COVID-19	Yes	Yes
	Security staff (for personnel and clinic settings)	Yes	Yes
	Nurses or other staff used to administer vaccine	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
Equipment	**Laboratory equipment & necessary maintenance contracts at PHL (includes state PHLs that are affiliated with clinical or academic institutions)**	Yes	May be allowable if support is not available through the ELC CoAg.

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
Equipment	**Laboratory equipment & necessary maintenance contracts at local or regional PHLs**	Yes, to the extent that equipment is necessary to successfully complete the Activities listed in the guidance, resources (e.g. equipment) may be purchased. Disposition of these items, including any reporting on their location/condition, is the responsibility of the prime recipient of funds & must be in accordance with grant regulations and OGS policies.	Yes, to the extent that equipment is necessary to successfully complete the Activities listed in the guidance, resources (e.g. equipment) may be purchased. Disposition of these items, including any reporting on their location/condition, is the responsibility of the prime recipient of funds and must be in accordance with grant regulations and OGS policies. Equipment may include items such as vaccine storage units.
	General equipment (generators, freezers, computers)	Yes	Yes, may be allowable as they support COVID- 19 vaccine administration & reporting
	Vaccine storage equipment & necessary maintenance contracts	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
	Hardware/software necessary for robust implementation of electronic laboratory & surveillance data exchange between recipient & other entities (e.g. healthcare entities, jurisdictional public health, & CDC)	Yes	Yes
	Hardware/software that may be used to assist with case investigation & contact tracing	Yes	No
	Equipment necessary to ensure safety of laboratory workers (e.g. BSCs, HVAC, etc.)	Yes	No
Supplies	**Collection supplies, test kits, reagents, consumables & other necessary supplies for existing testing or onboarding new platforms**	Yes	May be allowable if support is not available through the ELC CoAg.
	Collection supplies, test kits, reagents, consumables & other testing or onboarding new platforms at regional or local health departments	Yes	May be allowable if support is not available through the ELC CoAg.
	Ancillary supplies & consumables necessary to perform testing for SARS-CoV-2 within or outside of traditional PHL setting	Yes	May be allowable if support is not available through the ELC CoAg.
	PPE for laboratorians or other staff conducting sample collection or	Yes	May be allowable if support is not available through the ELC CoAg.

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
Supplies	**processing. Also includes PPE for general staff as needed & deemed necessary by the work conditions**		
	PPE for use during vaccine	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
Software	**Software or systems to assist with laboratory resource management (e.g. software for inventory management, temperature notifications, etc.), quality management, biosafety, or training needs**	Yes	Yes, as it applies to vaccine management and Immunization Information Systems
	Software/hardware necessary for robust implementation of electronic laboratory and surveillance data exchange between recipients and other entities, jurisdictional public health & CDC	Yes	Yes, as it applies to vaccine management and Immunization Information Systems
	Tools that assist in the rapid identification, electronic reporting, monitoring, analysis, & evaluation of control measures to reduce the spread of disease (e.g. GIS software, visualization dashboards, cloud services, etc.)	Yes	Yes, as it applies to vaccine management and Immunization Information Systems
	Software or applications that allow for more efficient case investigation & contact tracing	Yes	No
	Software associated with vaccine registries or tracking of vaccine	Case-by-case only. May be allowable if support is not available through the Immunization CoAg (IP19-1901)	Yes
	Vaccine Registry enhancements	Enhancements to registries already initiated with ELC resources may be completed if it does not interfere with the successful completion of all required activities; however, these should be considered one-time system improvements. The ELC will not be able to maintain the costs of these systems or upgrades.	Yes
Construction & Renovation	**Renovations & minor construction (e.g. alteration of less than 50% total square footage of an existing structure, installation of a concrete**	Yes, may be considered for unique cases where conditions do not currently allow for safe or effective testing and/or delivery of effective public health services.	Yes, on a case by case basis and as it relates to vaccines or vaccination activities.

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
	slab for modular laboratory units, etc.)		
Vehicles	**Leasing/purchasing vehicles (e.g. mobile testing, providing public health services in underserved areas, etc.)**	Yes, recipients will need to submit quotes with their revised budgets that are due within 60 days of award issuance and receive prior approval from OGS. After the revised NOA is issued, any further request for leasing/purchasing must be made through GrantSolutions and include the necessary quotes. Vehicles already purchased or leased for the purpose of testing may also be utilized for vaccine delivery	Leasing and rentals allowable, however, purchase is not
Quarantine & Isolation	**Quarantine & isolation support necessary for preventing the spread of COVID-19 (including wraparound services such as hoteling, food, laundry, mental health services, etc.)**	Yes, and may include wraparound services but not medical costs associated with treatment.	No
	Medication & patient treatment	No	No
Outreach & Education	**Expenses associated with outreach & assistance (e.g. support provided through community-based organizations) for those at higher risk of COVID-19**	Yes, these may include but are not limited to organizations that work with tribes, individuals experiencing homelessness, and racial and ethnic minority populations.	Yes, these may include but are not limited to organizations that work with tribes, individuals experiencing homelessness, and racial and ethnic minority populations.
	Health communications materials & health education services to inform & protect communities	Yes, health communications materials & health education services to inform & protect communities are allowable, if they do not duplicate activities covered by other CDC funding mechanisms (e.g., IP21-2106, IP21-2107). Recipients are reminded to be cognizant of the statutory & policy requirements for acknowledging the HHS/CDC funding when issuing statements, press releases, publications, requests for proposal, bid solicitations & other documents. In accordance with CDC General Terms & Conditions for Non-research Awards - Acknowledgement of Federal Funding, in your base award.	Yes, health communications materials & health education services to inform & protect communities are allowable, if they do not duplicate activities covered by other CDC funding mechanisms (e.g., IP21-2106, IP21-2107). Recipients are reminded to be cognizant of the statutory & policy requirements for acknowledging the HHS/CDC funding when issuing statements, press releases, publications, requests for proposal, bid solicitations & other documents. In accordance with CDC General Terms & Conditions for Non-research Awards - Acknowledgement of Federal Funding, in your base award.
	Support for social services & health education efforts that will facilitate compliance with isolation & quarantine and/or case investigation & contact tracing efforts	Yes	Yes, as it relates to vaccination activities
	Mass vaccination campaigns	Aspects of this activity may be supported if not already covered by another source.	Yes

Category	Expense	ELC Enhancing Detection Expansion	Immunization & VFC Cooperative Agreement
Stipends & Incentives	**Incentives to encourage participation by individuals (e.g., have testing done) or by a facility (e.g., onboard ELR for timely reporting of results)**	Stipends/incentives may be considered to encourage participation in testing and/or vaccination coverage for those put at higher risk for COVID-19 (individual level) or for facilities/agencies to enroll and/or report data to the health department (institutional level). Recipients interested in exploring this option (individual and/or institutional) must submit a plan that covers all of the following elements: (a) justification, (b) cost savings [e.g., how it will defray costs or have a positive return on investment], (c) defined amount, (d) qualifications for issuance, & (e) method of tracking. When submitting the revised budget within 60 days of award issuance, stipend/incentive plans must be included in the 'budget justification' section of the ELC budget workbook and receive CDC approval before implementation. After the revised NOA is issued, any subsequent requests for using funds to support stipends/incentives must be made in GrantSolutions, including the stipend/incentive plan, and receive CDC approval before implementation.	No, but please also speak with your POB Project Officer.
Contracts	**Contracts with academic institutions, private laboratories, other non-commercial healthcare entities, and/or commercial entities**	Yes	Yes, as it relates to vaccines or vaccination activities
	Contracts (or mini grants) with local or regional health departments	Yes	Yes
	Courier service (new or expansion of existing agreements)	Yes	Yes
	Contracts to support testing at non-traditional testing sites or POC tests	Yes	No
	Contracts to support testing at clinical, private, or academic institutions	Yes	No
Social Services	**Support for social services and health education efforts that will facilitate compliance with isolation & quarantine and/or case investigation & contact tracing efforts**	Support for social services & health education efforts that will facilitate compliance with isolation & quarantine and/or case investigation & contact tracing efforts.	Support for social services & education efforts that support vaccination activities.

12 Things States Need to Know about the Vaccine Adverse Event Reporting System (VAERS)

The federal government takes all reports of vaccine adverse events seriously, and CDC and the U.S. Food and Drug Administration (FDA) are actively engaged in safety monitoring of COVID-19 vaccines. CDC uses numerous vaccine safety monitoring systems, including VAERS, to watch for adverse events (possible side effects) after vaccination.

Q. What is the Vaccine Adverse Event Reporting System?

After a vaccine has been authorized or approved by the FDA, post-approval monitoring using VAERS begins. VAERS is a national system used by FDA and CDC to collect reports of adverse events that happen after vaccination. VAERS can provide vaccine safety experts with valuable information to assess possible safety concerns. VAERS is especially useful for quickly detecting unusual or unexpected patterns of adverse event reporting that might signal a possible safety problem with a vaccine.

Q. Who can report post-vaccination adverse events to VAERS?

Anyone can submit a report to VAERS. Healthcare professionals, health departments, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine are encouraged to submit a VAERS form if they experience any adverse events after getting any vaccine.

Q. What do CDC and FDA do when a VAERS report is submitted?

Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. All serious reports are reviewed daily by vaccine safety experts. Scientists at CDC and FDA use statistical models to help understand whether there are any safety signals for a vaccine product and compare them with safety signals for other vaccines to determine if further investigation is needed.

Helpful Hints for States:

- Work with your communications team when considering developing statements about reporting adverse events after COVID-19 vaccination.
- Each state has a vaccine safety coordinator who can serve as a liaison with local health departments, providers, and partners on vaccine safety issues.
- CDC staff is available to provide state and local health departments with technical support and communications around adverse events after COVID-19 vaccination.
- Contact COVID19VaxSafety@cdc.gov to reach CDC for non-urgent matters. For urgent matters, call **(770) 488-7100** to reach the CDC Emergency Operations Center.

Q. When does CDC follow up on reports submitted to VAERS?

VAERS staff obtains follow-up medical records for reports classified as serious. A serious report describes an event that resulted in permanent disability, hospitalization, life-threatening illness, or death. VAERS staff may also obtain follow-up medical records for adverse events of interest, like anaphylaxis. Reviewing these records can help CDC and FDA medical staff better understand cases.

www.cdc.gov/coronavirus/vaccines

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CS322534-A 02/03/21

Q. Will CDC follow up with people who submit VAERS reports?

The person who submits a VAERS report will receive a confirmation that VAERS has received the report or a reminder if important information was left out of the initial report. If additional information is needed, CDC may reach out to healthcare providers relevant to the case.

Q. What happens when a death is reported to VAERS?

When a death is reported to VAERS, CDC obtains medical records about the person's death, including an autopsy report, if available. If no autopsy was performed, CDC will obtain a death certificate and other relevant medical records. VAERS scientists will **not** reach out to the person who submitted the report, unless the name of the hospital or vaccination provider is **not** included.

Q: Do CDC and FDA provide VAERS reporters with an assessment following reports of serious adverse events, including death?

No. One of the limitations of VAERS is that VAERS generally cannot assess causality. However, as a hypothesis-generating system, VAERS is valuable for identifying potential vaccine safety concerns that can be studied further.

Q. Who are vaccine safety coordinators?

Vaccine safety coordinators are public health officials at jurisdiction health departments that serve as CDC's "eyes and ears" on vaccine safety issues and coordinate with CDC on incident response. They also serve as primary educators for vaccine safety reporting at the state and local level and coordinate local efforts to report vaccine adverse events to VAERS.

Q. What information from VAERS does CDC make available to vaccine safety coordinators each week?

Each week, CDC makes available via Epi-X a summary of VAERS reports received within the jurisdiction in the last week and a summary of VAERS data from other jurisdictions. CDC also sends a daily email notification whenever VAERS receives death reports from the jurisdiction. These reports are available via Epi-X.

Q. Do we need to follow up on VAERS reports filed in our jurisdiction?

Public health jurisdiction staff does **not** need to follow up on VAERS reports. VAERS staff will routinely follow up to obtain medical records for all reports of serious adverse events or death.

Q. When should we consider contacting CDC about COVID-19 vaccine adverse event reports?

Vaccine safety coordinators, immunization program managers, and other health department staff are welcome to contact CDC about vaccine safety issues at any time. Consider contacting CDC about:

- Unusual or unexpected vaccine adverse event reports
- Clusters of adverse events
- Vaccine administration errors
- Events that may impact public confidence in vaccination programs
- CDC laboratory and/or pathology support
- Requests for investigation by high-ranking state or local health officials
- Adverse event reports that may generate an increased level of media attention

Q. How can we contact CDC if there is an emergency relating to COVID-19 vaccine safety?

For public health emergencies, jurisdictions and providers may call the CDC Emergency Operations Center at **(770) 488-7100**.
For non-urgent concerns, jurisdictions and providers may email covid19vaxsafety@cdc.gov. For medical emergencies call **911**.

MS-DOH-21-1816-A-001607

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 1 (incl. ELC Reopening Schools Webinar, HHS Press Release, MMWR Early Releases, NIOSH Comms Resources, and more)
Date:	Thursday, April 1, 2021 1:04:09 PM
Attachments:	image001.png image002.png ELC Reopening Schools Guidance 26Mar2021-Final.pdf HHS COVID-19 Update - 329.msg HHS COVID-19 Update - 330.msg HHS COVID-19 Update - 331.msg MMWR ER - Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020 - March 31, 2021.pdf MMWR ER - Provisional Mortality Data — United States, 2020 - March 31, 2021.pdf Partner Key Update 331.msg safe-proper-sharps-disposal.pdf strategies-sharps-disposal-container.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- TODAY: Webinar - ELC Reopening Schools [Link]
  - CDC's Epidemiology and Laboratory Capacity (ELC) Program will host a webinar **TODAY**, Thursday, **April 1** at **4:00 pm EDT** regarding funding to enable and expand school-based screening testing. Attendees can expect a review of the *Reopening Schools* guidance (*attached), subject matter expert perspectives, and a Q&A session. The webinar will be recorded and a link to download will be made available afterwards, in addition to a copy of slides.
  - Call information is below:
    - Weblink: https://www.mymeetings.com/nc/join/
      Conference Number: PWXW2102397
      Direct link: https://www.mymeetings.com/nc/join.php?i=PWXW2102397&p=9125099&t=c
    - Telephone: 1-415-228-4882 or 800-369-2098
      Passcode: 9125099

HHS Press Release: "HHS to Expand Access to COVID-19 Vaccines for Older Adults and People with Disabilities" [Link]

- On **Monday, March 29**, HHS announced a partnership between CDC and the Administration for Community Living (ACL) to provide nearly $100 million in funding to help increase vaccinations among older adults and people with disabilities. From the announcement: *"With funding from CDC, ACL will issue nearly $93 million in grants to the aging and disability networks in every state and territory. These funds will help provide critical services to overcome barriers that are preventing millions of those most at risk for serious illness and death from COVID-19 from receiving vaccines. This partnership also will provide an additional $5 million in funding for national hotlines to assist older adults and people with disabilities in registering for a vaccination and to connect them with local disability and aging agencies that can provide services and supports necessary to access them."*
- The full press release is available on HHS' website here.

- NIOSH Resources: "Safe and Proper Sharps Disposal During the COVID-19 Mass Vaccination Campaign" [Attachments, Link]
  - The National Institute for Occupational Safety and Health (NIOSH) recently released a new suite of communications products aimed at preventing needlesticks at mass vaccination sites, as well as promoting proper sharps disposal. Please see attached for two printouts that can be posted for staff and office use. An accompanying webpage is available on CDC's website here.
- MMWR Early Release: "Provisional Mortality Data — United States, 2020" [Attachment, Link]
  - From the summary: *"The age-adjusted death rate increased by 15.9% in 2020. Overall death rates were highest among non-Hispanic Black persons and non-Hispanic American Indian or Alaska Native persons. COVID-19 was the third leading cause of death, and the COVID-19 death rate was highest among Hispanics."*
- MMWR Early Release: "Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020" [Attachment, Link]
  - From the summary: *"Among 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both."*

Standing Updates

- CDC Partner Update – March 31 [Attachment]
  - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Updates – March 29, 30, & 31 [Attachments]
  - Please see attached for the latest COVID-19 updates from the HHS Office of

Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.

- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
  - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
  - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
  - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

ELC REOPENING SCHOOLS: SUPPORT FOR SCREENING TESTING TO REOPEN & KEEP SCHOOLS OPERATING SAFELY GUIDANCE

3/26/2021

Project E: Emerging Issues

Supported through the American Rescue Plan Act of 2021

MS-DOH-21-1816-A-001611

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ELC REOPENING SCHOOLS: SUPPORT FOR SCREENING TESTING TO REOPEN & KEEP SCHOOLS OPERATING SAFELY

GUIDANCE

PROJECT E: EMERGING ISSUES

BACKGROUND AND PURPOSE

To support safe, in-person instruction in kindergarten through grade 12 (K-12) schools, screening testing can provide another layer of prevention to protect students, teachers, and staff and slow the spread of SARS-CoV-2, the virus that causes Coronavirus Disease 2019 (COVID-19). While it is critical for schools to open as soon as possible (and remain open) for academic and social, emotional benefits, it is equally important to do so safely (see: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html)

To enable schools to establish COVID-19 screening testing programs to support and maintain in-person learning, the federal government is providing financial resources to enable and expand school-based screening testing. Screening guidance should be implemented in ways consistent with CDC guidance; however, it is recognized that there may be practical or resource limitations in some school districts that make adherence to this guidance difficult at the start of this initiative.

Approximately $30 billion has already been awarded to public health departments to support activities, including screening testing, through the *ELC Enhancing Detection* (ED) and *ELC ED Expansion* supplements. Using those supplemental funds, public health departments increased their ability to provide screening testing broadly to their communities, including congregate settings, like schools. However, few have set up comprehensive programs of weekly test screening in K-12 schools (public and private) across an entire jurisdiction (i.e., state, local, and territorial), which is the goal of this new effort.

Awarding $10 billion from the *American Rescue Plan Act of 2021*, P.L. 117-2, under the *ELC Reopening Schools* award, will afford recipients the ability to support comprehensive screening testing for K-12 schools (public and private). A key goal of this initiative is to establish screening testing programs in schools around the country in April 2021, extending through the end of the school year and into summer activities and subsequent school year, as funds allow. This approach also encourages continuity and enhancement of existing COVID-related activities, maintains the health department's integral role in the screening testing ecosystem, builds upon the work already begun under *ELC Enhancing Detection* (ED) and *ELC ED Expansion* supplements, and ensures a holistic assessment and monitoring of disease burden within any given community. Recipients should ensure equitable access to the support being provided by this opportunity and where appropriate, coordinate with other initiatives that may already be targeting areas with high SVI.

FUNDING STRATEGY & SUPPORT TO SCHOOL DISTRICTS

The $10 billion, under the *ELC Reopening Schools* award, will be awarded to the current 64 ELC recipients according to a population-based formula.

The objectives and goals of this funding are primarily focused on providing needed resources to implement screening testing programs in schools aligned with the CDC recommendations for K-12 (https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html). Therefore, a minimum of 85% of the award must be allocated to directly fund school districts or provide materials (e.g., test kits, PPE, staffing, etc.) and services (e.g., sample collection, laboratory testing, etc.) to increase screening testing in all K-12 schools (public or private) within the recipient's jurisdiction. Recipients may use a combination of approaches (examples follow below) to successfully provide the necessary support to schools.

Up to 15% may be used by recipients for coordination, management, technical assistance, monitoring, and data collection and reporting activities to support K-12 screening testing programs. These funds may not be applied to expenditures incurred before the date of award. However, recipients can use previously awarded funds for any school screening testing activities that are consistent with those awards and in a way that is not a duplication of effort but an enhancement or complementary effort. School screening testing is an allowable activity under the prior two supplemental awards: *ELC Enhancing Detection* and *ELC Enhancing Detection Expansion*.

Examples of providing funding directly to support school districts and private/charter schools **include, but are not limited to:**

1. Contracting with testing companies to directly implement programs in K-12 schools and school districts.
2. Partnering with local or chain pharmacies to provide screening testing for K-12 schools and school districts (e.g., contract or fee-for-service model).
3. Partnering directly with laboratories with or without established regional footprints.
4. Directly contracting with K-12 schools and school districts within a recipient's jurisdiction for the completion of the activities in this guidance.
5. Establishing an account to allow K-12 schools and school districts to be reimbursed for costs associated with screening testing.
6. Coordinating with the State Department of Education to facilitate financial support for K-12 schools and school districts.
7. Sub-awarding to Local Health Departments to support school screening testing directly

8. Supporting IT systems to monitor screening testing in K-1 K-12 schools and school districts and ensure positive results are linked to public health action.

   ** Each jurisdiction is different; it is assumed that any proposed approach will align with existing jurisdictional laws, regulations, and business practices, while remaining consistent with this award.*

Examples of providing materials and services to school districts and private/charter schools **include, but are not limited to:**

1. Recipient using purchasing authorities to obtain screening testing kits, and necessary supplies, and providing them to school districts and private/charter schools within their jurisdiction.
2. Providing courier services to improve turn-around time for results.
3. Providing Personal Protection Equipment (PPE).
4. Providing laboratory support.
5. Personnel support, onsite, such as a screening testing coordinator, for sample collection, or other additional staff needed to implement testing programs, etc.
6. Logistical and operational support, including IT systems and data management, as needed.

Financial expenditures will be monitored and assessed with recipients monthly.

ALLOWABLE COSTS

Recipients should consider requesting the following when developing the *ELC Reopening Schools* budgets. The financial resources provided are required, by law, to support school-based screening testing activities intended to reopen schools at the kindergarten through 12-grade level that were closed (partially or fully) due to COVID-19.

1. Personnel (term, temporary, students, overtime, contract staff, etc.).
2. Laboratory equipment used for COVID-19 testing and necessary maintenance contracts.
3. Collection supplies, test kits, reagents, consumables, and other necessary supplies for existing screening testing or onboarding new platforms to support school screening testing.
4. Personal Protective Equipment (PPE) (e.g., masks, gloves, gowns) for those (e.g., teachers and school staff) collecting samples and/or conducting screening testing.
5. Courier service contracts (new or expansion of existing agreements).
6. Hardware and software necessary for reporting to public health and communication and coordination of follow up on any positive cases detected.
7. Tools that assist in the rapid identification, electronic reporting, monitoring, analysis, and evaluation of control measures to reduce the spread of COVID-19, that may be translatable to other diseases (e.g., GIS software, visualization dashboards, cloud services).
8. Contracts with academic institutions, private laboratories, other non-commercial healthcare entities, and/or commercial entities that may provide all or part of the screening testing needs. This may include contracts with companies that offer comprehensive support for screening testing in K-12 (e.g., sample collection, screening testing, and reporting).
9. Software or systems to assist with laboratory resource management (e.g., software for inventory management, temperature notifications, etc.), quality management, biosafety, or training needs.
10. Leasing/purchasing vehicles (e.g., mobile screening testing, providing K-12 screening testing services in underserved areas, etc.). Note: Recipients will need to submit quotes with their revised budgets and receive prior approval from the Office of Grant Services (OGS). If need arises before or after the revised Notice of Grant Award (NOA) is issued, requests for leasing/purchasing must be made through GrantSolutions and include the necessary quotes.

11. Program incentives may be considered to encourage individuals to participate in screening testing. Recipients interested in exploring this option must submit a plan that covers all of the following elements: (a) justification, (b) cost savings [e.g., how it will defray costs or have a positive return on investment], (c) defined amount (not to exceed $25 per instance), (d) qualifications for issuance, and (e) method of tracking. When submitting the revised budget within 60 days of award issuance, the program incentive plan must be included in the 'budget justification' section of the ELC budget workbook and receive CDC approval before implementation. After the revised NOA is issued, any subsequent requests for using funds to support program incentives must be made in GrantSolutions, including the program incentive plan, and must receive CDC approval before implementation.
12. Wrap-around (e.g., hoteling, food, laundry, mental health services, etc.) services for those who test positive.
13. Expenses associated with outreach and assistance (e.g., support provided through community-based organizations).
14. Expenses associated with technical assistance to establish school-based screening testing programs (NGOs, academic institutions, foundations, etc.).

*ELC Reopening School*s funds can be used to cover screening testing costs (e.g., administration, etc.) fully. Recipients should follow all appropriate federal laws and regulations pertaining to testing reimbursements, including assuring that charges are not covered both by ELC funds and other reimbursement sources.

The above list covers the anticipated, most relevant costs associated with achieving the activities in this guidance. This list does not represent a full list of allowable costs. Recipients are referred to the cost principles regulation found at 45 CFR Part 75 Subpart E – Cost Principles.

In determining if costs are allowable, consideration must be given to applicable regulations; the overall underlying cooperative agreement (CK19-1904); be considered necessary and reasonable; and be considered allocable (see: 45 CFR 75.403). Any questions about specific budget items should be directed to the OGS and the ELC Project Officer.

Please also note, the CDC is not prescribing the tests that may be used for screening; however, they must have received an emergency use authorization (EUA).

COVID-19 TERMS AND CONDITIONS

Coronavirus Disease 2019 (COVID-19) Funds: A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the "CARES Act") (P.L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); the Consolidated Appropriations Act and the Coronavirus Response and Relief Supplement Appropriations Act, 2021 (P.L. 116-260) and/or the American Rescue Plan of 2021 [P.L. 117-2] agrees, as applicable to the award, to: 1) comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

In addition, to the extent applicable, Recipient will comply with Section 18115 of the CARES Act, with respect to the reporting to the HHS Secretary of results of tests intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19. Such reporting shall be in accordance with guidance and direction from HHS and/or CDC. HHS laboratory

reporting guidance is posted at: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.

Further, consistent with the full scope of applicable grant regulations (45 C.F.R. 75.322), the purpose of this award, and the underlying funding, the recipient is expected to provide to CDC copies of and/or access to COVID-19 data collected with these funds, including but not limited to data related to COVID-19 testing. CDC will specify in further guidance and directives what is encompassed by this requirement.

This award is contingent upon agreement by the recipient to comply with existing and future guidance from the HHS Secretary regarding control of the spread of COVID-19. In addition, recipient is expected to flow down these terms to any subaward, to the extent applicable to activities set out in such subaward.

To achieve the public health objectives of ensuring the health, safety, and welfare of all Americans, Recipient must distribute or administer testing without discriminating on non-public-health grounds within a prioritized group.

Acknowledgement of Federal Funding: When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as tool-kits, resource guides, websites, and presentations (hereafter "statements")--describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

1. The percentage and dollar amount of the total costs of the program or project funded with federal money; and,

2. The percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

> This **[project/publication/program/website, etc.]** [**is/was**] supported by the [**full name of the OPDIV/STAFFDIV**] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling **$XX** with 100 percent funded by [**OPDIV/STAFFDIV**]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [**OPDIV/STAFFDIV]/**HHS, or the U.S. Government. For more information, please visit [**OPDIV/STAFFDIV website, if available**].

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

> This [**project/publication/program/website, etc**.] [**is/was**] supported by the [full name of the **OPDIV/STAFFDIV**] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling **$XX** with **XX** percentage funded by **[OPDIV/STAFFDIV**]/HHS and **$XX** amount and **XX** percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [**OPDIV/STAFFDIV**]/HHS, or the U.S. Government. For more information, please visit [**OPDIV/STAFFDIV website, if available**].

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement.

Any amendments by the recipient to the acknowledgement statement must be coordinated with the HHS Awarding Agency.

If the recipient plans to issue a press release concerning the outcome of activities supported by HHS financial assistance, it should notify the HHS Awarding Agency in advance to allow for coordination.

Termination

This award may be terminated in whole or in part consistent with 45 CFR 75.372.

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

SUPPORTING MANAGEMENT OF ACTIVITIES AND RESOURCES

Recipients will need to ensure proper oversight of the use of funds under this award. Please note that 85% of the awarded amount is expected to directly support K-12 screening testing in school districts and private/charter schools within a jurisdiction. Up to 15% may be used by recipients for coordination, management, technical assistance, monitoring, and data collection and reporting activities to support K-12 screening testing programs.

Additionally, there are special reporting requirements (see 'Summary of Reporting Requirements' in the 'Performance Measures and Reporting' section) which will likely require dedicated personnel resources to ensure timeliness and completeness of data being reported.

Examples of support in the form of coordination, management, technical assistance, monitoring and reporting, include but are not limited to:

1. Contracting for the development of a web-based platform, linking school districts and private/charter schools with testing service providers, with a program overview, toolkit and resources, and communication materials (e.g., https://covidedtesting.com/).
2. Adapting, modifying or implementing testing program toolkits or playbooks to support school districts and private/charter schools in program design (https://www.rockefellerfoundation.org/wp-content/uploads/2021/02/The-RockefellerFoundation-Covid-19-K-12-Testing-Playbook-for-Educators-and-Leaders.pdf).

PROCESS FOR WORKPLAN AND BUDGET SUBMISSION

Within five (5) business days of receipt of this guidance, the recipient's Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions. The acknowledgement must be submitted on the recipient's official agency letterhead and utilize the 'Acknowledgement Letter for CK19-1904 – COVID Supplemental Funds' template provided at the end of this guidance document.

This funding will be awarded in the ELC Budget Period 2 (BP2) (i.e., August 1, 2020 – July 31, 2021) under CK19-1904. However, recipients should note that this supplemental funding is for a sixteen (16) month project period and will end on July 31, 2022. The expanded project period coincides with the end of Budget Period 3 (BP3) (i.e., August 1, 2021 – July 31, 2022) of the ELC Cooperative Agreement (CK19-1904).

To reduce burden on recipients, given the multiple ELC COVID awards, the workplan will be streamlined for this award. Please see the 'Activities' section of this guidance for details pertaining to the three (3) required activities under this award.

To allow recipients to focus efforts on initiating activities (i.e. getting at least 85% of the award to support school districts and private/charter schools to increase screening testing, begin screening testing, etc.), recipients are given sixty (60) days from time of award for the submission of a revised budget in GrantSolutions via budget revision amendment. During this period, all funds will be available and recipients are expected to use funding expeditiously to conduct activities consistent with this guidance.

In cases of recipients entering into contractual agreements for school district support, to meet the OGS requirement for prior approval, submission of contract details can be made via Grant Note until the revised budget is officially submitted as a budget revision amendment in GrantSolutions.

Given this award has a 16-month funding period, revised budgets should reflect activities and associated costs that will end on July 31, 2022. Recipients are reminded that expanded authority[1] applies, in terms of carryover of unobligated from one budet period to the next budget period to cover the approved workplan activities.

REQUIRED TASKS

Note: If a recipient does not meet the below required tasks and has not received written approval for an extension from CDC, recipient may have their funds restricted in the Payment Management System (PMS) for specific costs/activities. Recurring or repeat non-compliance may result in additional restrictions or other actions being taken, consistent with applicable grant regulations.

In addition to the programmatic activities noted below in further detail, recipient responsibilities include but are not limited to:

1. Within **five (5) business days** of receipt of this guidance the Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions. The acknowledgement must be submitted on the recipient's official agency letterhead and utilize the 'Acknowledgement Letter for CK19-1904 – COVID Supplemental Funds' template provided at the end of this guidance document.
2. Regular participation in calls with CDC/HHS for technical assistance and monitoring of activities supported through this cooperative agreement.
3. On-time submission of all requisite reporting. This may include but is not limited to reporting of performance measures, progress on milestones, and/or financial updates within REDCap.
4. Report expenditures and unliquidated obligations (ULOs) on a monthly basis. On the 5th day of the month, the expenditures and ULOs from the prior month shall be reported in the REDCap 'ELC ED Expansion Financial Reporting' page.

[1] Expanded Authority is provided to recipients through 45 CFR Part 75.308, which allows carryover of unobligated balances from one budget period to a subsequent budget period. Unobligated funds may be used for purposes within the scope of the project as originally approved. Recipients will report use, or intended use, of unobligated funds in Section 12 "Remarks" of the annual Federal Financial Report.

5. Documentation of any necessary budget change/reallocation through GrantSolutions and REDCap.
6. Within ten (10) business days after receipt of the Notice of Award recipients shall report on the below via REDCap. After June, reporting for the remainder of the project period will be adjusted, at the recipient level, based on the school calendar and school district progress.
    a. Brief narrative that describes the methods used to provide support to schools;
    b. Budget estimates for providing up to the 85% of total award in support to schools;
    c. List of school districts and private/charter schools and estimated enrollment number for K-12 that are receiving support; and
    d. Frequency of testing.
7. **Weekly reporting**, within fifteen (15) business days from issuance of the award and until the end of June 2021, recipients shall report on the below via REDCap. After June, reporting for the remainder of the project period will be adjusted, at the recipient level, based on the school calendar and school district progress.
    a. The number of tests conducted by school district;
    b. Test type; and
    c. Cases identified.

ACTIVITIES

This award has three (3) required overarching activities that are designed to meet the immediate needs to safely reopen schools and the ongoing efforts to keep schools operating safely.

Activity 1: Rapid deployment of screening testing resources

The focus for Activity 1 is to jumpstart the ability for jurisdictions to implement school testing (estimated timeframe April to June). A minimum of 85% (direct and indirect) of the award must be allocated to support schools (public or private) that cover all or some K-12 grades within the recipient's jurisdiction. Recipients may use a combination of mechanisms to successfully provide the necessary support to schools. While not exhaustive, examples of mechanisms to provide financial support are listed in the 'Funding Strategy' section above. Additionally, examples of types of support may be found under the 'Allowable Costs' section. Recipients will need to support school district implementation with technical assistance and monitoring, as well as identifying public health actions needed based on school screening testing information. Recipients should assure that school districts and private/charter schools have adequate plans for action when they identify a positive test result.

Recipients may also plan and implement support for screening programs in school-affiliated summer programs, including camps and summer instruction. Recipients can also consider summer programs outside of schools that focus on providing equitable access to educational and recreational activities.

Initial reporting requirements

Within ten (10) business days after receipt of the Notice of Award and until the end of June 2021, recipients shall provide weekly reports on the below via REDCap. After June, reporting for the remainder of the project period will be adjusted, at the recipient level, based on the school calendar and school district progress.

1. A brief narrative that describes the method(s) that will be used to provide support to schools (e.g., partnerships with pharmacies, contracts for comprehensive screening testing services, reimbursable accounts with school districts and private/charter schools , or any combination of mechanisms).
2. Budget estimates for each method of support being provided up to the 85% of the total award.
3. A list of all school districts and private/charter schools supported with these funds and estimated enrollment numbers of K-12 students in each district and private/charter schools implementing screening testing programs.

Activity 2: Development of K-12 screening testing implementation plan

Recipients will develop a comprehensive screening testing plan[2] to support SARS-CoV-2 screening testing in K-12 schools across their communities for the 2021-2022 school year. In developing the plan, the information collected and lessons learned from Activity 1 (e.g., any limits in ability to conduct this program whether legal or practical, etc.) should inform planning for the 2021-2022 school year. The plan should include the approach(es) utilized to provide screening testing support to K-12 schools and a timeline for implementation that is consistent with CDC testing guidance and K-12 operational planning guidance (https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html). Existing plans may also be used or modified where appropriate. The plan is intended to be used by the jurisdiction, therefore not collected by CDC, and should address the specific needs within that jurisdiction.

Activity 3: Implementation screening testing action plan

Using the screening testing plan as a guide, recipients will progress through the stepwise implementation of the plans to support schools safely opening/remaining open for the 2021-2022 school year. The implementation plan should include methods to monitor effectiveness and integrate modifications as needed based on lessons learned over time.

Please note that additional supplemental guidance may be released to recipients based on information collected from performance measures, milestone progress reporting, and/or additional scientific understanding of SARS-CoV-2.

PERFORMANCE MEASURES

As noted above, within 10 business days of receipt of this guidance, recipients must provide a list of all school districts and private/charter schools implementing screening testing programs, that are supported with these funds, which will be used for weekly reporting. This list should include the number of K-12 students enrolled in each. This list will be utilized for the subsequent performance measure reporting.

Reporting to ELC via REDCap will commence within 15 business days after receipt of the Notice of Award and until the end of June 2021. Recipients shall provide weekly reports on the below via REDCap. After June, reporting for the remainder of the project period will be adjusted, at the recipient level, based on the school calendar and school district progress. It is expected that a substantial portion of the resources provided through this opportunity will be focused on establishing screening programs (April to June).

[2] For schools that host school-affiliated summer programs (in-person learning or summer camp), action plans should include details about screening testing over the summer months. Recipients can also consider summer programs outside of schools that focus on providing equitable access to educational and recreational activities.

1. Number of tests conducted by school districts and private/charter schools
2. Test type (e.g. antigen vs PCR)
3. Cased identified

ELC Reopening Schools Metrics for Week #1 for Recipient: X				
School District	Enrollment	Tests Conducted PCR	Tests Conducted Antigen	Cases (All test types)
District A				
District B				
District ….				

The ELC Program Office will utilize existing data sources whenever possible to reduce the reporting burden on recipients and, where appropriate, existing ELC performance measures may be used.

School districts and private/charter schools will not report test results directly to CDC under this award. For purposes of programmatic support to screening efforts, schools should be required by the recipient to report all positive results to the health department for public health action. Funds may be used to support data reporting by schools and their implementing partners. This project must be conducted in accordance with existing laws.

SUMMARY OF REPORTING REQUIREMENTS

The following is a summary of the reporting requirements for the ELC Reopening Schools award.

1. Within five (5) business days of receipt of this guidance, the Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions.
2. Within ten (10) business days after receipt of the Notice of Award recipients shall provide the below via REDCap.
    a. Brief narrative that describes the methods used to provide support to schools;
    b. Budget estimates for providing up to the 85% of total award in support to schools;
    c. List of school districts and private/charter schools and estimated enrollment number for K-12 that are receiving support; and
    d. Frequency of testing.
3. Within fifteen (15) business days from issuance of the award and until the end of June 2021, recipients shall provide weekly reports on the below via REDCap. After June, reporting for the remainder of the project period will be adjusted, at the recipient level, based on the school calendar and school district progress.
    a. The number of tests conducted by school districts and private/charter schools;
    b. Test type; and
    c. Cases identified.
4. Weekly reporting, in REDCap, on the financial support to school districts and private/charter schools until end of June 2021.
5. Monthly fiscal reports, entered in REDCap with final report in GrantSolutions via Grant Note, beginning 30 days after NOAs are issued.
6. Performance measure data.
7. CDC may require recipients to develop annual progress reports (APRs). CDC will provide APR guidance and optional templates should they be required.

ACKNOWLEDGEMENT LETTER: DUE WITHIN FIVE (5) DAYS OF NOA RECEIPT

ELC Reopening Schools: Support for Screening testing to Reopen & Keep Schools Operating Safely

Date:

Organization Name:

Subject: Acknowledgement Letter for CK19-1904 – COVID-19 Supplemental Funds – ELC Reopening Schools

Reference: Guidance for the use of supplemental funding (April 2021) for CK19-1904 *ELC Reopening Schools: Support for Screening Testing to Reopen & Keep Schools Operating Safely* through the American Rescue Plan Act of 2021.

This is to acknowledge that I have received, reviewed, and understand the requirements in the attached programmatic guidance.

The federal funding received will be in support of the supplemental funding referenced herein and will be spent in accordance with the legislation and programmatic guidance.

_____

Authorized Official

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Monday, March 29, 2021 8:42 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 3/29

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 29, 2021:

President Biden's remarks on Monday on the COVID-19 Response and State of Vaccinations:

- **New Vaccination Goal:** Last week we set a goal of 200 million shots by day 100 of our administration, double the original goal that I had set. To make that progress, over the last three days, we've had a record number of shots in arms with over 10 million shots recorded over the weekend. No other country has come close: 100 million shots in less than 60 days, and now we're moving on to the next 100 million shots in just 40 days. Nearly 75 percent of Americans over the age of 65 have received at least one vaccination shot. At least 90 percent of all adults in this country will be eligible to be vaccinated by April 19th, and the remaining 10 percent will be eligible no later than May 1 st. Moreover, 33 million doses of vaccine will be available to vaccinators this week.
- **Importance of Avoiding a Surge:** This is not the time to lessen our efforts, and if we let our guard down now, we could see the virus getting worse, not better. I am reiterating my call for every governor, mayor, and local leader to maintain and reinstate the mask mandate. Mask up. It's a patriotic duty, and it's the only way we ever get back to normal.
- **Increasing Vaccine Availability - 90/90 Initiative:** I am directing my COVID team to ensure there is a vaccine site within five miles of 90 percent of all Americans by April 19th. This is part of the Administration's "90/90" Initiative: by April 19 th, three weeks from today, 90 percent of adults — people over 18 and over — will be eligible get vaccinated and 90 percent of all Americans will be living within five miles of a place they can get a shot. We will also increase the current 17,000 pharmacies giving out vaccines to nearly 40,000 pharmacies within the next three weeks. We will also add 12 more federally-run mass vaccination sites, where currently, over 60 percent of the shots given at the existing sites goes to minorities communities. Lastly, I am directing millions of dollars, through the Department of Health and Human Services, to provide assistance, including transportation, to more vulnerable seniors and people with disabilities to help them get their shots.

Highlights from Friday and Monday's White House COVID-19 Response Team briefings:

Jeff Zients:

- **Increasing the Vaccine Supply:** The Administration has taken aggressive action to accelerate the production timelines of Pfizer, Moderna, and Johnson & Johnson, including using the Defense Production Act to expedite critical supplies, equipment, and materials, and brokering the historic partnership between Merck and Johnson & Johnson. J&J appears on track to deliver 20 million doses by the end of March, delivering 11 million doses this week, and both Pfizer and Moderna appear on track to meet their first-quarter targets.
- **Increasing the Number of Vaccinators:** The Administration has deployed over 6,500 federal personnel to serve as vaccinators and to support vaccinations, including calling on FEMA, retired doctors and nurses, and active-duty military to administer shots. In the coming weeks, at the President's direction, we will increase the 2,900 active-duty military men and women in the field to over 6,000 active-duty troops.
- **Increasing the Number of Places to get Vaccinated:** Across the country, there are nearly 50,000 sites where Americans can go to get a shot. We will continue to increase the number of local pharmacies administering the vaccine and expand community health centers providing the vaccine in the coming weeks. Importantly, over 65 percent of the shots administered at these community health centers have been to people of color. In addition to pharmacies and community health centers, there are over 650 federally supported community vaccination sites across the country. The Administration has also committed to deploying more than 500 mobile clinics as well as a program to get vaccines directly to dialysis centers.
- **Vaccine Eligibility Expansions:** Forty-six states and the District of Columbia have already announced plans to open up eligibility no later than May 1st. Fourteen states have already opened eligibility to all adults or will open eligibility in the next week. Twelve additional states are opening up eligibility to all adults by April 15th. In total, about half the states will have opened up eligibility to all adults by mid-April.

Andy Slavitt:

- **Number of People Vaccinated:** The U.S. is now averaging 2.7 million vaccinations over the last seven days. As of today, 73 percent of seniors have now received their first dose. Thirty-six percent — more than one in three adults — have received their first dose. Overall, more than 50 million Americans — approaching one in five adults — are fully vaccinated.
- **Federal Vaccination Sites:** Two new federally run mass vaccination sites will open: the first is at America's Center Convention Complex in St. Louis, Missouri, and the second is at Roosevelt High School in Gary, Indiana. These sites will join the 21 operational sites the administration has opened, which have already administered a combined 1.7 million shots.
- **Vaccine Passports:** The government is not viewing its role as the place to create a passport, nor a place to hold the data of citizens. We view this as something that the private sector is doing and will do. We are leading an interagency process right now to ensure that some important criteria are met with these credentials. Number one, that there is equitable access, including access to technology. It is also important that we recognize that there are still many millions of Americans that have not yet been vaccinated, which is a fundamental equity issue. Privacy of information, security of information, and a marketplace of solutions are all things that are part of what we believe in, as is the ability for people to access this for free and in multiple languages.

Dr. Walensky:

- **Case Update:** Yesterday, the US surpassed 30 million cases of COVID-19. CDC's most recent data show that the seven-day average of new cases is slightly less than 60,000 cases per day. This is a 10 percent increase compared to the prior seven-day period. Hospitalizations have also increased, with the most recent seven-day average at about 4,800 admissions per day. Deaths have increased nearly 3 percent to a seven-day average of approximately 1,000 deaths per day.
- **Avoiding a Surge:** The trajectory of the pandemic in the United States looks similar to many other countries in Europe, including Germany, Italy, and France looked like just a few weeks ago. And since that time, those countries have experienced a consistent and worrying spike in cases. Similarly, while the United States was stagnated at around 40,000 to 50,000 cases a day for a couple of weeks, we

now see a steady rise of cases towards 60,000 to 70,000 cases a day. Many states are opening up at levels that we wouldn't necessarily recommend, and we have also seen an uptick in travel. We also know that about 25 percent of all sequenced virus is now the B.1.1.7 variant, which is more transmissible and accounts for 8,000 cases in 51 jurisdictions. I will be speaking with many governors tomorrow, and I would encourage the public to follow the public health prevention strategies consistently, while we work to get the American public vaccinated.

- **Real World Effectiveness of Vaccine:** An MMWR study was released (see more info below) which found that the risk of infection was reduced by 90 percent after individuals received the two recommended doses of the Pfizer and Moderna vaccines. The study also found that people started to get a protective effect, even after the first dose, the risk of infection decreased by 80 percent after two weeks. Findings of this are all consistent with the clinical trial data. Importantly, people in the study received self-collected nasal swabs each week for laboratory testing, allowing CDC to look at evidence of COVID-19 infection whether or not people had symptoms. This study also demonstrates that two vaccines can reduce the risk of COVID-19 infections, not just in symptomatic infections but also in asymptomatic or pre-symptomatic infections. These findings underscore the importance of getting both of the recommended doses of the vaccine in order to get the greatest level of protection against COVID-19, especially as our concerns about variants escalate.
- **Updated Underlying Conditions:** After a thorough review of the evidence, we have simplified the list of underlying conditions for consumers and created a new page for healthcare providers. This will make it easier for patients and the public and providers to understand the important information related to their underlying medical conditions and its potential impact on COVID-19 severity. We've also updated the list of underlying medical conditions to include substance use disorders, based on evidence that having these conditions can increase risk of severe illness or death from COVID-19.
- **CDC's Commitment to Health Equity:** CDC will provide $3 billion from the CARES Act and the American Rescue Plan to 64 jurisdictions to support broad-based vaccine distribution, access, and administration efforts. 75 percent of the funding must focus on specific programs and initiatives intended to increase vaccine access, acceptance, and uptake among racial and ethnic minority communities. In addition, 60 percent of the funding must go to support local health departments, community-based organizations, and community health centers. In addition, CDC announced a separate investment of $300 million that will train, deploy, and engage more community health workers to help communities and individuals hardest hit by the pandemic.

Dr. Fauci:

- **Effects of COVID-19:** While the most important and common manifestation of COVID-19 is the acute respiratory distress syndrome, we now know there are neurological disorders, cardiac dysfunction, acute kidney injury, and hypercoagulability that can occur if contracting the virus. The bottom line: This is a very, very bad disease.
- **New Clinical Trial Among College Students:** This is a randomized, open-label, controlled study involving 12,000 college kids between 18 and 26 years of age at more than 20 universities; these students will be followed over five months. The students are going to be randomized into two groups: 6,000 will receive the Moderna vaccine immediately and another 6,000 will be vaccinated with a delay of four months later, serving as a control cohort. Importantly, about 25,000 individuals will be identified by the participants in the main study as "close contacts" and they will provide periodic blood samples along with the students in the study. The purpose of this study is to determine whether vaccinated people get infected asymptomatically, and if they do, do they transmit the infection to other.

Vaccine Updates

Vaccine Eligibility and Proximity: Today, President Biden unveiled new actions to get more people vaccinated quickly and announced that by April 19, 90% of adults in the U.S. will be eligible for vaccination and 90% will have a vaccination site within 5 miles of where they live. This announcement builds on last week's historic $10 billion investment to expand access to COVID-19 vaccines in the hardest-hit and highest-risk communities.

Developing Vaccines Quickly: Bringing a new vaccine to the public involves many steps including vaccine development, clinical trials, US Food and Drug Administration (FDA) authorization or approval, manufacturing, and distribution. Many different public organizations and private companies have worked together to make COVID-19 vaccines available to the public. While COVID-19 vaccines have been developed rapidly, all steps have been taken to ensure their safety and effectiveness.

Vaccinating People in Dialysis Clinics: The federal government is partnering with dialysis organizations, local and state jurisdictions to increase access to COVID-19 vaccines for patients and healthcare personnel in outpatient dialysis clinics. This partnership complements existing jurisdictional efforts to ensure equitable and effective access to COVID-19 vaccines and will increase availability of COVID-19 vaccines for patients in dialysis clinics. These patients are disproportionately affected by COVID-19 and are at high risk of severe illness from COVID-19.

Connecticut First State to Open COVID -19 Vaccine Mobile Unit: In the ongoing effort to bring the COVID vaccine to communities and people in socially vulnerable areas, Connecticut will open the country's first Mobile Vaccination Unit (MVU) on March 29, 2021 at the Beardsley Zoo in Bridgeport, Connecticut. The MVU will travel throughout Connecticut for 60 days to reach populations in 17 communities. Destinations were targeted based on the CDC's Social Vulnerability Index, U.S. Census Bureau's Community Resilience Estimates, low vaccine coverage, metrics and other barriers to vaccine access. The MVU will be used to complement ongoing efforts of local public health departments, health care providers, pharmacies, community and faith-based organizations, employers, private sector vaccinators and other federal resources.

Medical Reserve Corps Volunteers Aid COVID-19 Vaccination Efforts: More than 300 Medical Reserve Corps (MRC) units are assisting with COVID-19 vaccination efforts in 43 states, Puerto Rico, American Samoa, and the Northern Mariana Islands. Additional MRC units are preparing to activate to support vaccinations as more doses become available. MRC is sponsored nationally by HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and the agency provides the MRC network with technical assistance, strategy and policy development, training, and other related services. The units are managed and deployed at the state, territorial or local level, often by local health departments and emergency management agencies.

Baltimore Fait Community Promoting COVID-19 Vaccine Confidence: The African American faith community in Baltimore has been integral to educating the public about the risks posed by flu and the importance of vaccination. This work now provides immunization partners with lessons learned for the COVID-19 vaccination program.

Testing

EUA for Twist Bioscience Corporation: The FDA issued an emergency use authorization (EUA) to the Twist Bioscience Corporation for their SARS-CoV-2 NGS Assay. The SARS-CoV-2 NGS Assay is a next-generation sequencing (NGS) based test for the identification of SARS-CoV-2 RNA from respiratory samples, such as nose or throat swabs and washes, from people who are suspected of having COVID-19. This is the second whole genome sequencing diagnostic test for the qualitative detection of SARS-CoV-2 RNA authorized by the FDA. The test can be performed in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that meet the requirements to perform high-complexity testing.

Automated Antigen Detection Assay for Acute COVID-19: BARDA is expanding its existing partnership with DiaSorin SpA on the development of a COVID-19 immunoassay. This new test detects the presence of SARS-CoV-2 in nasal swabs or nasopharyngeal swabs to diagnose acute COVID-19 disease. DiaSorin intends to develop, validate, manufacture, market, and obtain regulatory authorization in the United States and worldwide for this new, fully automated, chemiluminescent, antigen assay for the qualitative detection of the SARS-CoV-2 virus using nasal swabs or nasopharyngeal swabs. This assay will allow testing of nasal swabs in addition to traditional nasopharyngeal swabs, thereby expanding the utility of the assay by simplifying collection and enhancing patient comfort and safety.

Performing Broad-Based Testing: This tool is intended to help public health departments, healthcare providers, and administrators of congregate settings prepare for broad-based viral testing in correctional facilities and homeless service settings, after known or suspected exposure to the virus that causes COVID-19 or when there is moderate to substantial transmission in the community.

Testing Updates: As of Friday, 348 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 258 molecular tests and sample collection devices, 74 antibody and other immune response tests, and 16 antigen tests. There are 42 molecular authorizations that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home tests, one over-the-counter (OTC) at-home antigen test, and one OTC molecular test.

Funding

Access to COVID-19 Vaccines for Older Adults and People with Disabilities As part of President Biden's announcement today that the Administration will take further action to expand access to COVID-19 vaccines, HHS, through a partnership between the CDC and the Administration for Community Living (ACL), will provide nearly $100 million to help increase vaccinations among older adults and people with disabilities. This effort will help advance the key goals of protecting those most vulnerable and advancing equity within President Biden's National Strategy for the COVID-19 Response and Pandemic Preparedness.

Health Equity Funding: The Centers for Medicare & Medicaid Services Office of Minority Health (CMS OMH) is excited to release a notice of funding opportunity for the Minority Research Grant Program (MRGP), which provides up to $250,000 in funding to health equity researchers at minority-serving institutions. The MRGP allows researchers at minority-serving institutions (MSIs) to build their portfolios while conducting studies pertinent to the health care needs of racial and ethnic minorities, people with disabilities, sexual and gender minorities, and rural populations. Those interested in applying are encouraged to review the notice of funding opportunity CMS-1W1-21-002. The deadline to submit applications is Friday, June 11, 2021, at 3:00 p.m. ET.

Information for Specific Populations

Underlying Medical Conditions Associated with High Risk for Severe COVID-19: This webpage provides an evidence-based resource for healthcare providers caring for patients with underlying medical conditions who are at higher risk of developing severe outcomes of COVID-19. Severe outcomes are defined as hospitalization, admission to the intensive care unit (ICU), intubation or mechanical ventilation, or death. View CDC's page on scientific evidence for conditions that increase risk of severe illness.

Older Adults: The risk of severe illness from COVID-19 increases with age. This is why CDC recommends that adults 65 years and older are one of the first groups to receive COVID-19 vaccines. Getting a COVID-19 vaccine is an important step to help prevent getting sick from COVID-19. That said, it might take time before enough vaccines are made for everyone who wants to be vaccinated.

Infection Control for Nursing Homes: Given their congregate nature and resident population served (e.g., older adults often with underlying chronic medical conditions), nursing home populations are at high risk of being affected by respiratory pathogens like SARS-CoV-2 and other pathogens, including multidrug-resistant organisms (e.g., carbapenemase-producing organisms, Candida auris). As demonstrated by the COVID-19 pandemic, a strong infection prevention and control (IPC) program is critical to protect both residents and healthcare personnel (HCP). Even as nursing homes resume more normal practices and begin relaxing restrictions, nursing homes must sustain core IPC practices and remain vigilant for SARS-CoV-2 infection among residents and HCP in order to prevent spread and protect residents and HCP from severe infections, hospitalizations, and death.

People with Certain Medical Conditions: CDC updated their page for people with certain medical conditions. This page includes conditions such as liver disease, cancer, and more.

Drug Use & Substance Use Disorder: Having a substance use disorder can make you more likely to get severely ill from COVID-19. People who use drugs may also have underlying medical conditions that put them at increased risk for severe illness from COVID-19, and they may have concerns and questions related to their risk.

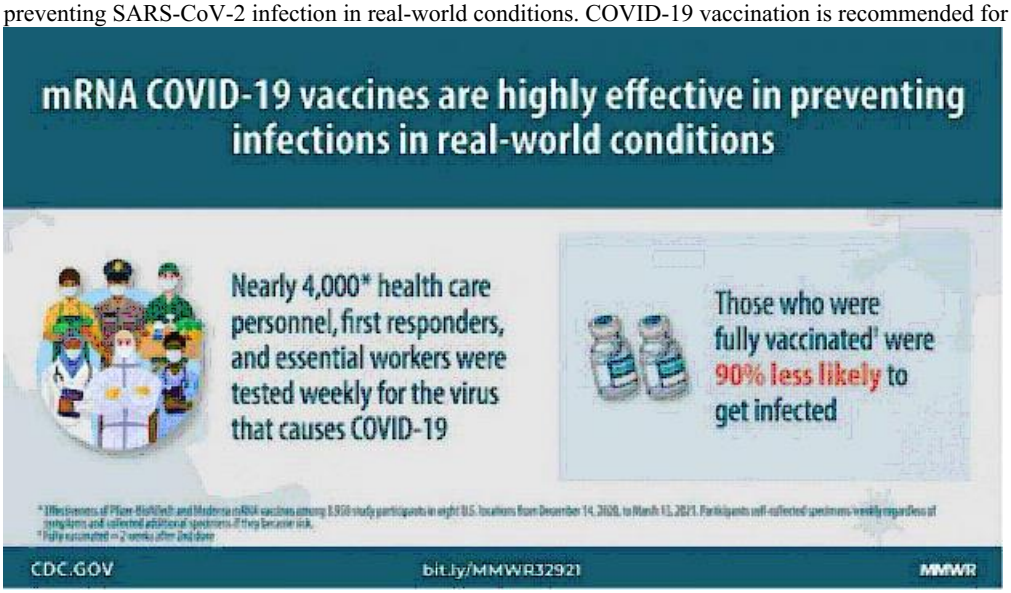
State Vets & Animal Health Officials: CDC updated their resources for state vets and animal health officials.

Temporary Halt in Residential Evictions: CDC Director Dr. Rochelle Walensky signed a declaration determining that the evictions of tenants could be detrimental to public health control measures to slow the spread of SARS-Cov-2, the virus that causes COVID-19.

Research

Use of Mental Health Care during the COVID-19 Pandemic: CDC released an MMWR on symptoms of anxiety or depressive disorder and use of mental health care among adults during the COVID-19 pandemic. During August 2020–February 2021, the percentage of adults with recent symptoms of an anxiety or a depressive disorder increased from 36.4% to 41.5%, and the percentage of those reporting an unmet mental health care need increased from 9.2% to 11.7%. Increases were largest among adults aged 18–29 years and those with less than a high school education. Trends in mental health can be used to evaluate the impact of strategies addressing adult mental health status and care during the pandemic and to guide interventions for disproportionately affected groups.

Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2: CDC released an MMWR on interim estimates of v accine effectiveness of BNT162b2 and mRNA-1273 COVID-19 vaccines in preventing SARS-CoV-2 infection among health care personnel, first responders, and other essential and frontline workers**.** Prospective cohorts of 3,950 health care personnel, first responders, and other essential and frontline workers completed weekly SARS-CoV-2 testing for 13 consecutive weeks. Under real-world conditions, mRNA vaccine effectiveness of full immunization (≥14 days after second dose) was 90% against SARS-CoV-2 infections regardless of symptom status; vaccine effectiveness of partial immunization (≥14 days after first dose but before second dose) was 80%. Authorized mRNA COVID-19 vaccines are effective for preventing SARS-CoV-2 infection in real-world conditions. COVID-19 vaccination is recommended for all eligible persons.



Benefits of mRNA COVID-19 Vaccines: A new CDC study provides strong evidence that mRNA COVID-19 vaccines are highly effective in preventing SARS-CoV-2 infections in real-world conditions among health care personnel, first responders, and other essential workers. These groups are more likely than the general population to be exposed to the virus because of their occupations. The study looked at the effectiveness of Pfizer-BioNTech and Moderna mRNA vaccines in preventing SARS-CoV-2 infections among 3,950 study participants in six states over a 13-week period from December 14, 2020 to March 13, 2021. Results showed that following the second dose of vaccine (the recommended number of doses), risk of infection was reduced by 90 percent two or more weeks after vaccination. Following a single dose of either vaccine, the participants' risk of infection with SARS-CoV-2 was reduced by 80 percent two or more weeks after vaccination.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Tuesday, March 30, 2021 9:02 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 3/30

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 30, 2021:

Case Update

New Cases (based on 7-day rolling average)
- **30,085,827** US cases
- **13.2% increase** in new cases (7-day average), as of March 30th; (was 1.8% increase last week)

Testing
- **364,465,712** tests completed (3/30)
- **5.0% positive test rate** as of the week of 3/23 – 3/30 (was 4.7% last week)

Hospitalizations
- **1,936,304** total COVID hospital admissions
- The 7-day average (3/23-3/30) number of new confirmed COVID-19 admissions **increased by 1.1%** week on week (from 4,517 to 4,693 admissions per day)

Deaths
- **546,704** total US deaths
- The 7-day average (3/23-3/29) number of reported deaths **increased by 6.7%** week on week (from 928 to 985 deaths per day)

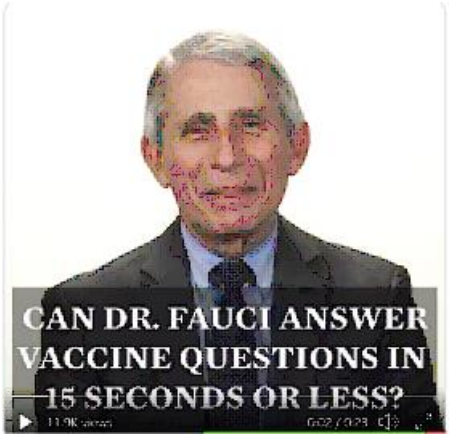
Vaccines
- **147,602,345** vaccine doses **administered** (3/30)
- **28.9%** (96 million people) of the population has received **1 or more doses** and **16.1%** (53.4 million people) of the population have been **fully vaccinated**
- **73.1%** of adults 65 and older have received **at least 1 dose** and **49.8%** have been **fully vaccinated**

Vaccine Updates

Fact Sheet on Johnson & Johnson Janssen Vaccine: CDC updated their general information on the Johnson & Johnson Vaccine. The J&J/Janssen vaccine is recommended for people aged 18 years and older. Learn more about how CDC is making COVID-19 vaccine recommendations and CDC's vaccine rollout recommendations.

Reported Adverse Events After COVID-19 Vaccination: Over 145 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through March 29, 2021. During this time, the Vaccine Adverse Event Reporting System (VAERS) received 2,509 reports of death (0.0017%) among people who received a COVID-19 vaccine. CDC and FDA physicians review each case report of death as soon as notified and CDC requests medical records to further assess reports. A review of available clinical information including death certificates, autopsy, and medical records revealed no evidence that vaccination contributed to patient deaths. CDC and FDA will continue to investigate reports of adverse events, including deaths, reported to VAERS.

Dr. Fauci on Getting Vaccinated: In a brief video, Dr. Fauci explains why everyone should get vaccinated.



Testing and Treatment

COVID-19 Response at a Glance: FDA has updated its FDA COVID-19 Response At-A-Glance Summary, which provides a quick look at facts, figures and highlights on the FDA's response efforts.

New Drug Application Approved to Assist with Intubation: On March 29, the FDA approved an abbreviated new drug application for succinylcholine chloride injection USP 200 mg/10 mL, which is indicated, in addition to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. Side effects of succinylcholine chloride injection include anaphylaxis, hyperkalemia, and malignant hyperthermia. The FDA recognizes the increased demand for certain products during the COVID-19 public health emergency, and we remain deeply committed to facilitating access to safe and effective medical products to help address critical needs of the American public.

Strategies for Safe Sharps Disposal: The CDC offered strategies for how to protect yourself from needlestick injuries while administering COVID-19 vaccines or while helping at vaccination sites. Additionally, a shortage in the supply of FDA-cleared sharps disposal containers may occur during the COVID-19 mass vaccination campaign or as a result of other causes. Healthcare facilities and COVID-19 vaccination sites must use sharps disposal containers that meet Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens standard requirements to dispose of contaminated needles and other sharps. Use FDA-cleared containers whenever possible. Conserve your FDA-cleared sharps disposal containers to help avoid a potential supply shortage. If FDA-cleared sharps disposal containers are unavailable, then consider using alternative containers that meet the OSHA requirements after checking your state's specific disposal requirements at SafeNeedleDisposal.org and discussing disposal options with your medical waste vendors.

COVID-19 Electronic Laboratory Reporting Implementation by State: CDC has been rapidly onboarding state and jurisdictional health departments to a more detailed form of COVID-19 electronic laboratory reporting (CELR). As of Tuesday, March 30th, 53 jurisdictions have converted to electronic laboratory reporting, representing approximately 92% of the total laboratory testing volume in the country.

FDA Testing Update: As of today, 349 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 258 molecular tests and sample collection devices, 74 antibody and other immune response tests, and 17 antigen tests. There are 42 molecular authorizations that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home test, one over-the-counter (OTC) at-home antigen test, and one OTC molecular test.

Information for Specific Populations

CDC Update on COVID-19 in Pets: A small number of pets worldwide, including cats and dogs, have been reported to be infected with the virus that causes COVID-19. The virus that causes COVID-19 can spread from people to animals in some situations, mostly during close contact. This is monitored frequently, and updates will continue to be posted.

CDC Recommendations for Managing Malaria and COVID-19: Ministries of Health and National Malaria Control Programs (NMCPs) need to ensure that malaria prevention and treatment activities are implemented while also protecting patients, health care providers, and public health officials from COVID-19 exposure. The CDC put forth key considerations for continuing essential malaria prevention and control activities safely and effectively, supplementing country Ministry of Health guidance.

CMS Updates

MIPS Application Extension: CMS has re-opened the 2020 extreme and uncontrollable circumstances application for the Merit-based Incentive Payment System (MIPS) eligible clinicians, groups, virtual groups, and APM entities who are unable to submit data due to COVID-19. For the 2020 performance year, we will be using our Extreme and Uncontrollable Circumstances policy to allow clinicians, groups, and virtual groups to submit an application requesting reweighting of one or more Merit-based Incentive Payment System (MIPS) performance categories due to the current COVID-19 public health emergency. To provide additional support to clinicians during this time, we are extending the deadline to submit a COVID-19 related extreme and uncontrollable circumstances application for PY 2020 to Wednesday, March 31, 2021 at 8 p.m. ET.

Research

Measles Vaccine Used as Base for Experimental COVID-19 Vaccine: Scientists developed a SARS-CoV-2 vaccine by adding a key coronavirus gene to the measles vaccine. The experimental vaccine protected against COVID-19 in animal studies, supporting further development. The vaccine prevented the virus from replicating in the lungs and nasal passages, produced a strong T cell response, and produced levels of neutralizing antibodies in rodents higher than those found in recovered COVID-19 patients. This vaccine candidate could potentially be used against both COVID-19 and measles.

T-Cells Recognize Recent SARS-CoV-2 Variants: In a study of recovered COVID-19 patients, researchers from the NIAID, NIH, and colleagues determined that SARS-CoV-2-specific CD8+ T-cell responses remained largely intact and could recognize virtually all mutations in the B.1.1.7 (U.K.), B.1.351 (South Africa), and B.1.1.248 (Brazil) variants. While larger studies are needed, the researchers note that their findings suggest that the T-cell response in convalescent individuals, and most likely in vaccines, are largely not affected by the mutations found in these variants and should offer protection against emerging variants. Optimal immunity to SARS-Cov-2 likely requires strong multivalent T-cell responses in addition to neutralizing antibodies and other responses to protect against current SARS-CoV-2 strains and emerging variants. The authors stress the importance of monitoring the anti-SARS-CoV-2 T-cell responses in order to determine if booster vaccinations are needed.

Increased Mortality Rate from the 'U.K. Variant' B.1.1.7: NIH Director, Dr. Francis Collins, examines studies conducted by Nicholas Davies, Karla Diaz-Ordaz, and Ruth Keogh, London School of Hygiene and Tropical Medicine, regarding the increased mortality rate from 'U.K. Variant' B.1.1.7. The researchers' estimates suggest that B.1.1.7 infection was associated with 55 percent greater mortality compared to other SARS-CoV-2 variants over this time period. This finding is in line with another recent study reported in the *British Medical Journal*, which found that the B.1.1.7 variant was associated with a 64 percent greater chance of death compared to earlier variants.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Wednesday, March 31, 2021 8:24 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 3/31

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 31, 2021:

Highlights from the White House COVID-19 Response Team briefing:

Andy Slavitt:

- **Increasing Vaccination Sites:** The President committed to opening at least 12 more federally run mass vaccination sites, adding to the existing total of 25 sites. Three new sites will open next week in Memphis, Tennessee, Milwaukee, Wisconsin, and Greenbelt, Maryland, in addition to the two we announced on Monday in St. Louis, Missouri, and Gary, Indiana. Each of these sites is the first federally run mass vaccination site in its respective state, and each can administer 3,000 vaccinations a day.
- **Mask Mandates:** We need every governor, mayor, and local leader to maintain or reinstate mask mandates. And we need every American to do their part so that we can win this race and save lives.

Dr. Walensky:

- **Case Update:** CDC's most recent data show that the seven-day average of new cases is slightly less than 62,000 cases per day. We continue to see an increase, and this is almost a 12 percent increase from the seven-day period prior. Hospitalizations also continue to increase. The most recent seven-day average — about 4,900 admissions per day — is up from 4,600 admissions per day in the prior seven-day period. The seven-day average of deaths remains slightly above 900 deaths per day.
- **Inequities in COVID-19 Deaths:** COVID-19 deaths were highest for older adults and males, and were higher, as we previously saw, among American Indian and Alaska Natives, Hispanics, non-Hispanic Blacks, and non-Hispanic Native Hawaiian and Pacific Islander persons compared to non-Hispanic whites. In fact, among nearly all these ethnic and racial minority groups, the COVID-19-related deaths were more than double the death rate of non-Hispanic white persons. Based on the current state of the pandemic, these impacts have remained in 2021, where we continue to see that communities of color account for an outsize portion of these deaths.
- **Number of People Vaccinated:** This week, we will reach 100 million people who have received at least one dose of the COVID-19 vaccine in the United States — a remarkable feat in such a short period of time. Further, over 70 percent of people over age 65, our most vulnerable group, have received at least one vaccine dose. In addition to increasing the number of mass vaccination sites across the country with FEMA, expanding the Federal Retail Pharmacy Program, and ensuring that all Americans have a vaccine site within five miles of their home, we are also activating mobile vaccination units and clinics. CDC is also excited to partner with the Administration for Community Living to support their efforts to get older, at-risk adults and those with disabilities vaccinated.
- **Guidance for Adult Day Service Centers:** CDC updated COVID-19 guidance for adult day service centers. These populations are at high risk for severe COVID-19 disease, and this guidance will help center administrators and staff protect themselves and adults receiving their services by promoting and engaging in preventive behaviors that reduce COVID-19 spread and help maintain healthy operations and environments of these facilities.
- **B.1.1.7 Variant:** We now have B.1.1.7 (U.K. variant) as 26 percent of the circulating variant across the United states, and it is the predominant strain in at least five regions of the United States. The variant is more transmissible – somewhere between 50 and 70 percent more transmissible than the wild-type strain. Therefore, to the extent that people are not practicing those standard mitigation strategies, we do think that more infections will result because of B.1.1.7. We believe that the current mitigation strategies of masking and distancing would work just as well against the current, the wild-type strain, as they do the B.1.1.7 strain.

Dr. Fauci:

- **Importance of Getting Vaccinated:** We are seeing now immune protection against COVID-19 variants when individuals are vaccinated against the wild-type strain, namely the common virus in society, on two mechanisms: the antibody response that has a spillover effect and the cross-reactivity. Vaccination is not only going to protect us against the common COVID-19 virus in society, but it has the potential, to a greater or lesser degree, to also protect against a range of variants. So, when vaccination becomes available, get vaccinated.

Vaccine Updates

Federal Retail Pharmacy Program: CDC updated their general information on the Federal Retail Pharmacy Program for COVID-19 Vaccination. As the program expands and supply becomes more readily available, the allocation may be adjusted to reflect partner size (number of store locations nationwide), reach (percent of the total US population living within 5 miles of a store location), and ability to vaccinate (throughput). The program, which will scale up to eventually include COVID-19 vaccination at all 40,000+ retail locations, will make it easier for individuals to access free COVID-19 vaccine at a pharmacy in their community, and improve vaccine uptake while decreasing the logistical and operations burden on state, local, and territorial health departments.

Johnson & Johnson Janssen Vaccine: CDC updated their general information on the Johnson & Johnson Vaccine. The J&J/Janssen vaccine is recommended for people aged 18 years and older. Learn more about how CDC is making COVID-19 vaccine recommendations and CDC's vaccine rollout recommendations.

FEMA Vaccination Sites: FEMA announced that it will open a COVID-19 vaccination site in Greenbelt, Maryland on April 7th. The center's capacity is expected to be up to 3,000 shots per day. President Biden also committed to opening sites in Memphis, TN and Milwaukee, WI. These sites join many new FEMA vaccination sites recently announced, including in Boston, Massachusetts; Essex, New Jersey; Norfolk, Virginia; and Yakima, Washington, all of which open today. In the next week, federal communication vaccination center pilot sites in Gary, Indiana and St. Louis, Missouri are scheduled to open, as well. The agency has provided more than $4.47 billion for expenses related to COVID-19 vaccination at 100% federal cost share.

Peace Corps Assistance in COVID-19 Response: FEMA and the Peace Corps announced a historic partnership to combat the COVID-19

pandemic, marking only the second time in the Peace Corp's history where volunteers will serve a domestic deployment. The Peace Corps will soon begin recruiting for the special domestic deployment through Peace Corps Response, a program that sends in individuals with specialized experienced to short-term service assignment of up to 12 months. Assignments will focus on urgent needs as identified by FEMA and on communities that have been traditionally under-served.

Evaluating Moderna COVID-19 Variant Vaccine: An investigational vaccine designed to protect against the B.1.351 SARS-CoV-2 variant has been administered as part of a new Phase 1 clinical trial evaluating the vaccine candidate's safety and immunogenicity in adult volunteers. The vaccine, known as mRNA-1273.351, was developed by the biotechnology company ModernaTX, Inc., based in Cambridge, Massachusetts. The trial is led and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The trial will enroll approximately 210 healthy adult volunteers at four clinical research sites in the United States that are part of the NIAID-funded Infectious Diseases Clinical Research Consortium (IDCRC).

HHS Podcast: HHS's new podcast, *COVID-19 Immunity in Our Community*, features top medical experts to answer questions on COVID-19 vaccines. Today's episode, "Building Vaccine Trust Within the Black Community," discusses how we can start to rebuild the Black community's trust in the vaccines, in order to achieve herd immunity and, hopefully, regain some sense of normalcy in our everyday lives.

Testing and Treatment

Covid-19 Precautions: CDC updated their COVID-19 page, reiterating that it is critical to keep taking precautions to prevent COVID-19. Learn more about how to protect yourself and others from CDC's recommendations.

COVID-19 Self Testing: CDC and NIH launched an innovative community health initiative called "Say Yes! COVID Test" starting in two locales, Pitt County, North Carolina, and coming soon to Chattanooga/Hamilton County, Tennessee. As many as 160,000 residents across the two communities will have access to free, rapid antigen tests that they can administer themselves to use three times a week for one month. NIH will provide the tests (also called a home-test or at-home test) and evaluate the effectiveness of the initiative, which aims to determine if frequent self-administered COVID-19 testing helps residents reduce community transmission of SARS-CoV-2, the virus that causes COVID-19 disease.

$147 Million to Expand Production of Swabs: DOD and HHS awarded $146.7 million to Puritan Medical Products on March 26 for renovations in the company's Orlinda, Tenn. facility to increase production capacity of foam tip swabs used in COVID-19 diagnostic tests. Funded through HCEA, the award will help the company boost total production capacity of the swabs to 250 million per month by February 2022.

Monoclonal Antibody Treatments: 3 EUAs for monoclonal antibody (mAb) treatments for mild-to-moderate COVID-19 in at-risk patients: bamlanivimab, casirivimab/imdevimab, and bamlanivimab/etesevimab. Learn more about FDA-authorized monoclonal treatments that can help at-risk patients fight the disease.

HHS Innovative Challenge for Masks: The U.S. Department of Health and Human Services launches $500,000 innovation challenge competition today encouraging American inventors to aid the nation's COVID-19 response by designing effective, comfortable face masks for personal use that resolve the common complaints people have about wearing masks. The contest taps into the nation's creativity and entrepreneurial spirit to help curb the spread of SARS-CoV-2, the virus that causes COVID-19.

Information for Specific Populations

Healthcare Workers: CDC updated their guidance for managing patients with COVID-19, including clinical guidance, home and hospital care, care for special populations, disease severity, and more.

Guidance for Adult Day Services Centers: CDC released guidance for administrators and staff to prevent the spread of COVID-19. Adult Day Services Centers (ADSCs) provide social or health services to community-dwelling adults aged 65 and over and adults of any age living with disability. Older adults and persons with disabilities are at highest risk for severe illness from COVID-19 including hospitalization, intensive care, and death. ADSC administrators and staff can help protect themselves and program participants (that is, adults attending ADSCs) from COVID-19 by promoting and engaging in preventive behaviors that reduce spread and maintain healthy operations and environments at ADSC facilities. This guidance is meant to supplement — not replace — any Federal, state, tribal, local, or territorial public health and safety laws, rules, and regulations with which adult day services center programs must comply. CDC has also developed recommendations for participants at ADSCs and their caregivers.

Suggestions for Youth and Summer Camps: CDC offers suggestions for ways in which camp administrators can help protect campers, staff, and communication, and prevent the spread of COVID-19. Camp administrators can determine, in collaboration with state and local health officials, whether and how to implement these considerations, making adjustments to meet the unique needs and circumstances of the local community. Implementation should be guided by what is feasible, practical, acceptable, and tailored to the needs of each community. These suggestions are meant to supplement— not replace —any state, local, territorial, or tribal health and safety laws, rules, and regulations with which camps must comply.

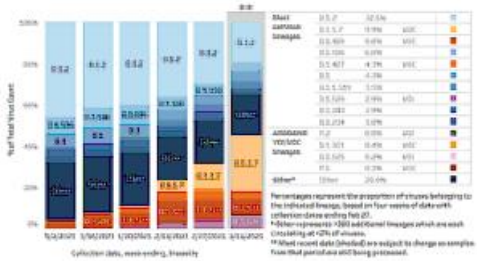
Essential Services for Malaria: CDC updated their key considerations for continuing essential malaria prevention and control activities safely and effectively. These considerations should supplement country Ministry of Health guidance.

CMS Updates

Medicare Fee-for-Service Billing: CMS updated their COVID-19 Frequently Asked Questions on Medicare Fee-for-Service (FFS) Billing. The policies set out in this FAQ are effective for the duration of the public health emergency unless superseded by future legislation. The FAQs in this document supplement the previously released FAQs, 1135 Waiver FAQs.

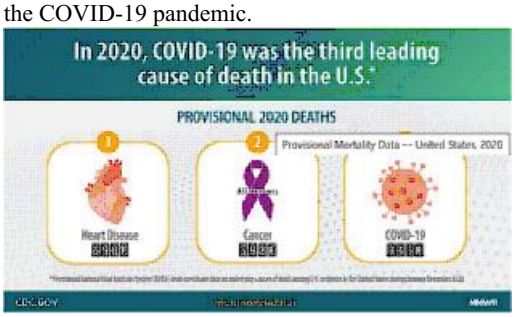
Research

Variant Proportions in the U.S: CDC's national genomic surveillance program identifies new and emerging SARS-CoV-2 variants to determine implications for COVID-19 diagnostics, treatments, or vaccines authorized for use in the United States. Monitoring the spread of emerging variants in the United States relies on widespread, rapid sequencing. To accelerate sequencing in the United States, CDC has contracted with commercial diagnostic laboratories, and, in partnership with the Association of Public Health Laboratories (APHL), has implemented the National SARS-CoV-2 Strain Surveillance (NS3) program to provide a comprehensive and population-based US surveillance system. This data, along with data from many other sources, are used to inform national and state public health actions related to variants.



COVID-19 2020 Mortality Surveillance: The Morbidity and Mortality Weekly Report (*MMWR*) on death certificate-based ICD-10 diagnosis codes for COVID-19 mortality surveillance addresses that among the 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both. These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of death certificate diagnoses is essential for an authoritative public record.

Provisional 2020 Mortality Data: The Morbidity and Mortality Weekly Report (*MMWR*) on provisional mortality data in the United States in 2020 addresses that the age-adjusted death rate increased by 15.9% in 2020. Overall death rates were highest among non-Hispanic Black persons and non-Hispanic American Indian or Alaska Native persons. COVID-19 was the third leading cause of death, and the COVID-19 death rate was highest among Hispanics. Provisional death estimates provide an early indication of shifts in mortality trends. Timely and actionable data can guide public health policies and interventions for populations experiencing higher numbers of deaths that are directly or indirectly associated with the COVID-19 pandemic.



Case Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 cases will remain stable or have an uncertain trend over the next 4 weeks, with 223,000 to 723,000 new cases likely reported in the week ending April 24, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of new reported cases per week will likely decrease in 4 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported cases are uncertain or predicted to remain stable in the other states and territories. View previous case forecasts.

Hospitalization Forecasts: This week's national ensemble predicts that the number of new daily confirmed COVID-19 hospital admissions will remain stable or have an uncertain trend over the next 4 weeks, with 2,300 to 8,700 new confirmed COVID-19 hospital admissions likely reported on April 26, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of daily confirmed COVID-19 hospital admissions will likely increase in 6 jurisdictions and decrease in 12 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported hospital admissions are uncertain or predicted to remain stable in the other states and territories. View previous hospitalization forecasts.

Death Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 deaths will remain stable or have an uncertain trend over the next 4 weeks, with 3,100 to 10,200 new deaths likely reported in the week ending April 24, 2021. The national ensemble predicts that a total of 565,000 to 585,000 COVID-19 deaths will be reported by this date. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of newly reported deaths per week will likely decrease in 8 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported deaths are uncertain or predicted to remain stable in the other states and territories. View previous death forecasts.

Marvin Figueroa, Director
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Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

CSTE

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
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Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020

Adi V. Gundlapalli, MD, PhD[1]; Amy M. Lavery, PhD[1]; Tegan K. Boehmer, PhD[1]; Michael J. Beach, PhD[1]; Henry T. Walke, MD[1]; Paul D. Sutton, PhD[2]; Robert N. Anderson, PhD[2]

Approximately 375,000 deaths during 2020 were attributed to COVID-19 on death certificates reported to CDC (*1*). Concerns have been raised that some deaths are being improperly attributed to COVID-19 (*2*). Analysis of *International Classification of Diseases, Tenth Revision* (ICD-10) diagnoses on official death certificates might provide an expedient and efficient method to demonstrate whether reported COVID-19 deaths are being overestimated. CDC assessed documentation of diagnoses co-occurring with an ICD-10 code for COVID-19 (U07.1) on U.S. death certificates from 2020 that had been reported to CDC as of February 22, 2021. Among 378,048 death certificates listing U07.1, a total of 357,133 (94.5%) had at least one other ICD-10 code; 20,915 (5.5%) had only U07.1. Overall, 97.3% of 357,133 death certificates with at least one other diagnosis (91.9% of all 378,048 death certificates) were noted to have a co-occurring diagnosis that was a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), a significant contributing condition (e.g., hypertension or diabetes), or both. Overall, 70%–80% of death certificates had both a chain-of-event condition and a significant contributing condition or a chain-of-event condition only; this was noted for adults aged 18–84 years, both males and females, persons of all races and ethnicities, those who died in inpatient and outpatient or emergency department settings, and those whose manner of death was listed as natural. These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of co-occurring diagnoses on the death certificate is essential for a comprehensive and authoritative public record. Continued messaging and training (*3*) for professionals who complete death certificates remains important as the pandemic progresses. Accurate mortality surveillance is critical for understanding the impact of variants of SARS-CoV-2, the virus that causes COVID-19, and of COVID-19 vaccination and for guiding public health action.

Death certificates were processed using standard CDC protocols to convert all written text and diagnoses to ICD-10 codes (*4*). Individual data elements were extracted for analysis from death certificates that had the ICD-10 code for COVID-19 (U07.1) listed in Part I (the section for reporting chain of events leading directly to death, the immediate cause of death, and the underlying cause of death) or Part II (the section for reporting all other significant conditions that contributed to death) of the death certificate for deaths that occurred during the calendar year 2020 (Supplementary Figure, https://stacks.cdc.gov/view/cdc/104571) (*3*) and had been reported to CDC by February 22, 2021. First, the location of ICD-10 diagnoses in relation to the COVID-19 diagnosis was used to categorize the co-occurring diagnoses as being in the chain of events that directly caused the death (chain-of-event conditions) or a significant condition contributing to death (significant contributing conditions). Any co-occurring ICD-10 code that appeared on the same line or above U07.1 in Part I was considered to be a chain-of-event condition. Any ICD-10 code that appeared on a line below U07.1 in Part I or in Part II was considered to be a contributing condition. Second, the highest-frequency ICD-10 codes noted in ≥1% of all death certificates with COVID-19 listed in Part I and at least one diagnosis other than COVID-19 were reviewed for consistency and plausibility with conditions known to be associated with severe outcomes in patients with COVID-19 (*5*–*8*). Conditions consistent with those known to be associated with severe COVID-19 outcomes were coded as chain-of-event or significant contributing conditions regardless of their location on the death certificate. For example, a death certificate with an ICD-10 code for respiratory failure listed below U07.1 would be coded as a chain-of-event condition

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

MS-DOH-21-1816-A-001635

because respiratory failure caused by COVID-19 led directly to the death. Third, less frequently appearing ICD-10 codes that were determined to be consistent with those associated with severe COVID-19 outcomes were also coded as chain-of-event or significant contributing conditions. Finally, death certificates were categorized into five mutually exclusive categories according to the ICD-10 codes recorded on the death certificate 1) only the ICD-10 code for COVID-19; 2) at least one other co-occurring ICD-10 code for a chain-of-event condition; 3) at least one other co-occurring ICD-10 code for a significant contributing condition; 4) an ICD-10 code for both a chain-of-event and significant contributing condition; or 5) an ICD-10 code that could not be categorized as a plausible chain-of-event or significant contributing condition based on current knowledge. Results were stratified by age, sex, race/ethnicity, and setting of death reported on the death certificate. All analyses were conducted using SAS (version 9.4; SAS Institute) and Stata (version 15.0; StataCorp).

Among 378,048 death certificates with the ICD-10 code U07.1, 94.5% (357,133) had at least one other ICD-10 code, whereas 5.5% (20,915) listed only U07.1 (Table 1); 330,198 (87%) listed COVID-19 in Part I. Death certificates with only U07.1 and no other diagnosis accounted for 2.9%–6.6% of death certificates for decedents across all age, sex, and racial/ethnic categories (Table 1). Having only COVID-19 listed on the death certificate was slightly more frequent for death certificates that listed "dead on arrival" (34; 10%) or "decedent's home" (2,006; 8.6%) as the place of death or "pending" (seven; 13.5%) as the manner of death.

Overall, 97.3% of 357,133 death certificates with at least one other diagnosis (91.9% of all 378,048 death certificates) were noted to have a co-occurring diagnosis that was a plausible chain-of-event condition (e.g., pneumonia, respiratory failure, adult respiratory distress syndrome, cardiac arrest, or sepsis), or significant contributing condition (e.g., hypertension, diabetes, dementia, or chronic obstructive pulmonary disease) (*5*), or both. The most frequent chain-of-event ICD-10 diagnosis codes on 330,198 death certificates that listed COVID-19 on Part I of the death certificate were J18.9 (pneumonia) (45%) and J96.0 (acute respiratory failure) (20%) (Table 2); the most frequent significant contributing condition ICD-10 codes were I10 (essential hypertension) (18%) and E14.9 (diabetes mellitus) (10%). Nearly 75% of all death certificates had a chain-of-event condition, alone or in combination with a significant contributing condition; this finding was noted for adults aged 18–84 years, males and females, persons of all races and ethnicities, those who died in inpatient and outpatient or emergency department settings, and those whose manner of death was listed as natural (Table 1).

Nearly 18% of death certificates had a co-occurring significant contributing condition only (Table 1). This finding was more frequent for death certificates indicating that the death occurred in the decedent's home (38.3%), a nursing home or long-term care facility (38.5%), or hospice facility (23.2%). A small proportion (9,638; 2.5%) of death certificates had co-occurring diagnosis codes that could not be plausibly categorized as either a chain-of-event or significant contributing condition. This finding was more frequent among decedents aged <18 years (64; 35.2%) and 18–29 years (145; 10.2%); these age groups represented only 0.4% (1,608) of all death certificates. This was recorded more frequently among decedents who died at home (1,259; 5.4%), were declared "dead on arrival" (15; 4.4%), or whose manner of death was self-inflicted (39; 63.9%), homicide (13; 43.8%), "could not determine" (18; 26.5%), or accidental (417; 20.0%).

Deaths reported from inpatient settings accounted for 240,770 (64%) of all death certificates; 86% of these had co-occurring diagnoses identified as chain-of-event and significant contributing conditions (104,250; 43%) or chain-of-event conditions only (103,475; 43%). A higher proportion of deaths reported from nursing homes or long-term care facilities (22% of all death certificates) listed contributing conditions only (39%) on the death certificate. Contributing conditions were also noted in a larger proportion of death certificates listing the decedent's home as the location of death (38%); these death certificates were less likely to have co-occurring chain-of-event diagnoses listed on the death certificate.

Discussion

Among death certificates from calendar year 2020 listing COVID-19 and at least one other co-occurring diagnosis, the documentation is consistent with these deaths being attributable to COVID-19. Specifically, in 97% of 357,133 death certificates with COVID-19 and at least one other diagnosis, the documented chain-of-event and significant contributing conditions were consistent with those reported in clinical and epidemiologic studies to occur among patients with severe COVID-19–associated outcomes (*5*,*9*). Only 5.5% of death certificates had COVID-19 without any other conditions listed. Attributability of death to COVID-19 could not be evaluated for these death certificates and represents an opportunity for improvement in documentation.

A small proportion (2.5%) of death certificates documented conditions that have not currently been described to be associated with COVID-19 critical illness or death. This was noted more often among those who died at home, declared dead on arrival, and whose manner of death was not natural. In particular, a higher percentage of decedents aged <18 years (35.2%) and 18–29 years (10.2%) did not have a chain-of-event or

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TABLE 1. Distribution of death certificates with COVID-19 diagnosis* across five mutually exclusive categories defined by presence and classification of co-occurring diagnoses, by demographic characteristics, setting of death, and manner of death characteristics — National Center for Health Statistics, United States, January–December 2020

Characteristic	No. of death certificates	No. (row %)				
		COVID-19 only	COVID-19 and ≥1 chain-of-event condition only	COVID-19 and ≥1 significant contributing condition only	COVID-19 and ≥1 chain-of-event and ≥1 significant contributing condition	COVID-19 with no plausible chain-of-event or significant contributing condition
Total	**378,048**	**20,915 (5.5)**	**128,603 (34.0)**	**67,184 (17.8)**	**151,708 (40.1)**	**9,638 (2.5)**
Age group, yrs						
<18	182	8 (4.4)	70 (38.5)	18 (9.9)	22 (12.1)	64 (35.2)
18–29	1,426	77 (5.4)	636 (44.6)	167 (11.7)	401 (28.1)	145 (10.2)
30–39	4,161	275 (6.6)	1,712 (41.1)	550 (13.2)	1,371 (32.9)	253 (6.1)
40–49	11,053	660 (6.0)	4,551 (41.2)	1,408 (12.7)	3,982 (36.0)	452 (4.1)
50–64	55,719	2,911 (5.2)	22,788 (40.9)	6,693 (12.0)	21,666 (38.9)	1,661 (3.0)
65–74	80,705	3,841 (4.8)	30,439 (37.7)	10,756 (13.3)	33,820 (41.9)	1,849 (2.3)
75–84	104,294	5,277 (5.1)	34,784 (33.4)	17,858 (17.1)	44,179 (42.4)	2,196 (2.1)
≥85	120,508	7,866 (6.5)	33,623 (27.9)	29,734 (24.7)	46,267 (38.4)	3,018 (2.5)
Sex						
Female	172,615	10,007 (5.8)	55,207 (32.0)	35,525 (20.6)	67,186 (38.9)	4,690 (2.7)
Male	205,423	10,907 (5.3)	73,392 (35.7)	31,658 (15.4)	84,518 (41.1)	4,948 (2.4)
Race/Ethnicity						
Hispanic or Latino	70,011	3,680 (5.3)	28,035 (40.0)	7,875 (11.2)	29,016 (41.4)	1,405 (2.0)
American Indian or Alaska Native, non-Hispanic	4,460	266 (6.0)	1,652 (37.0)	501 (11.2)	1,920 (43.0)	121 (2.7)
Asian, non-Hispanic	13,339	676 (5.1)	5,352 (40.1)	1,687 (12.6)	5,331 (40.0)	293 (2.2)
Black, non-Hispanic	59,468	3,114 (5.2)	21,065 (35.4)	9,151 (15.4)	24,688 (41.5)	1,450 (2.4)
Native Hawaiian or Pacific Islander, non-Hispanic	679	20 (2.9)	224 (33.0)	73 (10.8)	350 (51.5)	12 (1.8)
White, non-Hispanic	227,387	12,961 (5.7)	71,227 (31.3)	47,531 (20.9)	89,379 (39.3)	6,289 (2.8)
Multiracial, non-Hispanic	1,123	43 (3.8)	379 (33.7)	165 (14.7)	512 (45.6)	24 (2.1)
Unknown	1,581	155 (9.8)	669 (42.3)	201 (12.7)	512 (32.4)	44 (2.8)
Setting of death						
Inpatient	240,770	10,084 (4.2)	103,475 (43.0)	18,719 (7.8)	104,250 (43.3)	4,242 (1.8)
Outpatient/Emergency department	12,851	830 (6.5)	4,287 (33.4)	2,411 (18.8)	4,971 (38.7)	352 (2.7)
Dead on arrival	339	34 (10.0)	98 (28.9)	70 (20.6)	122 (36.0)	15 (4.4)
Decedent's home	23,455	2,006 (8.6)	3,634 (15.5)	8,977 (38.3)	7,579 (32.3)	1,259 (5.4)
Hospice facility	10,458	412 (3.9)	2,722 (26.0)	2,430 (23.2)	4,612 (44.1)	282 (2.7)
Nursing home/Long-term care facility	82,843	6,986 (8.4)	13,183 (15.9)	31,904 (38.5)	27,597 (33.3)	3,173 (3.8)
Other	7,163	549 (7.7)	1,170 (16.3)	2,612 (36.5)	2,522 (35.2)	310 (4.3)
Unknown	169	14 (8.3)	34 (20.1)	61 (36.1)	55 (32.5)	5 (3.0)
Manner of death						
Accidental	2,080	0 (—)	233 (11.2)	890 (42.8)	540 (26.0)	417 (20.0)
Could not determine	68	1 (1.5)	16 (23.5)	14 (20.6)	19 (27.9)	18 (26.5)
Homicide	32	0 (—)	6 (18.8)	6 (18.8)	6 (18.8)	14 (43.8)
Natural	344,307	20,399 (5.9)	116,812 (33.9)	63,981 (18.6)	134,267 (39.0)	8,848 (2.6)
Pending investigation	52	7 (13.5)	7 (13.5)	9 (17.3)	28 (53.8)	1 (1.9)
Self-inflicted	61	0 (—)	8 (13.1)	10 (16.4)	4 (6.6)	39 (63.9)
Missing	31,448	508 (1.6)	11,521 (36.6)	2,274 (7.2)	16,844 (53.6)	301 (1.0)

* *International Classification of Diseases, Tenth Revision* code U07.1.

significant contributing condition listed on the death certificate, even though their death certificates did have at least one other diagnosis code along with COVID-19 in Part I or II. Although these age categories constituted a very small proportion of the entire decedent group, the information on the death certificate provides a starting point for identification of other conditions that might contribute to mortality in younger persons. Detailed evaluation of death certificates might provide insights into rare and lesser known conditions that are not yet understood to be associated with or contribute to death from COVID-19.

The findings in this report are subject to at least two limitations. First, the accuracy of documentation of chain-of-event and significant contributing conditions on death certificates is known to be suboptimal (*10*); the effect of COVID-19 on

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TABLE 2. Highest-frequency *International Classification of Diseases, Tenth Revision* (ICD-10) codes listed in death certificates with COVID-19 in Part I of death certificate and at least one diagnosis other than COVID-19 (330,198) — National Center for Health Statistics, United States, January–December 2020

Condition (ICD-10 code)	No. (% of 330,198*)
Conditions listed as chain-of-event conditions on ≥1% of death certificates†	
Pneumonia, unspecified (J18.9)	148,530 (45.0)
Acute respiratory failure (J96.0)	66,609 (20.2)
Respiratory failure, unspecified (J96.9)	47,045 (14.2)
Cardiac arrest, unspecified (I46.9)	36,983 (11.2)
Adult respiratory distress syndrome (J80)	36,297 (11.0)
Sepsis, unspecified (A41.9)	20,117 (6.1)
Viral pneumonia, unspecified (J12.9)	12,421 (3.8)
Asphyxia (R09.0)	10,641 (3.2)
Respiratory arrest (R09.2)	7,009 (2.1)
Conditions listed as significant contributing conditions on ≥1% of death certificates§	
Essential (primary) hypertension (I10)	58,930 (17.8)
Unspecified diabetes mellitus without complications (E14.9)	34,038 (10.3)
Unspecified dementia (F03)	32,189 (9.7)
Chronic obstructive pulmonary disease, unspecified (J44.9)	24,678 (7.5)
Atherosclerotic heart disease (I25.1)	22,162 (6.7)
Type 2 diabetes mellitus without complications (E11.9)	21,038 (6.4)
Atrial fibrillation and flutter (I48)	19,784 (6.0)
Congestive heart failure (I50.0)	16,841 (5.1)
Tobacco use (F17.9)	16,424 (5.0)
Chronic kidney disease, unspecified (N18.9)	14,525 (4.4)
Alzheimer disease, unspecified (G30.9)	11,220 (3.4)
Hypertensive heart disease without (congestive) heart failure (I11.9)	9,881 (3.0)
Hyperlipidemia, unspecified (E78.5)	9,330 (2.8)
Other specified disorders of kidney and ureter (N28.8)	8,958 (2.7)
Obesity, unspecified (E66.9)	8,913 (2.7)
Chronic kidney disease, stage 5 (N18.5)	7,955 (2.4)
Stroke, not specified as hemorrhage or infarction (I64)	6,494 (2.0)
Heart failure, unspecified (I50.9)	6,436 (1.9)
Conditions listed on ≥0.5% of death certificates and not identified as known chain-of-event conditions or significant contributing conditions¶	
Other specified general symptoms and signs (R68.8)	1,124 (0.3)
Other lack of normal physiologic development, underweight (R62.8)	734 (0.2)
Dyspnea (R06.0)	363 (0.1)
Senility (R54)	331 (0.1)
Other and unspecified infectious disease (B99.9)	247 (0.1)
Gastrointestinal hemorrhage (K92.2)	213 (0.1)
Unspecified protein energy deficiency (E46)	204 (0.1)
Influenza due to unidentified influenza virus (J11.1)	174 (0.1)
Urinary tract infection (N39.0)	150 (0.0)
Malaise and fatigue (R53)	145 (0.0)
Unspecified fall (W19)	139 (0.0)
Multiple sclerosis (G35)	124 (0.0)

* A total of 330,198 death certificates had COVID-19 listed in Part I of death certificate and at least one other diagnosis listed on the death certificate.
† COVID-19 diagnosis listed in Part I of the death certificate; chain-of-event conditions listed on the same line or above the COVID-19 diagnosis in Part I of the death certificate.
§ COVID-19 diagnosis listed in Part I of the death certificate; significant contributing conditions listed below the COVID-19 line in Part I or in Part II of the death certificate.
¶ COVID-19 diagnosis listed in Part I of the death certificate; co-occurring conditions listed anywhere on the death certificate and not identified as known chain-of-event or significant contributing conditions.

completion of death certificates merits further study, with an emphasis on variation by time, jurisdiction in which the death occurred, age group, race, ethnicity, and setting of death. Second, CDC was unable to compare death certificate data with decedent's medical records or autopsy reports for end-of-life events and co-occurring diagnoses. Medical record review is needed to confirm findings from this study and elucidate more information for decedents with only COVID-19 listed on their death certificate or those that could not be plausibly categorized as attributable to COVID-19 based on death certificate data alone.

These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of co-occurring diagnoses on the death certificate is essential for a comprehensive and authoritative public record. Continued messaging to and training of professionals who complete death certificates (*3*) remains important as the pandemic progresses. Accurate mortality surveillance is critical for understanding the impact of SARS-CoV-2 variants and of COVID-19 vaccinations and for guiding public health action.

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Summary

What is already known about this topic?

During 2020, approximately 375,000 U.S. deaths were attributed to COVID-19.

What is added by this report?

Among 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both.

What are the implications for public health practice?

These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of death certificate diagnoses is essential for an authoritative public record.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020

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Approximately 375,000 deaths during 2020 were attributed to COVID-19 on death certificates reported to CDC (*1*). Concerns have been raised that some deaths are being improperly attributed to COVID-19 (*2*). Analysis of *International Classification of Diseases, Tenth Revision* (ICD-10) diagnoses on official death certificates might provide an expedient and efficient method to demonstrate whether reported COVID-19 deaths are being overestimated. CDC assessed documentation of diagnoses co-occurring with an ICD-10 code for COVID-19 (U07.1) on U.S. death certificates from 2020 that had been reported to CDC as of February 22, 2021. Among 378,048 death certificates listing U07.1, a total of 357,133 (94.5%) had at least one other ICD-10 code; 20,915 (5.5%) had only U07.1. Overall, 97.3% of 357,133 death certificates with at least one other diagnosis (91.9% of all 378,048 death certificates) were noted to have a co-occurring diagnosis that was a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), a significant contributing condition (e.g., hypertension or diabetes), or both. Overall, 70%–80% of death certificates had both a chain-of-event condition and a significant contributing condition or a chain-of-event condition only; this was noted for adults aged 18–84 years, both males and females, persons of all races and ethnicities, those who died in inpatient and outpatient or emergency department settings, and those whose manner of death was listed as natural. These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of co-occurring diagnoses on the death certificate is essential for a comprehensive and authoritative public record. Continued messaging and training (*3*) for professionals who complete death certificates remains important as the pandemic progresses. Accurate mortality surveillance is critical for understanding the impact of variants of SARS-CoV-2, the virus that causes COVID-19, and of COVID-19 vaccination and for guiding public health action.

Death certificates were processed using standard CDC protocols to convert all written text and diagnoses to ICD-10 codes (*4*). Individual data elements were extracted for analysis from death certificates that had the ICD-10 code for COVID-19 (U07.1) listed in Part I (the section for reporting chain of events leading directly to death, the immediate cause of death, and the underlying cause of death) or Part II (the section for reporting all other significant conditions that contributed to death) of the death certificate for deaths that occurred during the calendar year 2020 (Supplementary Figure, https://stacks.cdc.gov/view/cdc/104571) (*3*) and had been reported to CDC by February 22, 2021. First, the location of ICD-10 diagnoses in relation to the COVID-19 diagnosis was used to categorize the co-occurring diagnoses as being in the chain of events that directly caused the death (chain-of-event conditions) or a significant condition contributing to death (significant contributing conditions). Any co-occurring ICD-10 code that appeared on the same line or above U07.1 in Part I was considered to be a chain-of-event condition. Any ICD-10 code that appeared on a line below U07.1 in Part I or in Part II was considered to be a contributing condition. Second, the highest-frequency ICD-10 codes noted in ≥1% of all death certificates with COVID-19 listed in Part I and at least one diagnosis other than COVID-19 were reviewed for consistency and plausibility with conditions known to be associated with severe outcomes in patients with COVID-19 (*5*–*8*). Conditions consistent with those known to be associated with severe COVID-19 outcomes were coded as chain-of-event or significant contributing conditions regardless of their location on the death certificate. For example, a death certificate with an ICD-10 code for respiratory failure listed below U07.1 would be coded as a chain-of-event condition

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because respiratory failure caused by COVID-19 led directly to the death. Third, less frequently appearing ICD-10 codes that were determined to be consistent with those associated with severe COVID-19 outcomes were also coded as chain-of-event or significant contributing conditions. Finally, death certificates were categorized into five mutually exclusive categories according to the ICD-10 codes recorded on the death certificate 1) only the ICD-10 code for COVID-19; 2) at least one other co-occurring ICD-10 code for a chain-of-event condition; 3) at least one other co-occurring ICD-10 code for a significant contributing condition; 4) an ICD-10 code for both a chain-of-event and significant contributing condition; or 5) an ICD-10 code that could not be categorized as a plausible chain-of-event or significant contributing condition based on current knowledge. Results were stratified by age, sex, race/ethnicity, and setting of death reported on the death certificate. All analyses were conducted using SAS (version 9.4; SAS Institute) and Stata (version 15.0; StataCorp).

Among 378,048 death certificates with the ICD-10 code U07.1, 94.5% (357,133) had at least one other ICD-10 code, whereas 5.5% (20,915) listed only U07.1 (Table 1); 330,198 (87%) listed COVID-19 in Part I. Death certificates with only U07.1 and no other diagnosis accounted for 2.9%–6.6% of death certificates for decedents across all age, sex, and racial/ethnic categories (Table 1). Having only COVID-19 listed on the death certificate was slightly more frequent for death certificates that listed "dead on arrival" (34; 10%) or "decedent's home" (2,006; 8.6%) as the place of death or "pending" (seven; 13.5%) as the manner of death.

Overall, 97.3% of 357,133 death certificates with at least one other diagnosis (91.9% of all 378,048 death certificates) were noted to have a co-occurring diagnosis that was a plausible chain-of-event condition (e.g., pneumonia, respiratory failure, adult respiratory distress syndrome, cardiac arrest, or sepsis), or significant contributing condition (e.g., hypertension, diabetes, dementia, or chronic obstructive pulmonary disease) (*5*), or both. The most frequent chain-of-event ICD-10 diagnosis codes on 330,198 death certificates that listed COVID-19 on Part I of the death certificate were J18.9 (pneumonia) (45%) and J96.0 (acute respiratory failure) (20%) (Table 2); the most frequent significant contributing condition ICD-10 codes were I10 (essential hypertension) (18%) and E14.9 (diabetes mellitus) (10%). Nearly 75% of all death certificates had a chain-of-event condition, alone or in combination with a significant contributing condition; this finding was noted for adults aged 18–84 years, males and females, persons of all races and ethnicities, those who died in inpatient and outpatient or emergency department settings, and those whose manner of death was listed as natural (Table 1).

Nearly 18% of death certificates had a co-occurring significant contributing condition only (Table 1). This finding was more frequent for death certificates indicating that the death occurred in the decedent's home (38.3%), a nursing home or long-term care facility (38.5%), or hospice facility (23.2%). A small proportion (9,638; 2.5%) of death certificates had co-occurring diagnosis codes that could not be plausibly categorized as either a chain-of-event or significant contributing condition. This finding was more frequent among decedents aged <18 years (64; 35.2%) and 18–29 years (145; 10.2%); these age groups represented only 0.4% (1,608) of all death certificates. This was recorded more frequently among decedents who died at home (1,259; 5.4%), were declared "dead on arrival" (15; 4.4%), or whose manner of death was self-inflicted (39; 63.9%), homicide (13; 43.8%), "could not determine" (18; 26.5%), or accidental (417; 20.0%).

Deaths reported from inpatient settings accounted for 240,770 (64%) of all death certificates; 86% of these had co-occurring diagnoses identified as chain-of-event and significant contributing conditions (104,250; 43%) or chain-of-event conditions only (103,475; 43%). A higher proportion of deaths reported from nursing homes or long-term care facilities (22% of all death certificates) listed contributing conditions only (39%) on the death certificate. Contributing conditions were also noted in a larger proportion of death certificates listing the decedent's home as the location of death (38%); these death certificates were less likely to have co-occurring chain-of-event diagnoses listed on the death certificate.

Discussion

Among death certificates from calendar year 2020 listing COVID-19 and at least one other co-occurring diagnosis, the documentation is consistent with these deaths being attributable to COVID-19. Specifically, in 97% of 357,133 death certificates with COVID-19 and at least one other diagnosis, the documented chain-of-event and significant contributing conditions were consistent with those reported in clinical and epidemiologic studies to occur among patients with severe COVID-19–associated outcomes (*5*,*9*). Only 5.5% of death certificates had COVID-19 without any other conditions listed. Attributability of death to COVID-19 could not be evaluated for these death certificates and represents an opportunity for improvement in documentation.

A small proportion (2.5%) of death certificates documented conditions that have not currently been described to be associated with COVID-19 critical illness or death. This was noted more often among those who died at home, declared dead on arrival, and whose manner of death was not natural. In particular, a higher percentage of decedents aged <18 years (35.2%) and 18–29 years (10.2%) did not have a chain-of-event or

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TABLE 1. Distribution of death certificates with COVID-19 diagnosis* across five mutually exclusive categories defined by presence and classification of co-occurring diagnoses, by demographic characteristics, setting of death, and manner of death characteristics — National Center for Health Statistics, United States, January–December 2020

Characteristic	No. of death certificates	No. (row %)				
		COVID-19 only	COVID-19 and ≥1 chain-of-event condition only	COVID-19 and ≥1 significant contributing condition only	COVID-19 and ≥1 chain-of-event and ≥1 significant contributing condition	COVID-19 with no plausible chain-of-event or significant contributing condition
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Age group, yrs						
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Hispanic or Latino	70,011	3,680 (5.3)	28,035 (40.0)	7,875 (11.2)	29,016 (41.4)	1,405 (2.0)
American Indian or Alaska Native, non-Hispanic	4,460	266 (6.0)	1,652 (37.0)	501 (11.2)	1,920 (43.0)	121 (2.7)
Asian, non-Hispanic	13,339	676 (5.1)	5,352 (40.1)	1,687 (12.6)	5,331 (40.0)	293 (2.2)
Black, non-Hispanic	59,468	3,114 (5.2)	21,065 (35.4)	9,151 (15.4)	24,688 (41.5)	1,450 (2.4)
Native Hawaiian or Pacific Islander, non-Hispanic	679	20 (2.9)	224 (33.0)	73 (10.8)	350 (51.5)	12 (1.8)
White, non-Hispanic	227,387	12,961 (5.7)	71,227 (31.3)	47,531 (20.9)	89,379 (39.3)	6,289 (2.8)
Multiracial, non-Hispanic	1,123	43 (3.8)	379 (33.7)	165 (14.7)	512 (45.6)	24 (2.1)
Unknown	1,581	155 (9.8)	669 (42.3)	201 (12.7)	512 (32.4)	44 (2.8)
Setting of death						
Inpatient	240,770	10,084 (4.2)	103,475 (43.0)	18,719 (7.8)	104,250 (43.3)	4,242 (1.8)
Outpatient/Emergency department	12,851	830 (6.5)	4,287 (33.4)	2,411 (18.8)	4,971 (38.7)	352 (2.7)
Dead on arrival	339	34 (10.0)	98 (28.9)	70 (20.6)	122 (36.0)	15 (4.4)
Decedent's home	23,455	2,006 (8.6)	3,634 (15.5)	8,977 (38.3)	7,579 (32.3)	1,259 (5.4)
Hospice facility	10,458	412 (3.9)	2,722 (26.0)	2,430 (23.2)	4,612 (44.1)	282 (2.7)
Nursing home/Long-term care facility	82,843	6,986 (8.4)	13,183 (15.9)	31,904 (38.5)	27,597 (33.3)	3,173 (3.8)
Other	7,163	549 (7.7)	1,170 (16.3)	2,612 (36.5)	2,522 (35.2)	310 (4.3)
Unknown	169	14 (8.3)	34 (20.1)	61 (36.1)	55 (32.5)	5 (3.0)
Manner of death						
Accidental	2,080	0 (—)	233 (11.2)	890 (42.8)	540 (26.0)	417 (20.0)
Could not determine	68	1 (1.5)	16 (23.5)	14 (20.6)	19 (27.9)	18 (26.5)
Homicide	32	0 (—)	6 (18.8)	6 (18.8)	6 (18.8)	14 (43.8)
Natural	344,307	20,399 (5.9)	116,812 (33.9)	63,981 (18.6)	134,267 (39.0)	8,848 (2.6)
Pending investigation	52	7 (13.5)	7 (13.5)	9 (17.3)	28 (53.8)	1 (1.9)
Self-inflicted	61	0 (—)	8 (13.1)	10 (16.4)	4 (6.6)	39 (63.9)
Missing	31,448	508 (1.6)	11,521 (36.6)	2,274 (7.2)	16,844 (53.6)	301 (1.0)

* *International Classification of Diseases, Tenth Revision* code U07.1.

significant contributing condition listed on the death certificate, even though their death certificates did have at least one other diagnosis code along with COVID-19 in Part I or II. Although these age categories constituted a very small proportion of the entire decedent group, the information on the death certificate provides a starting point for identification of other conditions that might contribute to mortality in younger persons. Detailed evaluation of death certificates might provide insights into rare and lesser known conditions that are not yet understood to be associated with or contribute to death from COVID-19.

The findings in this report are subject to at least two limitations. First, the accuracy of documentation of chain-of-event and significant contributing conditions on death certificates is known to be suboptimal (*10*); the effect of COVID-19 on

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TABLE 2. Highest-frequency *International Classification of Diseases, Tenth Revision* (ICD-10) codes listed in death certificates with COVID-19 in Part I of death certificate and at least one diagnosis other than COVID-19 (330,198) — National Center for Health Statistics, United States, January–December 2020

Condition (ICD-10 code)	No. (% of 330,198*)
Conditions listed as chain-of-event conditions on ≥1% of death certificates†	
Pneumonia, unspecified (J18.9)	148,530 (45.0)
Acute respiratory failure (J96.0)	66,609 (20.2)
Respiratory failure, unspecified (J96.9)	47,045 (14.2)
Cardiac arrest, unspecified (I46.9)	36,983 (11.2)
Adult respiratory distress syndrome (J80)	36,297 (11.0)
Sepsis, unspecified (A41.9)	20,117 (6.1)
Viral pneumonia, unspecified (J12.9)	12,421 (3.8)
Asphyxia (R09.0)	10,641 (3.2)
Respiratory arrest (R09.2)	7,009 (2.1)
Conditions listed as significant contributing conditions on ≥1% of death certificates§	
Essential (primary) hypertension (I10)	58,930 (17.8)
Unspecified diabetes mellitus without complications (E14.9)	34,038 (10.3)
Unspecified dementia (F03)	32,189 (9.7)
Chronic obstructive pulmonary disease, unspecified (J44.9)	24,678 (7.5)
Atherosclerotic heart disease (I25.1)	22,162 (6.7)
Type 2 diabetes mellitus without complications (E11.9)	21,038 (6.4)
Atrial fibrillation and flutter (I48)	19,784 (6.0)
Congestive heart failure (I50.0)	16,841 (5.1)
Tobacco use (F17.9)	16,424 (5.0)
Chronic kidney disease, unspecified (N18.9)	14,525 (4.4)
Alzheimer disease, unspecified (G30.9)	11,220 (3.4)
Hypertensive heart disease without (congestive) heart failure (I11.9)	9,881 (3.0)
Hyperlipidemia, unspecified (E78.5)	9,330 (2.8)
Other specified disorders of kidney and ureter (N28.8)	8,958 (2.7)
Obesity, unspecified (E66.9)	8,913 (2.7)
Chronic kidney disease, stage 5 (N18.5)	7,955 (2.4)
Stroke, not specified as hemorrhage or infarction (I64)	6,494 (2.0)
Heart failure, unspecified (I50.9)	6,436 (1.9)
Conditions listed on ≥0.5% of death certificates and not identified as known chain-of-event conditions or significant contributing conditions¶	
Other specified general symptoms and signs (R68.8)	1,124 (0.3)
Other lack of normal physiologic development, underweight (R62.8)	734 (0.2)
Dyspnea (R06.0)	363 (0.1)
Senility (R54)	331 (0.1)
Other and unspecified infectious disease (B99.9)	247 (0.1)
Gastrointestinal hemorrhage (K92.2)	213 (0.1)
Unspecified protein energy deficiency (E46)	204 (0.1)
Influenza due to unidentified influenza virus (J11.1)	174 (0.1)
Urinary tract infection (N39.0)	150 (0.0)
Malaise and fatigue (R53)	145 (0.0)
Unspecified fall (W19)	139 (0.0)
Multiple sclerosis (G35)	124 (0.0)

* A total of 330,198 death certificates had COVID-19 listed in Part I of death certificate and at least one other diagnosis listed on the death certificate.
† COVID-19 diagnosis listed in Part I of the death certificate; chain-of-event conditions listed on the same line or above the COVID-19 diagnosis in Part I of the death certificate.
§ COVID-19 diagnosis listed in Part I of the death certificate; significant contributing conditions listed below the COVID-19 line in Part I or in Part II of the death certificate.
¶ COVID-19 diagnosis listed in Part I of the death certificate; co-occurring conditions listed anywhere on the death certificate and not identified as known chain-of-event or significant contributing conditions.

completion of death certificates merits further study, with an emphasis on variation by time, jurisdiction in which the death occurred, age group, race, ethnicity, and setting of death. Second, CDC was unable to compare death certificate data with decedent's medical records or autopsy reports for end-of-life events and co-occurring diagnoses. Medical record review is needed to confirm findings from this study and elucidate more information for decedents with only COVID-19 listed on their death certificate or those that could not be plausibly categorized as attributable to COVID-19 based on death certificate data alone.

These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of co-occurring diagnoses on the death certificate is essential for a comprehensive and authoritative public record. Continued messaging to and training of professionals who complete death certificates (*3*) remains important as the pandemic progresses. Accurate mortality surveillance is critical for understanding the impact of SARS-CoV-2 variants and of COVID-19 vaccinations and for guiding public health action.

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Summary

What is already known about this topic?

During 2020, approximately 375,000 U.S. deaths were attributed to COVID-19.

What is added by this report?

Among 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both.

What are the implications for public health practice?

These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of death certificate diagnoses is essential for an authoritative public record.

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Provisional Mortality Data — United States, 2020

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CDC's National Vital Statistics System (NVSS) collects and reports annual mortality statistics using data from U.S. death certificates. Because of the time needed to investigate certain causes of death and to process and review data, final annual mortality data for a given year are typically released 11 months after the end of the calendar year. Daily totals reported by CDC COVID-19 case surveillance are timely but can underestimate numbers of deaths because of incomplete or delayed reporting. As a result of improvements in timeliness and the pressing need for updated, quality data during the global COVID-19 pandemic, NVSS expanded provisional data releases to produce near real-time U.S. mortality data.* This report presents an overview of provisional U.S. mortality data for 2020, including the first ranking of leading causes of death. In 2020, approximately 3,358,814 deaths† occurred in the United States. From 2019 to 2020, the estimated age-adjusted death rate increased by 15.9%, from 715.2 to 828.7 deaths per 100,000 population. COVID-19 was reported as the underlying cause of death or a contributing cause of death for an estimated 377,883 (11.3%) of those deaths (91.5 deaths per 100,000). The highest age-adjusted death rates by age, race/ethnicity, and sex occurred among adults aged ≥85 years, non-Hispanic Black or African American (Black) and non-Hispanic American Indian or Alaska Native (AI/AN) persons, and males. COVID-19 death rates were highest among adults aged ≥85 years, AI/AN and Hispanic persons, and males. COVID-19 was the third leading cause of death in 2020, after heart disease and cancer. Provisional death estimates provide an early indication of shifts in mortality trends and can guide public health policies and interventions aimed at reducing numbers of deaths that are directly or indirectly associated with the COVID-19 pandemic.

CDC analyzed provisional NVSS death certificate data for deaths occurring among U.S. residents in the United States during January–December 2020. The numbers and rates of overall deaths and COVID-19 deaths were assessed by age, sex, and race/ethnicity (categorized as Hispanic, non-Hispanic White [White], Black, non-Hispanic Asian, non-Hispanic AI/AN, non-Hispanic Native Hawaiian or other Pacific Islander [NH/PI], non-Hispanic multiracial, and unknown). Causes of death were coded according to the *International Classification of Diseases, Tenth Revision* (ICD-10), which describes disease classification and the designation of underlying cause of death (*1*,*2*). Numbers and rates of COVID-19 deaths include deaths for which COVID-19 was listed on the death certificate as a confirmed or presumed underlying cause of death or contributing cause of death (ICD-10 code U07.1). COVID-19 was the underlying cause of approximately 91% (345,323) of COVID-19–associated deaths during 2020 (*3*). Leading underlying causes of death were calculated and ranked (*4*). Deaths that occurred in the United States among residents of U.S. territories and foreign countries were excluded.§ Age was unknown for 86 (<0.01%) decedents, and race/ethnicity was unknown for 9,135 (0.27%). There were no records with unknown sex. To describe the trend in deaths during 2020, the number of deaths from all causes and from COVID-19 were calculated for each week. Midyear U.S. Census Bureau population estimates (July 1, 2020) were used to calculate estimated death rates per 100,000 standard population (*5*). Age-adjusted death rates were calculated for deaths by sex and race/ethnicity, and crude death rates were calculated by age. Age-adjusted death rates for 2020 were also compared with those from 2019 (*6*).

In 2020, approximately 3,358,814 deaths occurred in the United States (Table). The age-adjusted rate was 828.7 deaths

* https://www.cdc.gov/nchs/nvss/deaths.htm

† Based on death records received and processed as of March 21, 2021, for deaths occurring in the United States among U.S. residents. Data included in this analysis include >99% of deaths that occurred in 2020.

§ At the time of analysis, 1.1% of total NVSS deaths and 0.6% of COVID-19 deaths that occurred in the United States were among residents of U.S. territories and foreign countries.

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TABLE. Provisional* number and rate of total deaths and COVID-19–related deaths, by demographic characteristics — National Vital Statistics System, United States, 2020

Characteristic	No. (rate)†	
	Total deaths	COVID-19 deaths§
Total	**3,358,814 (828.7)**	**377,883 (91.5)**
Age group, yrs		
<1	19,146 (506.0)	43 (1.1)
1–4	3,469 (22.2)	24 (0.2)
5–14	5,556 (13.6)	67 (0.2)
15–24	35,470 (83.2)	587 (1.4)
25–34	72,678 (157.9)	2,527 (5.5)
35–44	103,389 (246.2)	6,617 (15.8)
45–54	189,397 (467.8)	17,905 (44.2)
55–64	436,886 (1,028.5)	44,631 (105.1)
65–74	669,316 (2,068.8)	80,617 (249.2)
75–84	816,307 (4,980.2)	104,212 (635.8)
≥85	1,007,114 (15,007.4)	120,648 (1,797.8)
Unknown	86 (—)	5 (—)
Sex		
Female	1,602,366 (689.2)	172,689 (72.5)
Male	1,756,448 (990.5)	205,194 (115.0)
Race/Ethnicity		
Hispanic	304,488 (724.1)	68,469 (164.3)
White, non-Hispanic	2,467,419 (827.1)	228,328 (72.5)
Black, non-Hispanic	443,116 (1,105.3)	59,871 (151.1)
Asian, non-Hispanic	90,519 (457.9)	13,334 (66.7)
American Indian or Alaska Native, non-Hispanic	24,279 (1,024.0)	4,504 (187.8)
Native Hawaiian or other Pacific Islander, non-Hispanic	4,424 (828.4)	679 (122.3)
Multiracial, non-Hispanic	15,434 (378.8)	1,125 (31.8)
Unknown	9,135 (—)	1,573 (—)

* National Vital Statistics System provisional data are incomplete. Data from December are less complete due to reporting lags. These data exclude deaths that occurred in the United States among residents of U.S. territories and foreign countries.

† Deaths per 100,000 standard population. Age-adjusted death rates are provided by sex and race/ethnicity.

§ Deaths with confirmed or presumed COVID-19 as an underlying or contributing cause of death, with *International Classification of Diseases, Tenth Revision* code U07.1.

per 100,000 population, an increase of 15.9% from 715.2 in 2019. The highest overall numbers of deaths occurred during the weeks ending April 11, 2020, (78,917) and December 26, 2020 (80,656) (Figure 1). Death rates were lowest among persons aged 5–14 years (13.6) and highest among persons aged ≥85 years (15,007.4); age-adjusted death rates were higher among males (990.5) than among females (689.2).

During 2020, COVID-19 was listed as the underlying or contributing cause of 377,883 deaths (91.5 per 100,000 population). COVID-19 death rates were lowest among children aged 1–4 years (0.2) and 5–14 years (0.2) and highest among those aged ≥85 years (1,797.8). Similar to the rate of overall deaths, the age-adjusted COVID-19–associated death rate among males (115.0) was higher than that among females (72.5).

Age-adjusted death rates differed by race/ethnicity. Overall age-adjusted death rates were lowest among Asian (457.9 per 100,000 population) and Hispanic persons (724.1) and highest among Black (1,105.3) and AI/AN persons (1,024.0). COVID-19–associated death rates were lowest among multiracial (31.8) and Asian persons (66.7) and highest among AI/AN (187.8) and Hispanic persons (164.3). COVID-19 was listed as the underlying cause of 345,323 deaths during 2020 and was the third leading underlying cause of death, after heart disease (690,882 deaths) and cancer (598,932) (Figure 2).

Summary

What is already known about this topic?

The COVID-19 pandemic caused approximately 375,000 deaths in the United States during 2020.

What is added by this report?

The age-adjusted death rate increased by 15.9% in 2020. Overall death rates were highest among non-Hispanic Black persons and non-Hispanic American Indian or Alaska Native persons. COVID-19 was the third leading cause of death, and the COVID-19 death rate was highest among Hispanics.

What are the implications for public health practice?

Provisional death estimates provide an early indication of shifts in mortality trends. Timely and actionable data can guide public health policies and interventions for populations experiencing higher numbers of deaths that are directly or indirectly associated with the COVID-19 pandemic.

Discussion

During January–December 2020, the estimated 2020 age-adjusted death rate increased for the first time since 2017, with an increase of 15.9% compared with 2019, from 715.2 to 828.7 deaths per 100,000 population. COVID-19 was the underlying or a contributing cause of 377,883 deaths (91.5 deaths per 100,000). COVID-19 death rates were highest among males, older adults, and AI/AN and Hispanic persons. The highest numbers of overall deaths and COVID-19 deaths occurred during April and December. COVID-19 was the third leading underlying cause of death in 2020, replacing suicide as one of the top 10 leading causes of death (*6*).

The findings in this report are subject to at least four limitations. First, data are provisional, and numbers and rates might change as additional information is received. Second, timeliness of death certificate submission can vary by jurisdiction. As a result, the national distribution of deaths might be affected by the distribution of deaths from jurisdictions reporting later, which might differ from those in the United States overall. Third, certain categories of race (i.e., AI/AN and Asian) and Hispanic ethnicity reported on death certificates might have been misclassified (*7*), possibly resulting in underestimates of death rates for some groups. Finally, the cause of death for certain persons might have been misclassified. Limited availability of testing for SARS-CoV-2, the virus that causes COVID-19, at

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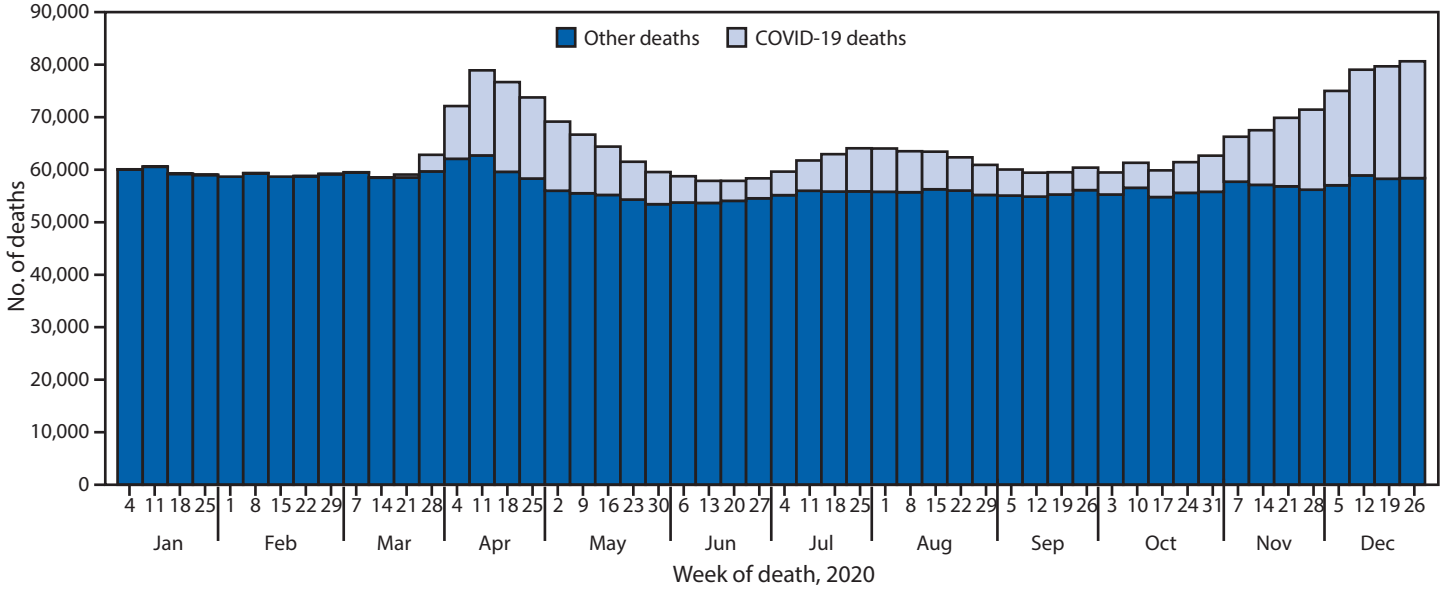
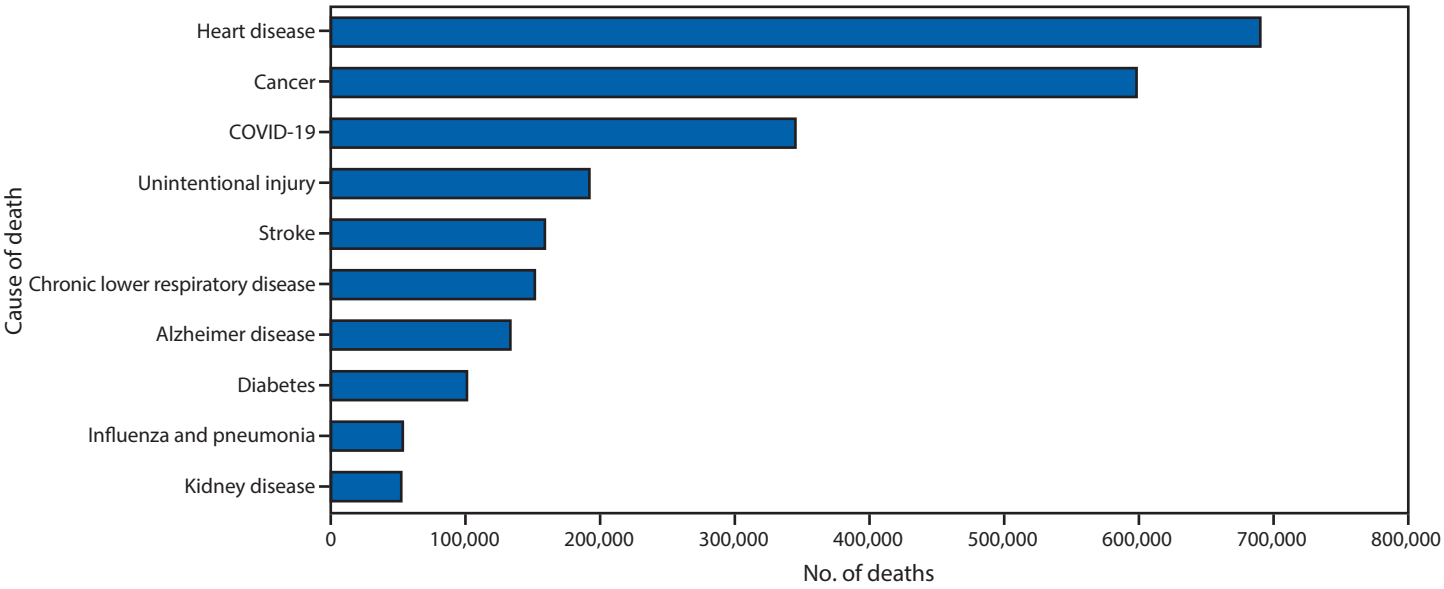
FIGURE 1. Provisional* number of COVID-19–related deaths† and other deaths, by week — National Vital Statistics System, United States, 2020



* National Vital Statistics System provisional data are incomplete. Data from December are less complete due to reporting lags. Deaths that occurred in the United States among residents of U.S. territories and foreign countries were excluded.
† Deaths with confirmed or presumed COVID-19 as an underlying or contributing cause of death, with *International Classification of Diseases, Tenth Revision* code U07.1.

FIGURE 2. Provisional* number of leading underlying causes of death† — National Vital Statistics System, United States, 2020



* National Vital Statistics System provisional data are incomplete. Data from December are less complete due to reporting lags. Deaths that occurred in the United States among residents of U.S. territories and foreign countries were excluded.
† Deaths with confirmed or presumed COVID-19 as an underlying or contributing cause of death, with *International Classification of Diseases, Tenth Revision* code U07.1.

the beginning of the COVID-19 pandemic might have resulted in an underestimation of COVID-19–associated deaths.

This report provides an overview of provisional U.S. mortality data for 2020. Provisional death estimates can give researchers and policymakers an early indication of shifts in mortality trends and provide actionable information sooner than the final mortality data that are released approximately 11 months after the end of the data year. These data can guide public health policies and interventions aimed at reducing numbers of deaths that are directly or indirectly associated with the COVID-19 pandemic and among persons most affected, including those who are older, male, or from disproportionately affected racial/ethnic minority groups.

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Sent: Wednesday, March 31, 2021 3:31 PM EDT
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Mueller, Trisha (CDC/DDNID/NCCDPHP/DRH) <czj5@cdc.gov>; Maass, Emily (CDC/DDPHSIS/CSTLTS/DPIFS) <pyo9@cdc.gov>; Harris Sharpe, Bria (CDC/DDNID/NCBDDD/DBDID) <qov0@cdc.gov>
Subject: Partner Key Update 3/31

Good afternoon partners,

Please see below recently updated and/or released COVID-19 resources and meetings.

If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov.

Thank you for your partnership.

Best,
Bria Harris-Sharpe

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

March 31, 2021

CDC Resources

- **Guidance for Adult Day Services Centers:** Updated guidance and strategies for administrators and staff to prevent the spread of COVID-19 in Adult Day Services has been recently released. Adult Day Services Centers (ADSCs) are professional care settings where community-dwelling adults receive social or health services for some part of the day. ADSCs often serve adults age 65 years or older who may require supervised care and adults (of any age) living with dementia, cognitive decline, or disability. ADSCs are designed to provide a safe, community-based group setting where specific needs are addressed and individualized therapeutic, social, or health services are delivered. These centers provide needed services to participants and also support caregiver employment and provide respite, which benefits the mental health of both participants and caregivers.
- **Vaccine resources:** Below are resources to help emerging issues of misinformation, disinformation, and provide information to places where intervention efforts can positively impact vaccine confidence across the U.S
    - COVID-19 Vaccine Community Features
    - Updated COVID-19 Vaccination for Communities
    - How to Talk about COVID-19 Vaccines with Friends and Family
    - COVID Data Tracker Weekly Review
    - Communications Resources for COVID-19
    - Vaccine Social Media Toolkit
    - Audience-specific COVID-19 Vaccination Toolkits
    - Frequently Asked Questions about COVID-19 Vaccination
    - Content Syndication
- **ELC Guidance for School Testing:** To enable schools to establish COVID-19 screening testing programs to support and maintain in-person learning, the federal government is providing financial resources to enable and expand school-based screening testing. Screening guidance should be implemented in ways consistent with CDC guidance; however, it is recognized that there may be practical or resource limitations in some school districts that make adherence to this guidance difficult at the start of this initiative.

MMWR Resources

- **Provisional Mortality Data — United States, 2020**: Provisional death estimates provide an early indication of shifts in mortality trends. Timely and actionable data guide public health policies and interventions for populations experiencing higher numbers pf deaths that are directly or indirectly associated with the COVID-19 pandemic.
- **Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020:** Approximately 375,000 deaths during 2020 were attributed to COVID-19 on death certificates reported to CDC. Concerns have been raised that some deaths are being improperly attributed to COVID-19. Analysis of International Classification of Diseases, Tenth Revision diagnoses on official death certificates might provide an expedient and efficient method to demonstrate whether reported COVID-19 deaths are being overestimated.

Upcoming Meetings

- **CDC's COVID-19 Related Response Strategies:** Thursdays from 2:00-3:00 PM EDT. CDC's 2019 Novel Coronavirus (COVID-19) response team hosts a **Response Strategies call** series to provide state and local partners with once weekly national technical assistance calls to share science-based mitigation strategies, lessons learned, and state-to-state information sharing. **To be added to this weekly series, please email** eocevent424@cdc.gov.
- **FEMA Funeral Assistance Program:** With FEMA participation, The International Association of Coroners & Medical Examiners (IACME) will host a webinar to provide information on the Funeral Assistance program, including death certificate requirements for program eligibility on **Thursday, April 1, 2021, at 12 PM PST/3 PM EDT**. There will be a brief question and answer session. To register, click here.

Additional Resources

- **Federal Emergency Management Agency (FEMA) to Help Pay Funeral Costs for COVID-19-Related Deaths:** In early April, FEMA will begin providing financial assistance financial assistance for funeral expenses incurred after Jan. 20, 2020 for deaths related to coronavirus (COVID-19) to help ease some of the financial stress and burden caused by the pandemic. FEMA is now moving rapidly to implement this funeral assistance program nationwide.

Safe and Proper Sharps Disposal During the COVID-19 Mass Vaccination Campaign

Sharps are objects that can pierce the skin (for example, contaminated syringes and needles, lancets, scalpels, infusion needle sets, connection needles, auto injectors), as defined in the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens standard. This fact sheet reenforces how you can protect yourself from needlestick injuries while administering COVID-19 vaccines or while helping at vaccination sites.

Protect Yourself From a Needlestick Injury

- Place sharps disposal containers as close as possible to you or within arm's reach. When a wall mount is not possible, set the container on a table or a cart in an upright position (preferably secured). Do not place sharps disposal containers on the floor or the ground.
- Immediately after you use a sharp, engage any safety feature, and place it in a sharps disposal container that is closable, puncture-resistant, leakproof on the sides and bottom, and biohazard-labeled or color-coded.
- Do not remove, recap, break, or bend contaminated needles or separate contaminated needles from syringes before discarding them into a sharps disposal container as this increases the risk of a needlestick injury and a bloodborne pathogen exposure. Best practice is to immediately place the connected needle and syringe into the sharps disposal container.
- Use sharps containers to dispose of needles and other sharps contaminated with blood or other potentially infectious material.
- Close the container when it is filled to the clearly marked fill line or when it is ¾ full if it has no fill line.
- Do not overfill sharps disposal containers—even during supply shortages—as this increases the risk of a needlestick injury and a bloodborne pathogen exposure.

Sharps Disposal Containers are for Needles and Sharps Only

- Place only needles and sharps in sharps disposal containers.
- Do not put anything in sharps disposal containers that can be placed in regular waste containers (such as uncontaminated trash, gauze, alcohol pads, needle caps, and gloves).
- Place non-sharp, contaminated material, such as gauze contaminated with blood or other potentially infectious material, in a red biohazard waste disposal bag.
- Follow your local guidelines for proper disposal methods. Visit https://safeneedledisposal.org

If you experience a needlestick from a used or contaminated needle, seek immediate evaluation and treatment.

Call the PEP (post-exposure prophylaxis) hotline at 1–888–448–4911 immediately for guidance on treating exposures.

Learn More about Sharps Disposal

SafeNeedleDisposal.org
https://safeneedledisposal.org

Food and Drug Administration (FDA): How to get rid of a sharps container
https://www.fda.gov/files/medical%20devices/published/How-to-Get-Rid-of-a-Sharps-Container--Printable-Version.pdf

OSHA: Bloodborne pathogens and needlestick prevention
https://www.osha.gov/bloodborne-pathogens

OSHA: Bloodborne Pathogens standard
https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

OSHA: Protecting yourself when handling contaminated sharps
https://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact02.html

OSHA: Poster for COVID-19 vaccination sites
https://www.osha.gov/sites/default/files/publications/OSHA4109.pdf

CDC: Emergency sharps information (what to do in case of a needlestick)
https://www.cdc.gov/niosh/topics/bbp/emergnedl.html

National Institute for Occupational Safety and Health (NIOSH): Preventing needlestick injuries at COVID-19 vaccination sites
https://blogs.cdc.gov/niosh-science-blog/2021/03/02/ needlestick-prevention/

cdc.gov/coronavirus

MS-DOH-21-1816-A-001651

CS 323144-B 03/25/2021

Strategies for Sharps Disposal Container Use During Supply Shortages

For Managers and Purchase Agents

A shortage in the supply of Food and Drug Administration (FDA)-cleared sharps disposal containers may occur during the COVID-19 mass vaccination campaign or as a result of other causes. Healthcare facilities and COVID-19 vaccination sites must use sharps disposal containers that meet Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens standard requirements to dispose of contaminated needles and other sharps. Use FDA-cleared containers whenever possible.

Conserve your FDA-cleared sharps disposal containers to help avoid a potential supply shortage. If FDA-cleared sharps disposal containers are unavailable, then consider using alternative containers that meet the OSHA requirements after checking your state's specific disposal requirements at SafeNeedleDisposal.org and discussing disposal options with your medical waste vendors.

FIRST, conserve your FDA-cleared sharps disposal containers by doing the following:

- Place only sharps (as defined in OSHA's Bloodborne Pathogens standard, for example, contaminated syringes, needles, lancets, scalpels, infusion needle sets, connection needles, auto-injectors) in sharps disposal containers.
- Do not remove, recap, break, or bend contaminated needles or separate contaminated needles from syringes before discarding them into a sharps disposal container. Best practice is to immediately place the connected needle and syringe into the sharps disposal container.
- Place contaminated dressings, gauze, cotton materials, tubing, and contaminated cleanup items in biohazard waste disposal bags.
- Place uncontaminated non-sharps in a standard trash can. Always place sharps in sharps disposal containers, not in the trash.
- Consider using reusable FDA-cleared sharps disposal containers. These can be reused after being picked up, processed, and disinfected by a regulated medical waste removal service according to state and local regulations.
- Ensure containers are filled to the recommended capacity prior to removal, but do not overfill. Filling above the fill line or more than ¾ full of the alternative container can increase the risk of a needlestick injury and a bloodborne pathogen exposure.
- Follow the manufacturer's instructions for use.

SECOND, follow these procedures when FDA-cleared sharps disposal containers are scarce or unavailable:

NOTE: Once the availability of FDA-cleared sharps disposal containers returns to normal, healthcare facilities and COVID-19 vaccination sites should promptly resume usual practices.

- Consider avoiding timed sharps container disposal, where containers are removed at set intervals regardless of fill level. Removing and replacing sharps disposal containers based on set time intervals rather than when they are at the recommended capacity can waste valuable container space during a shortage.
- Ask your distributors about all types of FDA-cleared sharps disposal containers that are available. For example, using an FDA-cleared sharps disposal container that does not fit within the wall brackets at your facility is better than not having a sharps disposal container at all.
- Consider using alternative containers, after checking your state's specific disposal requirements at SafeNeedleDisposal.org and discussing disposal options with your medical waste vendors.
- Acceptable alternative containers must meet OSHA's Bloodborne Pathogens standard requirements:
  - » Made of heavy-duty, puncture-resistant plastic or metal
  - » Leakproof on the sides and bottom
  - » Have an opening large enough to accommodate a sharp but not large enough for a hand to enter
  - » Have a tight-fitting and puncture-resistant lid
  - » Remain upright and stable during use and handling
  - » Are clearly labeled or color-coded in accordance with OSHA labeling standards:
    - to warn of biohazardous sharps waste inside the container,
    - to indicate what should and should not be placed into the container, and
    - to indicate that it is not an FDA-cleared sharps disposal container

>>> See the back for ideas

CDC OSHA

cdc.gov/coronavirus

MS-DOH-21-1816-A-001652

CS 323144-A 03/26/2021

Alternative sharps disposal containers must meet OSHA requirements and may include the following items:

Heavy-duty plastic household containers, such as empty plastic laundry detergent, windshield wiper fluid, cat litter, or bleach containers that have been emptied and thoroughly rinsed

New, never used, heavy-duty paint or chemical buckets with a secure lid and a removeable spout large enough for sharps to be inserted but too small for a hand to enter

New, never used, heavy-duty plastic or metal gas or diesel fuel containers with tight caps

New, never used, heavy-duty plastic chemical-dispensing containers (2.5 or 5 gallon) with tight caps

Report supply shortages to the FDA

The FDA encourages health care facilities to report any supply disruptions of sharps disposal containers to the device shortages mailbox deviceshortages@fda.gov. This mailbox is monitored closely and is a valuable resource to augment FDA efforts to detect and mitigate potential supply chain disruptions.

For more information

FDA: How to get rid of a sharps container
https://www.fda.gov/files/medical%20devices/published/How-to-Get-Rid-of-a-Sharps-Container--Printable-Version.pdf

FDA: Sharps disposal containers
https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/sharps-disposal-containers

NIOSH (National Institute for Occupational Safety and Health): Preventing needlestick injuries at COVID–19 vaccination sites
https://blogs.cdc.gov/niosh-science-blog/2021/03/02/needlestick-prevention/

NIOSH: Selecting, evaluating, and using sharps disposal containers
https://www.cdc.gov/niosh/docs/97-111/

OSHA: Bloodborne Pathogens standard
https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

OSHA: Bloodborne pathogens and needlestick prevention
https://www.osha.gov/bloodborne-pathogens

OSHA: Bloodborne pathogens fact sheet
https://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact02.html

OSHA: Poster for COVID-19 vaccination sites
https://www.osha.gov/sites/default/files/publications/OSHA4109.pdf

MS-DOH-21-1816-A-001653

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 14 (incl. COCA Call, MMWR Early Release, CDC Partner Update Call, AMCHP Scholarships, and more)
Date:	Wednesday, April 14, 2021 4:01:47 PM
Attachments:	image001.png image002.png TOMORROW CDC COCA Call Johnson JohnsonJanssen COVID-19 Vaccine and Cerebral Venous Sinus Thrombosis with Thrombocytopenia Update for Clinicians on Early Detection and Treatment.msg COVID-19 Partner Updates April 14th 2021.msg HHS COVID-19 Update - 413.msg MMWR ER - April 14, 2021.pdf CBO_Tribal Government Scholarship.pdf Healthcare Quality and Worker Safety (Apr 14).pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC COCA Call: Johnson & Johnson/Janssen COVID-19 Vaccine and Cerebral Venous Sinus Thrombosis with Thrombocytopenia – Update for Clinicians on Early Detection and Treatment [Attachment, Link]
    - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **tomorrow**, Thursday, **April 15** at **2:00 pm EDT** to present the latest evidence on cerebral venous sinus thrombosis (CVST) with thrombocytopenia associated with the administration of the Johnson & Johnson/Janssen COVID-19 vaccine. Speakers will discuss what is known about CVST, the importance of early detection, and updated vaccine recommendations. Call information is below:
        - Weblink: https://www.zoomgov.com/j/1614336614?pwd=ZVhQUHoyaG4zVFdua2czcE9EU20wUT09
          Telephone: (669) 254 5252 or (646) 828 7666
          Webinar ID: 161 433 6614
          Passcode: 160026
          Post-Event
          Recording: https://emergency.cdc.gov/coca/calls/2021/callinfo_041521.asp
- MMWR Early Release: "Laboratory Modeling of SARS-CoV-2 Exposure Reduction Through Physically Distanced Seating in Aircraft Cabins Using Bacteriophage Aerosol — November

2020" [Attachment, Link]
    - From the report: *"Based on laboratory modeling of exposure to SARS-CoV-2 on single-aisle and twin-aisle aircraft, exposures in scenarios in which the middle seat was vacant were reduced by 23% to 57%, compared with full aircraft occupancy, depending upon the model."*
- CDC Partner Update Call: "When to Clean, When to Disinfect, and What Science Says about SARS-CoV-2 on Surfaces" [Link]
    - CDC will host the next installment of its weekly partner call **Monday, April 19** at **3:00 pm EDT**. Dr. Cynthia Ogden will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Dr. Vincent Hill will discuss how SARS-CoV-2 impacts cleaning and disinfecting surfaces.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 4/19" in the subject line. The call will be recorded and posted to CDC's website here.
- AMCHP CBO and Tribal Government Conference Scholarships [Attachment, Link]
    - The Association of Maternal & Child Health Programs (AMCHP) is offering approximately 16 need-based scholarships to its annual conference taking place May 24–27, 2021. These scholarships are intended for community-based organizations or tribal governments. To apply, complete this survey by May 7. Questions may be sent to evidence@amchp.org.
- CDC COVID-19 Healthcare Quality and Worker Safety Information [Attachment]
    - Weekly summary, published April 13

Standing Updates

- CDC Partner Update – April 14 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Updates – April 13 [Attachment]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.

- Request Form for CSTE COVID-19 Call Topics [Link]
    - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

Do you work at a community-based organization or one representing a tribal government? Interested in attending the AMCHP Conference?

AMCHP invites you to apply for our

Community-Based Organization (CBO) and Tribal Government Conference Scholarships

What are the Conference Scholarships?

AMCHP recognizes the value in having community members, those working at community-based organizations, and those representing tribal governments participate in the annual conference as a way to share their expertise and insights while learning from and networking with others. At the same time, AMCHP acknowledges that attending the conference can be cost prohibitive. To help reduce this barrier, AMCHP will be offering approximately 16 need-based scholarships.

What Can I Use the Scholarship For?

You are welcome to use the scholarship for one of the following options:

1) Full conference registration
2) Participation stipend of $300 which can be used for but is not limited to:

- Childcare support
- Compensation for time used to participate in the conference that would otherwise not be paid through work

How Do I Know If I'm Eligible to Apply?

Anyone representing a community-based organization (CBO) or tribal government is welcome to submit a request. AMCHP defines a CBO as a public or private non-profit organization, or other organization such as an LLC, that is representative of a community or a significant segment of a community and works to meet community needs.

We will consider requests based on the following criteria:

- The size of your organization.
- Whether this is your first time attending the AMCHP conference.
- Whether an organization is led by or directly supporting Black, Indigenous, People of Color (BIPOC) communities; others experiencing systemic oppression including but not limited to the disability community, the LGBTQI+ community, etc.; or those representing groups that have been historically oppressed. This is directly aligned with AMCHP's commitment to living by its "All-In" Statement.

I'm Interested. How Do I Apply?

- Please complete the following **brief survey** to submit a request for the scholarship.
- You may submit a request until **Friday, May 7th**.

What is the Selection Process Like?

- Requests will be reviewed on a rolling basis based on the criteria outlined above.
- All decisions will be communicated by **May 14th**.

Once I'm Approved, What Next?

- If approved for **registration support or reimbursement**, you will be provided with a special registration link. No additional documentation is required.
- If approved for a **participation stipend**, you will be asked to complete a brief form.

AMCHP is currently accepting applications via

https://www.surveymonkey.com/r/AMCHPScholarshipSurvey

Have questions? Please contact **evidence@amchp.org**

AMCHP
ASSOCIATION OF MATERNAL & CHILD HEALTH PROGRAMS

MS-DOH-21-1816-A-001657

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Wednesday, April 14, 2021 2:52 PM EDT
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Mueller, Trisha (CDC/DDNID/NCCDPHP/DRH) <czj5@cdc.gov>
Subject: COVID-19 Partner Updates: April 14th, 2021

Good afternoon partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov. Thank you for your partnership.

Best,

William Carson

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

April 14th, 2021

CDC Resources

- **Health Alert: Cases of Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine:** Published April 13, 2021. Please see the following official CDC Health Alert for a detailed explanation for the medical reasoning behind the pausing of Johnson & Johnson COVID-19 vaccines being administered.
- **Strategies for Optimizing the Supply of N95 Respirators:** This guidance has been updated as of April 9. Acknowledged that the supply and availability of NIOSH-approved respirators have increased significantly over the last several months. Includes guidance for conventional, contingency, and crisis capacity strategies.
- **Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during Shortages:** This guidance has been updates as of April 9. This summary is intended to help healthcare facilities optimize supplies of disposable N95 filtering facepiece respirators when there is limited supply during the COVID-19 pandemic. The strategies are categorized in a continuum of care and further organized according to the hierarchy of controls.
- **Health Equity in Action:** CDC has launched a new web page, Health Equity in Action, for visitors to learn more about CDC's collaborative efforts to address health disparities among populations at higher risk for COVID-19. CDC and its partners are committed to reducing the disproportionate burden of COVID-19 among populations at increased risk for infection, severe illness, and death. Health Equity in Action highlights some of the multiple CDC efforts in place related to COVID-19 from across CDC's COVID-19 response and partnerships.

Morbidity and Mortality Weekly Report (MMWR)

- **April 14, Laboratory Modeling of SARS-CoV-2 Exposure Reduction Through Physically Distanced Seating in Aircraft Cabins Using Bacteriophage Aerosol — November 2020:** Link to the article here. A laboratory study modelling spread of COVID-19 in occupied aircrafts tested multiple seating scenarios and found vacant middle seats were associated with reduced exposure to the virus that causes COVID-19 compared with full occupancy. When paired with correct and consistent mask use and cabin ventilation, increasing physical distance between passengers, and lowering passenger density could help prevent COVID-19 spread during air travel.

Upcoming Meetings

- **Meeting of the Advisory Committee on Immunization Practices (ACIP):** Wednesday, April 14, 1:30 – 4:30 PM EST. ACIP will hold an emergency meeting on Wednesday, April 14 from 1:30-4:30 pm ET to discuss the reports and evidence to make any further recommendations. Agenda for this meeting is here.
- **Lessons from the Field: Guidance for Early Childhood Education Programs and Providers:** Wednesday, April 14, 3:00 – 4:00 EST. This webinar features a panel of practitioners who have worked to ensure the safety and wellbeing of the children and families they serve by implementing CDC guidance while providing early childhood education and childcare. Following a brief overview of the latest guidance from the CDC related to mitigation guidance in early childhood care, practitioners will share lessons learned and challenges overcome to sustain safe operations Register for the event here.

- **Community of Practice Call:** 2:00-3:00 PM EDT, Thursday, April 15, 2021. CDC invites partners to attend this week's Community of Practice call, the link to which can be foundhere.
- **COVID-19 Partner Update: When to Clean, When to Disinfect, and What Science Says about SARS-CoV-2 on Surfaces:** Monday, April 19, 3:00 – 4:00 PM EST. Dr. Cynthia Ogden will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Dr. Vincent Hill will discuss how SARS-CoV-2 impacts cleaning and disinfecting surfaces. Register for the event here.
- **Protecting Children's Environmental Health During COVID-19: Supporting Daycares and Other Early Childcare Settings:** April 28, 3:00 – 4:00 PM EST. The novel coronavirus (COVID-19) has highlighted new opportunities and challenges to protecting children's environmental health. This webinar will cover unique considerations for children's environmental health in underserved communities, success strategies, and coordination strategies among states, local health departments, and daycares and other early childcare settings during COVID-19. Register for the webinar here.

Additional Resources

- **Frequently Asked Questions for Vaccine Adverse Event Reporting System:** The Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in U.S. licensed vaccines.This FAQ page will help answer many questions you may have about how adverse reactions to vaccines are reported to the CDC and HHS.
- **National Institute of Health materials on Thrombocytopenia:** The NIH maintains a website on what is thrombocytopenia. The page also includes information on causes, risk factors, screening, prevention, signs, symptoms, diagnosis, and treatment.

COVID-19 Healthcare Quality and Worker Safety Information

CDC Health Alert

Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine

As of April 12, 2021, approximately 6.85 million doses of the Johnson & Johnson (J&J) COVID-19 vaccine (Janssen) have been administered in the United States. The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) are reviewing data involving six U.S. cases of a rare type of blood clot in individuals after receiving the J&J COVID-19 vaccine that were reported to the Vaccine Adverse Events Reporting System (VAERS). COVID-19

In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women aged 18–48 years. The interval from vaccine receipt to symptom onset ranged from 6–13 days. One patient died. Providers should maintain a high index of suspension for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J COVID-19 vaccine. When these specific type of blood clots are observed following J&J COVID-19 vaccination, treatment is different from the treatment that might typically be administered for blood clots. Based on studies conducted among the patients diagnosed with immune thrombotic thrombocytopenia after the AstraZeneca COVID-19 vaccine in Europe, the pathogenesis of these rare and unusual adverse events after vaccination may be associated with platelet-activating antibodies against platelet factor-4 (PF4), a type of protein. Usually, the anticoagulant drug called heparin is used to treat blood clots. In this setting, the use of heparin may be harmful, and alternative treatments need to be given.

CDC will convene an emergency meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14, 2021, to further review these cases and assess potential implications on vaccine policy. FDA will review that analysis as it also investigates these cases. Until that process is complete, CDC and FDA are recommending a pause in the use of the J&J COVID-19 vaccine out of an abundance of caution. The purpose of this Health Alert is, in part, to ensure that the healthcare provider community is aware of the potential for these adverse events and can provide proper management due to the unique treatment required with this type of blood clot.

View the CDC Health Alert

Updated **Post-COVID Conditions: Information for Healthcare Providers —** CDC has updated our information for healthcare providers related to health conditions that may persist or recur following infection with SARS-CoV-2, the virus that causes COVID-19. More information is included about what is currently known about these post-COVID conditions (previously referred

to as “Late Sequelae of COVID-19”), an umbrella term for the wide range of health consequences present for more than four weeks after infection. This webpage includes information about multiorgan system effects of COVID-19, the effects of COVID-19 treatment and hospitalizations, and the condition known as “long COVID.” CDC continues active investigation of post-COVID conditions and will provide updates as new data emerge. To learn more, please visit Post-COVID Conditions: Information for Healthcare Providers

Updated **Strategies for Optimizing the Supply of N95 Respirators** — This guidance has been updated to include the following:

- Acknowledged that the supply and availability of NIOSH-approved respirators have increased significantly over the last several months

- For conventional capacity strategies
    - Added language on extended use of N95 respirators as source control
    - Added language on use of respirators with exhalation valves
- For contingency capacity strategies
    - Added a strategy to prioritize respirators for HCP who are using them as PPE over those HCP who are only using them for source control
    - For extended use of N95 respirators as PPE, clarified that N95 respirators should be discarded immediately after being removed
- For crisis capacity strategies
    - Removed the strategy of using non-NIOSH approved respirators developed by manufacturers who are not NIOSH-approval holders
    - Highlighted that the number of reuses should be limited to no more than five uses (five donnings) per device by the same HCP to ensure an adequate respirator performance
    - Removed decontamination of respirators as a strategy with limited re-use
    - Emphasized that facemasks for caring for a patient with suspected or confirmed SARS-CoV-2 infection should only be used for certain scenarios as a last resort if respirators are severely limited
    - Removed the table “Suggested well-fitting facemask or respirator use, based upon distance from a patient with suspected or confirmed SARS-CoV-2 infection and use of source control”

To learn more, please visit Strategies for Optimizing the Supply of N95 Respirators: COVID-19

Updated **Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during Shortages —** This summary is intended to help healthcare facilities optimize supplies of disposable N95 filtering facepiece respirators when there is limited supply during the COVID-19 pandemic. The strategies are categorized in a continuum of care and further organized according to the hierarchy of controls. To learn more, please visit Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during Shortages

Additional Resources

COVID-19 Science Update — To help inform CDC's COVID-19 Response, as well as to help CDC staff stay up to date on the latest COVID-19 research, the Response's Office of the Chief Medical Officer has collaborated with the CDC Office of Library Science to create a series called *COVID-19 Science Update*

***Morbidity and Mortality Weekly Report (MMWR)* — Factors Associated with Participation in Elementary School–Based SARS-CoV-2 Testing — Salt Lake County, Utah, December 2020–January 2021** — CDC, in collaboration with the University of Utah Health and Economic Recovery Outreach Project, Utah Department of Health (UDOH), Salt Lake County Health Department, and one Salt Lake county school district, offered free, in-school, real-time reverse transcription–polymerase chain reaction (RT-PCR) saliva testing as part of a transmission investigation of SARS-CoV-2 in elementary school settings. Among 856 unique student contacts at 20 elementary schools, 594 who were exposed to 33 index patients at 13 elementary schools were analyzed. Compared with non-Hispanic White students, participation in the testing program was higher among students identifying as Hispanic/Latino White (PR = 1.21) and among members of a racial minority group (PR = 1.19). In-school specimen collection could be a useful strategy for facilitating SARS-CoV-2 testing among those at higher risk for infection, who might also have limited access to testing. You can learn more here: *Morbidity and Mortality Weekly Report*

***Morbidity and Mortality Weekly Report (MMWR)* – Community Transmission of SARS-CoV-2 Associated with a Local Bar Opening Event – Illinois, February 2021** — Forty-six cases of COVID-19 were linked to an indoor bar opening event that occurred during February 2021 in a rural Illinois county. Event patrons were linked to secondary cases among household, long-term care facility, and school contacts, resulting in one hospitalization and one school closure affecting 650 students. You can learn more here: *Morbidity and Mortality Weekly Report*

***Morbidity and Mortality Weekly Report (MMWR)* – COVID-19 Incidence and Mortality Among American Indian/Alaska Native and White Persons — Montana, March 13–November 30, 2020** — Aggregate analyses of data from selected U.S. states indicate that COVID-19 incidence and mortality are higher among American Indian or Alaska Native (AI/AN) persons than they are among White persons. COVID-19 incidence and mortality rates among AI/AN persons in Montana were 2.2 and 3.8 times, respectively, those among White persons. The case-fatality rate among AI/AN persons was 1.7 times that among White persons. These findings reinforce importance of using state-level surveillance to develop state and tribal COVID-19 vaccine allocation strategies and to inform local implementation of culturally appropriate public health measures that might help reduce COVID-19 incidence and mortality in AI/AN communities. You can learn more here: *Morbidity and Mortality Weekly Report*

***Morbidity and Mortality Weekly Report (MMWR)* – Use of Stay-at-Home Orders and Mask Mandates to Control COVID-19 Transmission — Blackfeet Tribal Reservation, Montana, June–December 2020** – Community mitigation measures (e.g., stay-at-home orders and mask use), coupled with case investigation and contact tracing with immediate isolation or quarantine, are primary approaches to preventing and controlling community SARS-CoV-2 transmission. In the Blackfeet Tribal Reservation, enforcement of stay-at-home orders and mandated use of face coverings in public, with potential fines and jail for noncompliance, were associated with a thirty-three-fold reduction in COVID-19 incidence from its peak of 6.40 cases per 1,000 residents per day on October 5 to 0.19 on November 7, 2020. Enforcement of stay-at-home orders and mask use mandates, coupled with robust public health investigations, have been shown to reduce COVID-19 incidence. You can learn more here: *Morbidity and Mortality Weekly Report*

***Morbidity and Mortality Weekly Report (MMWR)* – Provisional Mortality Data — United States, 2020** — The COVID-19 pandemic caused approximately 375,000 deaths in the United States during 2020. The age-adjusted death rate increased by 15.9% in 2020. Overall death rates were highest among non-Hispanic Black persons and non-Hispanic American Indian or Alaska Native persons. COVID-19 was the third leading cause of death, and the COVID-19 death rate was highest among Hispanics. Provisional death estimates provide an early indication of shifts in mortality trends. Timely and actionable data can guide public health policies and interventions for populations experiencing higher numbers of deaths that are directly or indirectly associated with the COVID-19 pandemic. You can learn more here: *Morbidity and Mortality Weekly Report*

***Morbidity and Mortality Weekly Report (MMWR)* – Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020** — During 2020, approximately 375,000 U.S. deaths were attributed to COVID-19. Among 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both. These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of death certificate diagnoses is essential for an authoritative public record. You can learn more here: *Morbidity and Mortality Weekly Report*

***Morbidity and Mortality Weekly Report (MMWR)* – Notes from the Field: COVID-19 Case Investigation and Contact Tracing Program — Spirit Lake Tribe, North Dakota, September–November 2020** — In late September 2020, the incidence of confirmed COVID-19 in North Dakota began increasing rapidly, from approximately 300 new cases per day to approximately 2,260 cases on November 13, 2020 (1). On October 20, the North Dakota Department of Health reported that contact tracing notification efforts were delayed. Because of the delay, COVID-19 patients were asked to notify their own contacts about potential exposure and encourage them to seek testing for SARS-CoV-2, the virus that causes COVID-19 (2). The Spirit Lake sovereign

nation in east central North Dakota is home to approximately 7,500 members of the Spirit Lake Tribe. In response to increasing incidence of COVID-19 on the Spirit Lake Reservation, CDC assisted the Spirit Lake Tribe in building a tribally managed program for comprehensive COVID-19 case investigations, case notification, contact tracing, contact testing, and contact management to ensure timely implementation of these critical epidemic control measures. You can learn more here: *Morbidity and Mortality Weekly Report*

***Morbidity and Mortality Weekly Report (MMWR)* – COVID-19 Stats: College and University COVID-19 Student Testing Protocols, by Mode of Instruction (N = 1,849) — United States, Spring 2021** — As of March 17, 2021, a total of 899 (49%) of 1,849 public and private, nonprofit 4-year U.S. colleges and universities provided some type of COVID-19 testing for asymptomatic students, including 548 (30%) institutions conducting classes in-person or in a hybrid format. Among institutions providing testing for asymptomatic students, 389 (43%) had protocols that required periodic testing for various subgroups (e.g., athletes, fraternity and sorority activity participants, and a random sample of students); 287 (32%) mandated that all students receive testing (ranging from every other day to once every other week), which did not vary by public or private, nonprofit status or by mode of instruction. Among institutions, 18% (338 of 1,849) did not mention a COVID-19 testing protocol on their websites, including 146 with in-person or hybrid instruction. Although asymptomatic transmission is estimated to account for approximately one half of SARS-CoV-2 transmission, a majority (950; 51%) of institutions did not publish a testing protocol for screening asymptomatic students in spring 2021. You can learn more here: *Morbidity and Mortality Weekly Report*

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Tuesday, April 13, 2021 6:57 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 4/13

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 13, 2021:

Highlights from Today's White House Briefing with Jeff Zients and Dr. Fauci

Jeff Zients

- **Johnson & Johnson:** As you all know, the FDA and CDC announced earlier today that out of an abundance of caution, they've recommended a pause in the use of Johnson & Johnson vaccine as they review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the Johnson & Johnson vaccine. Let me start by saying that this announcement will not have a significant impact on our vaccination program. The J&J vaccine makes up less than 5% of the more than 190 million recorded shots in arms in the United States to date.
- **Pfizer and Moderna Distribution:** The President took action earlier this year, before the J&J vaccine was even authorized, to secure enough Pfizer and Moderna doses for 300 million Americans by the end of July. Over the last few weeks, we have made available more than 25 million doses of Pfizer and Moderna each and every week. In fact, this week we will make available 28 million doses of these two vaccines. As we've done since we took office, we will continue to get the supply out the door as soon as it's available. We have more than enough supply of Pfizer and Moderna vaccines to continue the current pace of about three million shots per day. That puts us well on pace to meet the President's goal with 200 million shots by his 100th day in office and continue to reach every adult who wants to get vaccinated. We're now working with our state and federal partners to get anyone scheduled for a J&J vaccine quickly rescheduled for a Pfizer or Moderna vaccine.
- **Leading with Science:** The President has committed to the American people that his administration will always lead with science, tell the truth, and give Americans the facts as we know them. CDC and FDA will continue to do just that and provide regular updates to the public, and they will do so as they continue their investigation. The White House was notified last night that there would be an announcement this morning and therefore had no other involvement other than knowing last night that there would be an announcement this morning from the FDA and the CDC.

Dr. Fauci

- **Reasoning for the Pause:** This pause allows both the FDA and the CDC to further investigate these cases to try and understand some of the mechanisms of the situation, and some more details about the history of the individuals who were involved that might shed light on what we will do. It also makes physicians aware of what is going on. For example, if someone comes in with this really rather rare syndrome of thrombotic thrombocytopenia, where you get thrombosis, and the most common way to treat that is with Heparin, that would be a mistake in this situation, because it could be dangerous and make the situation much worse. When individuals, particularly younger women, who might come to a physician with a particular thrombotic phenomenon, which is something that happens for other reasons all the time, we want to alert physicians to take a history of a recent vaccination. The pause not only allows us to take a look at the cases and learn more, but it is also a signal out there to help the physicians. What I heard from the previous press discussion was the pause is going to be more like days to weeks, rather than weeks to months.
- **Effects on People Previously Vaccinated:** We know that there have been 6.85 million doses of J&J distributed in the United States thus far. So, someone who had it a month or two ago would say, "What does this mean for me?" It really doesn't mean anything. You're okay, because if you look at the time frame when this occurs, it's pretty tight from a few days, six to 13 days from the time of the vaccination. If someone was recently vaccinated, within days, I would tell them to, first of all, don't get an anxiety because, remember, it's less than one in a million. However, having said that, pay attention. Do you have symptoms? Headache? Do you have shortness of breath? Chest discomfort? Do you have anything that resembles a neurological syndrome? Obviously, if you have something as serious as a seizure, I mean, that's pretty clear. Headache is the very common component of it because the sinus thrombosis that they have is the draining of the blood in the brain and it will cause enough symptomatology to make you notice it. Just tell people to just watch out for not feeling very well.
- **Vaccine Confidence:** There have been now a 120 million people that have received at least one dose of a vaccine. Most of that, subtract the 6.85 million, is in the mRNA from Pfizer and Moderna. There have been no red flags signals from those. So, you're talking about tens and tens and tens of millions of people who've received vaccine with no adverse effect. This is a really rare event. If you look at what we know so far, there have been six out of the 6.85 million doses, which is less than one in a million. This pause is out of an abundance of caution to give us a time to take a good look at it and see if we can get further information.
- **Abundance of Caution:** Well, our FDA is internationally known for their capability of making sure that we have the safest products out there. That's what I meant when I said, "an abundance of caution." You want to make sure that safety is the important issue here. We are totally aware that this is a very rare event. We want to get this worked out as quickly as we possibly can, and that's why you see the word pause. In other words, we want to hold off for a bit and very well may go back to that, maybe with some conditions or maybe not. We want to leave that up to the FDA and the CDC to investigate this carefully. I don't think it was pulling the trigger too quickly.

Case Update

New Cases (based on 7-day rolling average)

- **31,076,891** US cases
- **6.5% increase** in new cases (7-day average), as of April 11th; (was 3.0% increase last week)

Testing

- **389,636,919** tests completed (4/13)
- **6.0%** positive test rate as of the week of 4/3 – 4/9 (was 5.7% last week)

Hospitalizations

- **2,009,551** total COVID hospital admissions
- The 7-day average (4/4 – 4/10) number of new confirmed COVID-19 admissions **increased** week on week (from 4,843 to 5,246

admissions per day)

Deaths

- **559,172** total US deaths
- The 7-day average (4/5 – 4/11) number of reported deaths **decreased** week on week (from 781 to 678 deaths per day)

Vaccines

- **192,282,781** vaccine doses **administered** (4/13)
- **36.8%** (122.3 million people) of the population has received **1 or more doses** and **22.7%** (75.3 million people) of the population have been **fully vaccinated**
- **79.2%** of adults 65 and older have received **at least 1 dose** and **62.5%** have been **fully vaccinated**

Vaccine Updates

Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine: As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases. Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution. Right now, these adverse events appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously. Listen to the joint media briefing with the FDA and CDC here. CDC has updated the following pages with the announcement of the pause: Johnson & Johnson General Information, Reported Adverse Events, Viral Vector Vaccines, Different Vaccines, Vaccines for COVID-19, Frequently Asked Questions about Vaccination, Key Things to Know, Vaccine Safety and Monitoring (including v-safe), and Coronavirus Disease 2019 (COVID-19).

Statement from Jeff Zients on Johnson & Johnson Vaccine: Jeff Zients, White House COVID-19 Response Coordinator, released a statement on Johnson & Johnson Vaccine. As FDA and CDC announced earlier today, out of an abundance of caution, they have recommended a pause in the use of the Johnson & Johnson vaccine as they review data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the Johnson & Johnson vaccine. This announcement will not have a significant impact on our vaccination plan: Johnson & Johnson vaccine makes up less than 5 percent of the recorded shots in arms in the United States to date. Based on actions taken by the President earlier this year, the United States has secured enough Pfizer and Moderna doses for 300 million Americans. Over the last few weeks, we have made available more than 25 million doses of Pfizer and Moderna each week, and in fact this week we will make available 28 million doses of these vaccines. This is more than enough supply to continue the current pace of vaccinations of 3 million shots per day and meet the President's goal of 200 million shots by his 100th day in office—and continue on to reach every adult who wants to be vaccinated. We are working now with our state and federal partners to get anyone scheduled for a J&J vaccine quickly rescheduled for a Pfizer or Moderna vaccine.

Vaccines by Jurisdiction: CDC updated their report on COVID-19 vaccine distribution, delivery, and administration by jurisdiction. The report provides an overview of the multiple channels being used to ensure all Americans have access to COVID-19 vaccine. Jurisdictional delivery and administration portfolios vary across the United States because of population variability.

V-Safe Pregnancy Registry: CDC updated their information on the v-safe COVID-19 Vaccine Pregnancy Registry. If you are pregnant, you might choose to be vaccinated when it's available to you. There is currently no evidence that antibodies formed from COVID-19 vaccination cause any problem with pregnancy, including the development of the placenta. However, data are limited about the safety of COVID-19 vaccines for people who are pregnant. The registry is collecting health information from people who received COVID-19 vaccination in the periconception period (within 30 days before last menstrual period) or during pregnancy. The information is critical to helping individuals and their healthcare providers make informed decisions about COVID-19 vaccination. Participation is voluntary, and participants may opt out at any time.

Addressing COVID-19 Health Disparities Among Racial and Ethnic Minority Communities: The FDA reaffirmed their commitment to addressing COVID-19 health disparities among racial and ethnic minority communities. The FDA's Center for Biologics Evaluation and Research (CBER) is working hand-in-hand with the FDA's Office of Minority Health and Health Equity (OMHHE) to address concerns about vaccines among diverse communities. OMHHE is in turn committed to protecting and promoting the health of diverse populations by focusing its efforts on research and outreach and communication strategies that address health disparities.

Testing and Treatment

FDA Testing Update: As of today, 358 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 262 molecular tests and sample collection devices, 75 antibody and other immune response tests, and 21 antigen tests. There are 45 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home tests, four over-the-counter (OTC) at-home antigen tests, and two OTC molecular tests. The FDA has authorized 7 antigen tests and 2 molecular tests for serial screening programs.

Reopening Guidance

Crew Disembarkations Through Commercial Travel: CDC updated their guidance for cruise ships and their crew members. CDC is committed to helping cruise lines provide for the safety and well-being of their crew members while onboard cruise ships and as they disembark. CDC is allowing crew members to disembark from all cruise ships in U.S. waters with certain precautions. Cruise lines with complete and accurate response plans are able to use commercial travel to disembark crew members from certain ships if the ships meet certain criteria set by CDC. CDC outlines which cruise ships operating or planning to operate in U.S. waters during the initial phases of the Framework for Conditional Sailing Order have met surveillance reporting requirements.

Information for Specific Populations

Long-term Care Facility Residents: CDC updated their information for long-term care facility (LTCF) residents on how to get a COVID-19 vaccine. If you have not already been vaccinated against COVID-19, you can: talk to the LTCF staff to determine if a vaccine can be made available to you on site and/or ask a family member or friend to help you schedule a vaccination appointment if a vaccine is not available on site. Studies show that COVID-19 vaccines are safe and effective, a COVID-19 vaccine cannot make you sick with COVID-19, and depending on the kind of COVID-19 vaccine you get, you might need a second shot 3 or 4 weeks after your first shot. After getting vaccinated, some people have side effects; these are normal signs that your body is building protection against COVID-19. You will not need to pay for a COVID-19 vaccine and the CDC recommends all LTCF residents to get vaccinated against COVID-19.

Temporary Halt in Residential Evictions: CDC updated their information on the temporary halt in residential evictions to prevent the further spread of COVID-19. Director Dr. Rochelle Walensky signed a declaration determining that the evictions of tenants could be detrimental to public health control measures to slow the spread of SARS-Cov-2, the virus that causes COVID-19.

COVID-19 Vaccines Available in Baltimore for Native Americans in DMV Area: Today, the Indian Health Service, Native American Lifelines of Baltimore, and the University of Maryland, Baltimore are announcing the availability of COVID-19 vaccines for American Indians and Alaska Natives living and working in and near the Baltimore and Washington, D.C., areas. Vaccines are being provided by the IHS Nashville Area and will be administered by the University of Maryland, Baltimore, in coordination with Native American Lifelines of Baltimore. Beginning Friday, April 16, 2021, vaccines will be available for tribal members and employees of Indian agencies and tribal organizations, as well as their spouses or partners and other household members. Appointments can be booked now here.

Vaccine Guidance and Resources for People with Disabilities and Older Adults: As part of a shared commitment to President Biden's National Strategy - PDF and Executive Order to ensure an equitable COVID-19 response, the Office for Civil Rights (OCR), the Administration for Community Living (ACL), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at HHS have published several new resources to help states, vaccination providers, and others leading COVID-19 response activities improve access to vaccines for people with disabilities and older adults. These resources clarify legal requirements, illustrate some of the barriers to vaccine access faced by people with disabilities and older people, and provide strategies – and examples of how the aging and disability network can help employ them – to ensure accessibility. The Office for Civil Rights released new guidance - PDF outlining legal standards under the federal civil rights laws prohibiting disability discrimination and providing concrete examples of the application of the legal standards in the context of COVID-19 vaccine programs and how to implement them. OCR also issued a fact sheet - PDF setting out specific steps that those involved in the planning and distribution of vaccines to combat the COVID-19 pandemic may wish to consider to promote compliance with disability rights laws and provide access to vaccination programs for people with disabilities. Earlier COVID-19 guidance from OCR addressed civil rights protections prohibiting discrimination on the basis of race, color, national origin - PDF, and civil rights of persons with limited English proficiency - PDF.

Research

Post-Acute COVID-19: The National Institute of Allergy and Infectious Disease (NIAID), in collaboration with other institutes and centers of the

National Institutes of Health, led a virtual "Workshop on Post-Acute Sequelae of COVID-19." A paper published recently in *Annals of Internal Medicine* describes the workshop. Over 1,200 registered participants including researchers, clinicians, and affected community members discussed what is known about sequelae after COVID-19 and the knowledge gaps that need to be addressed in future research.

NIH Trial of Anti-CD14 Antibody to Treat COVID-19 Respiratory Disease Begins: A clinical trial testing the safety and efficacy of an investigational monoclonal antibody for treating people who are hospitalized with respiratory disease and low blood oxygen due to infection with SARS-CoV-2, the virus that causes COVID-19, has begun. The Phase 2 trial, called the COVID-19 anti-CD14 Treatment Trial (CaTT), is sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The main goal of the CaTT study is to determine whether treatment with IC14 decreases the time it takes people with COVID-19 respiratory disease to recover such that they no longer need ongoing medical care in the hospital. Secondary goals are to determine the safety of IC14 in the study population and the efficacy of the drug at reducing the severity of COVID-19 respiratory disease. If the results of the CaTT study are promising, then IC14 may be tested in a larger Phase 3 efficacy trial.

Mapping Severe COVID-19 in the Lungs at Single-Cell Resolution: A team of NIH-funded researchers captured changes in the lungs over the course of a COVID-19 infection at unprecedented, single-cell resolution. The imaging data adds evidence that SARS-CoV-2, the coronavirus that causes COVID-19, primarily infects cells at the surface of the air sacs. Their findings also offer valuable clues for treating the most severe consequences of COVID-19, suggesting that a certain type of scavenging immune cell might be driving the widespread lung inflammation that leads to acute respiratory distress syndrome (ARDS), in which fluid and cellular infiltrates build up in the lung's air sacs, called alveoli, keeping them from exchanging oxygen with the bloodstream.

Immune Response to Vaccination After COVID-19: NIH released a study regarding the immune response to vaccination after COVID-19. Researchers found that after a single dose of the Pfizer-BioNTech vaccine, people with a prior COVID-19 infection had antibody levels similar to those of people without prior infection after two vaccine doses. The results, which need to be confirmed in large, diverse populations, may point to a strategy to stretch the currently limited supply of vaccines against COVID-19.

College and University COVID-19 Stats: CDC updated an *MMWR* on COVID-19 student testing protocols by mode of instruction at colleges and universities during the spring of 2021.

Non-COVID-19 Updates

Addressing the Black Maternal Health Crisis: Today—during Black Maternal Health Week—the Biden-Harris Administration is announcing initial actions it has taken to address the maternal health crisis in the United States. President Biden issued the first-ever presidential proclamation calling on all Americans to recognize the importance of addressing the crisis of Black maternal mortality and morbidity in this country, an executive order to implement a comprehensive approach to advancing racial equity, and an executive order to establish the White House Gender Policy Council to take a whole-of-government approach to gender equity. The Administration has taken the following actions to strengthen health equity and address racial disparities in maternal health through increased investment in reducing maternal mortality and morbidity; approval of the first Medicaid Section 1115 Waiver to broadly extend postpartum coverage; and $12 million in additional funds for maternal obstetrics care in rural communities

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
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Laboratory Modeling of SARS-CoV-2 Exposure Reduction Through Physically Distanced Seating in Aircraft Cabins Using Bacteriophage Aerosol — November 2020

Watts L. Dietrich[1]; James S. Bennett, PhD[1]; Byron W. Jones, PhD[2]; Mohammad H. Hosni, PhD[2]

Aircraft can hold large numbers of persons in close proximity for long periods, which can increase the risk for transmission of infectious disease.* Current CDC guidelines recommend against travel for persons who have not been vaccinated against COVID-19, and a January 2021 CDC order requires masking for all persons while on airplanes.[†,§] Research suggests that seating proximity on aircraft is associated with increased risk for infection with SARS-CoV-2, the virus that causes COVID-19 (*1*,*2*). However, studies quantifying the benefit of specific distancing strategies to prevent transmission, such as keeping aircraft cabin middle seats vacant, are limited. Using bacteriophage MS2 virus as a surrogate for airborne SARS-CoV-2, CDC and Kansas State University (KSU) modeled the relationship between SARS-CoV-2 exposure and aircraft seating proximity, including full occupancy and vacant middle seat occupancy scenarios. Compared with exposures in full occupancy scenarios, relative exposure in vacant middle seat scenarios was reduced by 23% to 57% depending upon the modeling approach. A 23% exposure reduction was observed for a single passenger who was in the same row and two seats away from the SARS-COV-2 source, rather than in an adjacent middle seat. When quantifying exposure reduction to a full 120-passenger cabin rather than to a single person, exposure reductions ranging from 35.0% to 39.4% were predicted. A 57% exposure reduction was observed under the vacant middle seat condition in a scenario involving a three-row section that contained a mix of SARS-CoV-2 sources and other passengers. Based on this laboratory model, a vacant middle seat reduces risk for exposure to SARS-CoV-2 from nearby passengers. These data suggest that increasing physical distance between passengers and lowering passenger density could help reduce potential COVID-19 exposures during air travel. Physical distancing of airplane passengers, including through policies such as middle seat vacancy, could provide additional reductions in SARS-CoV-2 exposure risk.

The study consisted of three components. The first involved analysis of data on virus aerosol dispersion in aircraft cabin mock-ups from a previous study conducted at KSU during July–August 2017 as part of a pandemic influenza research initiative (*3*). Next, these data were used to create a regression model to estimate the reduction in aerosol concentration as distance from a source increased. Finally, these regression models were applied to conceptual aircraft seating scenarios to simulate the reduction in exposure resulting from vacant middle seats in an aircraft cabin. Laboratory experiments were performed with bacteriophage MS2 virus obtained from the American Type Culture Collection.[¶] Bacteriophage MS2 has frequently been used as a surrogate for pathogenic viruses in aerosolization studies (*4*) and was used to approximate the airborne dispersion of SARS-CoV-2. During the aerosol dispersion study at KSU, mannequins with realistic passenger heat emission were seated in the cabin mock-ups, and then MS2 aerosol was introduced from a source location and collected at six different sample locations in the cabin. This process was repeated four times: twice in a single-aisle cabin and twice in a twin-aisle cabin (Figure 1), resulting in 24 total samples.** Because these data were collected before the COVID-19 pandemic, the effects of passengers wearing masks on the aerosol dispersion behavior were not measured. These viral aerosol data were then used to create a nonlinear regression model[††] which assesses the association between the number of plaque-forming

* https://www.who.int/whr/2007/en/
† https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-during-covid19.html
§ https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC_GMTF_01-29-21-p.pdf
¶ https://www.atcc.org

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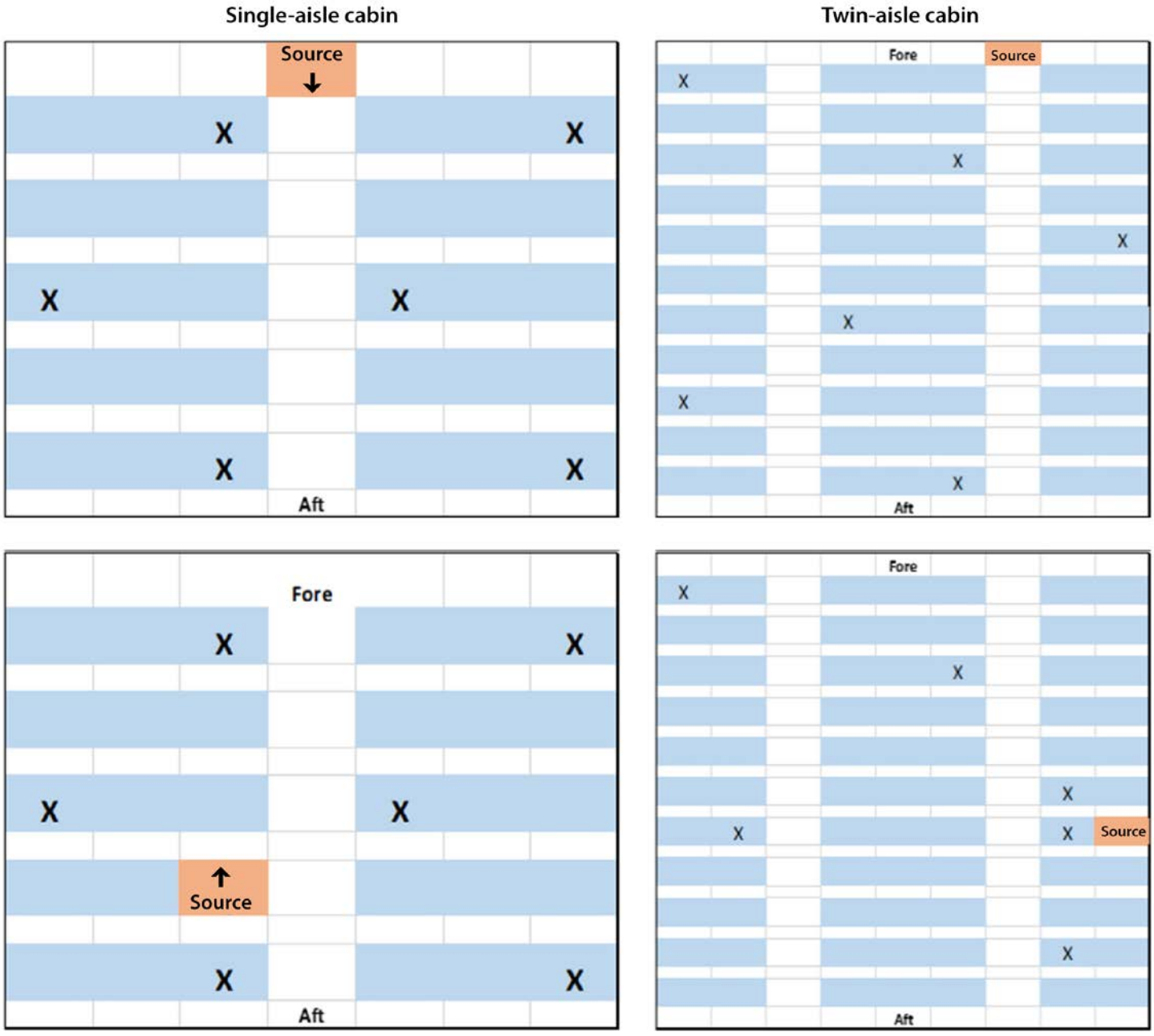
units (PFUs) (evidence of the presence of viable virus) and the distance between source and sample locations. For both single-aisle and twin-aisle scenarios, findings from the nonlinear regression model indicate that the number of PFUs declined exponentially with increasing distance (Supplementary Figure, https://stacks.cdc.gov/view/cdc/104935).

In November 2020, CDC applied this data-driven model to simulate the protective effect of a vacant middle seat versus full aircraft occupancy. Two analytical approaches were used. Both approaches analyzed reductions in relative exposures (the number of PFUs divided by the maximum predicted value) rather than absolute exposure.

FIGURE 1. Diagram of aircraft cabin configurations and source and sampling locations to assess exposure to aerosolized bacteriophage MS2 virus as a surrogate for airborne SARS-CoV-2 exposure in single-aisle and twin-aisle cabins* — Kansas State University, July–August 2017†



Source: Modified with permission from Lynch JA, Bennett JS, Jones B, Hosni MH. Viral particle dispersion and viability in commercial aircraft cabins. In: 2018 American Society of Heating, Refrigerating and Air-Conditioning Engineers Annual Conference Proceedings; June 23–27, 2018; Houston, TX; 2018.
Abbreviations: aft = back of the plane; fore = front of the plane; source = aerosol source; X = sampling location.
* For both single-aisle and twin-aisle cabin scenarios, two different source configurations were assessed for placement of infectious passengers: one with the source at the front of the plane in an aisle and one with the source in a seat. Each configuration consisted of six total sampling locations, for a total of 24 samples.
† Data were collected at Kansas State University during July–August 2017 as part of a pandemic influenza research initiative.

MS-DOH-21-1816-A-001672

The first approach considered only the extra distance between passengers created by the vacant middle seat. The regression model estimated exposure as a function of distance to assess the exposure reduction of moving an adjacent passenger one seat further away from an infectious passenger, leaving an empty middle seat between them. The distance effect was explored further to simulate the total exposure reduction for groups of passengers up to and including a full simulated cabin of 120 seats.[§§] A total of 300 simulations were tested using Monte Carlo methods, where the number (one to three) and placement of infectious passengers were varied. The total exposure reduction for all passengers in the cabin was predicted by placing a source at an arbitrary seat location and applying the regression model to calculate relative exposure at all other seat locations, which were summed to obtain a total exposure for the cabin.

The second approach combined the distance effect predicted by the regression model and the reduced occupancy effect predicted by simple probability estimation, as these are inseparable in realistic arrangements of infectious passengers and other passengers. When simply defining exposure risk as reduced occupancy, a vacant middle seat reduced exposure by an estimated 33% compared with full occupancy, in single-aisle, three-seats-per-side cabins, because there are 33% fewer potentially infectious passengers.

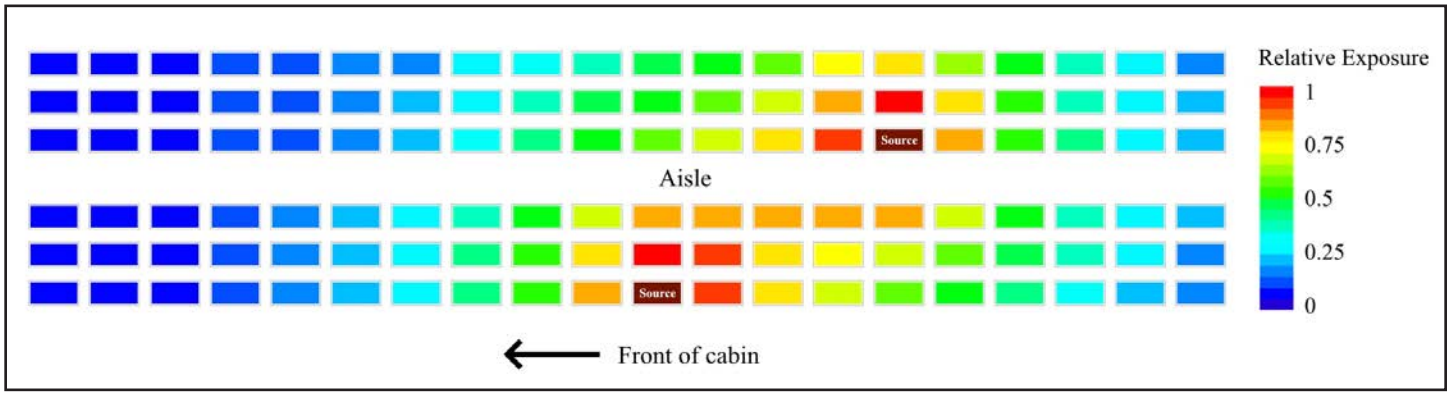
The first approach predicted a 23% exposure reduction by moving an adjacent passenger one seat further away from an infectious passenger. The total reduction in relative exposure for a full 120-seat cabin yielded reduction of 35.0%–36.4%, 35.1%–38.2%, and 35.9%–39.4% for one, two, and three infectious passengers, respectively, depending on their seating pattern. All sources were placed in window or aisle seats such that the potential reduction in number of infectious passengers onboard from vacant middle seating was not considered (Figure 2). The second approach was applied to a cluster of nine infectious passengers (including three in middle seats) among 18 total passengers in three rows (Figure 3). When the infectious and other passengers who would have had middle seats were removed, leaving six infectious passengers out of 12 total passengers remaining in the window and aisle seats, a 57% exposure reduction was observed.

** The laboratory cabin environments were a five-row section of an actual Boeing 737 fuselage and an 11-row section of a geometrically accurate mock-up, including original equipment seats, of a Boeing 767 cabin. Ventilation systems used actual Boeing 737 (single aisle) and 767 (twin aisle) equipment where practical, but with no jet engine, so that supply ventilation came from conditioned air in the laboratory rather than from a jet engine. Bacteriophage MS2 virus aerosol was introduced by spray bottle from a source location using three closely timed, consecutive sprays, totaling approximately 3.7 mL. For both single-aisle and twin-aisle cabin scenarios, two different source configurations were assessed: one with the source at the front of the plane and one with the source at the back. Each configuration consisted of six total seat locations; a total of 24 samples were evaluated. Viral aerosol samples were collected in bioaerosol liquid (10% glycerol in 1× phosphate buffered saline) impingers. These devices collected aerosol by drawing air though a small volume of liquid for 5 minutes; samplers were held in place with clamp and stand assemblies on seats, with the impinger intake facing forward to approximate seated head-height for an average adult. Collection fluid aliquots were evaluated for viral particle presence by plaque assay, and the number of plaque-forming units (PFUs) was considered proportional to the airborne concentration references of viable virus.

†† The virion data were fitted to exponential regression equations of the form, $C = Ae^{BD}$, with number of PFUs (C) as the dependent variable and the distance between spray and sampling locations (D) as the independent variable. A and B are constants determined by regression analysis, as was the coefficient of determination, R^2.

§§ This simulated cabin was single-aisle, with 20 rows and three seats per side, for a total of 120 seats; the distance between rows was 3 ft (0.9 m); the distance between adjacent seat centers was 1.6 ft (0.5 m). This number of rows is on the lower end of a typical Boeing 737 coach cabin, depending on the specific design. The total exposure reduction for all passengers in the cabin was predicted by placing a source at an arbitrary seat location and applying the regression model to calculate relative exposure at all other seat locations, which were summed to obtain a total exposure for the cabin.

FIGURE 2. Estimated reduction in relative exposure to aerosolized bacteriophage MS2 as a surrogate for SARS-CoV-2 through physically distanced seating in a single-aisle, 20-row simulated aircraft cabin* — November 2020



* A total of 300 simulations in which the number (one, two, or three) and placement of infectious passengers varied were tested using Monte Carlo methods. The simulated cabin had a single aisle, with 20 rows and three seats per side (120 total seats); the distance between rows was 3 ft (0.9 m); the distance between adjacent seats was 1.6 ft (0.5 m). In the source configuration shown here, the total reduction in exposure with vacant middle seats was calculated to be 35.4%.

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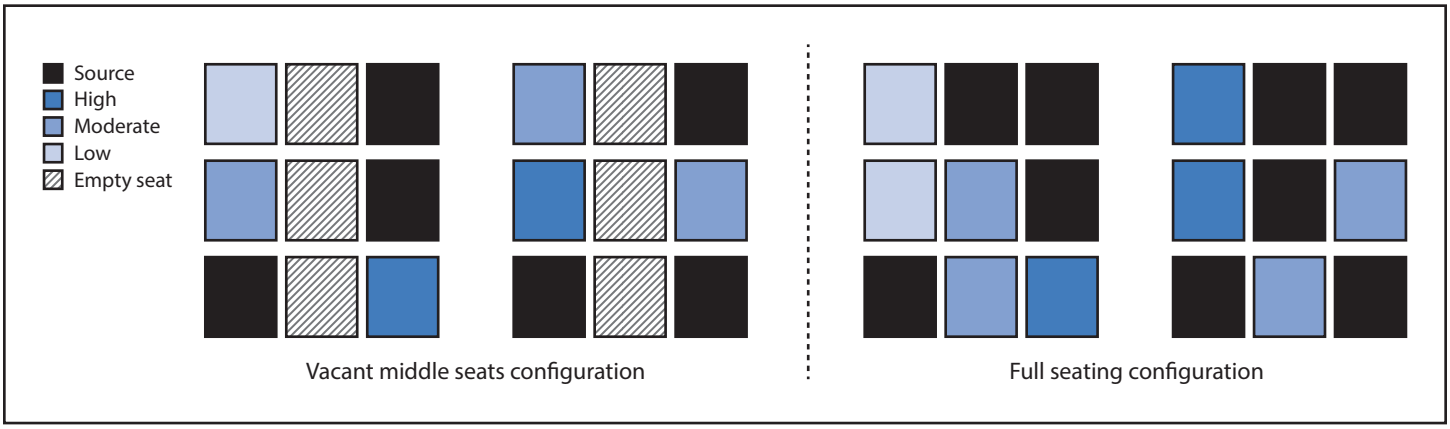
FIGURE 3. Relative estimated reduction in exposure to bacteriophage MS2 as a surrogate for SARS-CoV-2 through physically distanced seating in a single-aisle, three-row section of an aircraft cabin with full occupancy* compared with vacant middle seats† — November 2020



* A cluster of nine infectious passengers (including three in middle seats) among 18 total passengers in three rows. Removing the infectious and other passengers who would have had middle seats, leaving six infectious passengers out of 12 total passengers remaining in the window and aisle seats, resulted in an estimated 57% reduction in SARS-CoV-2 exposure. Exposures were as follows: 21.1 for six noninfectious passengers in the configuration with no middle seats; 48.7 for the nine noninfectious passengers with full occupancy.

† The local prevalence (the percentage of passengers in the three rows who are infectious) was held constant in the comparison to reasonably account for the fact that keeping middle seats vacant is expected to prevent both infectious and noninfectious passengers from sitting there.

Discussion

This laboratory-based model predicts a 23% to 57% reduction in exposure to viable virus particles when middle seats on an airline are kept vacant. This range is comparable to that reported in another study that used computational fluid dynamics simulation and considered cabin ventilation rates per passenger to show that keeping middle seats vacant reduced the risk for airborne infection by 45%.¶¶ Studies of tracer gas/particle dispersion generally indicate that distance is an important determinant of contaminant exposure on aircraft (*5*,*6*), including showing that airborne concentration decay with distance is similar for various contaminant types and closely mirrors infection patterns on aircraft; this finding supports the use of bacteriophage MS2 as a surrogate for SARS-CoV-2 exposure.*** Further, a recent investigation of SARS-CoV-2 transmission on an international flight found that seating proximity was strongly associated with infection risk: 75% of infected passengers were seated within two rows of the symptomatic passenger who likely originated the outbreak (*1*).

Aircraft cabin environmental control systems (ventilation systems) are designed to deliver amounts of clean air per occupant that conform to various standards.††† When these standards are adhered to, most virus particles are removed within several seat rows from a source on an aircraft, and the recirculated portion of the air supplied to each passenger has passed through high efficiency particle air (HEPA) filters.§§§ As aircraft ventilation removes airborne contaminants, it also causes some turbulent dispersion. This spreading effect of aerosols is larger than transient flows created by passenger or crew movement in the aisles under typical cruise conditions (*7*). Physical distancing is difficult on crowded flights, and sitting within 6 ft of others, sometimes for hours, might increase risk for SARS-CoV-2 exposure. To reduce this risk, the CDC order issued in January 2021 requires the wearing of masks by travelers to prevent spread of COVID-19, including all passengers on aircraft traveling into, within, or out of the United States, and recommends against travel for all unvaccinated persons.

It is important to recognize that the current study addresses only exposure and not transmission.¶¶¶ The impact of masking also was not considered in the current aerosol analysis because

¶¶ https://www.sae.org/publications/technical-papers/content/2021-01-0036/

*** MS2 virus when collected in SKC BioSamplers (as in the current study) showed similar resistance to sampling and environmental stresses as does Newcastle disease virus but greater resistance than influenza A and MHV coronavirus. However, the relative exposure method of the current study might diminish the importance of sampling resistance. In addition, the airborne transport behavior of virus aerosols depends on the aerodynamic diameter of the evaporated droplet nuclei and not on biologic properties of individual viruses.

††† Including requirements set by the Federal Aviation Administration (https://www.faa.go) and recommendations from the Environmental Protection Agency (https://www.epa.go), and American Society of Heating, Refrigeration, and Air-Conditioning Engineers (https:www.ashrae.org). Additional information is available at https://www.faa.gov/data_research/research/med_humanfacs/cer/media/In-FlightOnboardMonitoring.pdf and https://www.nap.edu/catalog/10238/the-airliner-cabin-environment-and-the-health-of-passengers-and-crew/FlightOnboardMonitoring.pdf

§§§ https://www.epa.gov/indoor-air-quality-iaq/what-hepa-filter-1

¶¶¶ Applicability to COVID-19 transmission would involve two steps: MS2 phage exposure relating to SARS-CoV-2 exposure and SARS-CoV-2 exposure being large enough to cause COVID-19 transmission in a person. Relative exposure removes the importance of source specifics, making MS2 aerosol experiments a reasonable substitute in terms of transport physics. Importantly, the threshold behavior of COVID-19 transmission depends on factors related to in vivo respiratory droplets typically associated with SARS-CoV-2 and host characteristics such as individual susceptibility and is beyond the scope of this study.

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masks are more effective at reducing fomite and droplet exposures than aerosol exposures (*8*,*9*). A case study of COVID-19 transmission on a flight with mandated mask wearing (*10*) suggests that some virus aerosol is emitted from an infectious masked passenger, such that distancing could still be useful. The findings in these studies indicate that masking seems to not eliminate all airborne exposures to infectious droplets and aerosols and support the importance of multicomponent prevention strategies as good practices; combining the effects of masking and distancing is more protective than either by itself.

The findings in this report are subject to at least four limitations. First, data were collected under higher relative humidity conditions in the laboratory than would be present during flight. Droplet evaporation into aerosol is more rapid under lower relative humidity. Because aerosols travel farther than droplets, the current study might underpredict the aerosol spread in an actual cabin environment. The slower evaporation in the current study might then overpredict the observed effect of distancing because this more rapid decrease makes estimated distance effects larger. Second, in the data used to build the regression models, most of the variability was within approximately 5 ft of the infection source. Although this near-zone variability weakens the quantification of the effect of short distances, the equations were the statistical best fit and had coefficient of determination (R^2) values (the percentage of the response variable variation explained by a model) above 70%, suggesting that the distance model explained most of the observed virus concentration behavior. Third, the use of spray bottles to emit droplets, followed by 5 minutes of air sampling, might not fully represent the variety of respiratory events that could transmit virus (e.g., exhalation, talking, coughing, and sneezing). Mandated mask use further alters the human respiratory source, making the relative exposure approach used here an important way to diminish bias related to release volume. Finally, the study only assessed aerosols, not fomites and droplets. Exposures decrease more rapidly with distance for these exposure paths; therefore, distancing would have an even larger protective effect than that observed in this study.

Based on a data-driven model, approaches to physical distancing, including keeping middle seats vacant, could reduce exposure to SARS-CoV-2 on aircraft. The extent to which exposure reduction might decrease transmission risk is not yet understood. Current CDC guidelines recommend against travel for persons who have not been vaccinated and require masking for all persons while on aircraft. Physical distancing of aircraft passengers, including through policies such as middle seat vacancy, could provide additional reductions in SARS-COV-2 exposure risk. This study could help inform future modeling of transmission risk, which might encompass determinants that were not fully explored here such as mask use, virus characteristics, and host characteristics, such as vaccination status.

Summary

What is already known about this topic?

Aircraft can hold large numbers of persons in close proximity for long periods, which are conditions that can increase the risk for transmitting infectious diseases.

What is added by this report?

Based on laboratory modeling of exposure to SARS-CoV-2 on single-aisle and twin-aisle aircraft, exposures in scenarios in which the middle seat was vacant were reduced by 23% to 57%, compared with full aircraft occupancy, depending upon the model.

What are the implications for public health practice?

Physical distancing of airplane passengers, including through policies such as middle seat vacancy, could provide additional reductions in risk for exposure to SARS-CoV-2 on aircraft.

Acknowledgment

CDC COVID-19 Emergency Response Team.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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MS-DOH-21-1816-A-001676

From: Centers for Disease Control and Prevention <no-reply@emailupdates.cdc.gov>
Sent: Wednesday, April 14, 2021 3:30 PM EDT
To: commandcenter@cste.org <commandcenter@cste.org>
Subject: TOMORROW: CDC COCA Call: Johnson & Johnson/Janssen COVID-19 Vaccine and Cerebral Venous Sinus Thrombosis with Thrombocytopenia – Update for Clinicians on Early Detection and Treatment

Johnson & Johnson/Janssen COVID-19 Vaccine and Cerebral Venous Sinus Thrombosis with Thrombocytopenia – Update for Clinicians on Early Detection and Treatment

You may participate in this COCA Call via Zoom

Overview

This COCA Call will present the latest evidence on cerebral venous sinus thrombosis (CVST) with thrombocytopenia associated with the administration of the Johnson & Johnson/Janssen COVID-19 vaccine. Speakers will discuss what is known about CVST, the importance of early detection, and updated vaccine recommendations.

If you are unable to attend the live COCA Call, the recording will be available for viewing on theCOCA Call webpage a few hours after the live event ends.

The slide set will be available under "Call Materials" on theCOCA Call webpage the day of the call.

Continuing Education (CE) will not be provided for this call.

Advanced registration is not required.

Date: Thursday, April 15, 2021

Time: 2:00 pm - 3:00 pm (ET)

A few minutes before the webinar starts, please click on the Zoom link below to join:https://www.zoomgov.com/j/1614336614?pwd=ZVhQUHoyaG4zVFdua2czcE9EU20wUT09

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COCA Call Objectives

At the conclusion of the session, the participant will be able to accomplish the following—

1. Cite background information on the topic covered during the presentation.
2. Discuss CDC's role in the topic covered during the presentation.
3. Describe the topic's implications for clinicians.
4. Discuss concerns and/or issues related to preparedness for and/or response to urgent public health threats.
5. Promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an interprofessional team of healthcare providers.

Presenters

Sara Oliver, MD
LCDR, U.S. Public Health Service
Co-lead, Advisory Committee for Immunization Practices COVID-19 Vaccines Work Group
COVID-19 Response
Centers for Disease Control and Prevention

Tom Shimabukuro, MD, MPH, MBA
CAPT, U.S. Public Health Service
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COVID-19 Response
Centers for Disease Control and Prevention

The Emergency Risk Communication Branch in the Division of Emergency Operations, Center for Preparedness and Response is responsible for the management of all COCA products.

For information about this update or other clinical issues, or to send your feedback, please contact us at coca@cdc.gov

- CDC Clinician Outreach and Communication Activity Facebook page—connect with COCA on Facebook
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- COCA RSS Feed—subscribe to be notified of conference calls, updates, and CDC guidance for health providers
- Crisis & Emergency Risk Communication Training—training program that draws from lessons learned during public health emergencies, and incorporates best practices from the fields of risk and crisis communication
- Health Alert Network—CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories

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From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 21 (incl. ELC K-12 Deliverables, 4/23 ACIP Meeting, CDC Partner Call, MMWR Early Releases, and more)
Date:	Wednesday, April 21, 2021 3:35:30 PM
Attachments:	image001.png image002.png Partner Update April 212021.msg HHS COVID-19 Update - 419.msg HHS COVID-19 Update - 420.msg MMWR ER - April 21, 2021 - COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021.pdf MMWR ER - April 21, 2021 - Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021.pdf ELC K-12 Reopening Schools [Email].pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- ELC K-12 Reopening Schools Deliverables [Attachment]
  - Please see attached for a message from CDC's Epidemiology and Laboratory Capacity (ELC) Team. This message aims to clarify two deliverables due **Friday, April 23**:
    1. Validation/correction of the 'School District Weekly Reporting Template', pre-populated with school districts in your jurisdiction.
    2. A brief narrative of how you plan to partner and provide resources to the districts in your jurisdiction.
  - Full instructions are available in the attached PDF. From the message: *"We do not expect that every district in every jurisdiction will be ready to adopt screening testing immediately. During Phase 2/Activity 2, we will ask you to describe your plan for working with the jurisdictions in more specific terms. [...] We will be sharing FAQs in coming days to provide additional clarity; in the meantime, please don't hesitate to reach out to your ELC Project Officer or leadership with any questions or clarifications."*
- CDC ACIP Emergency Meeting [Link]
  - CDC's Advisory Committee on Immunization Practices (ACIP) will hold another virtual

emergency meeting **Friday, April 23** from **11:00 am–5:00 pm EDT** regarding safety in the use of the Johnson & Johnson (Janssen) vaccine.
    - Registration is *not* required. The meeting will be broadcast on uStream here.
- CDC Partner Update Call: Keeping Up with Critical Diabetes Care and Prevention During COVID-19 [Link]
    - CDC will host the next installment of its weekly partner call **Monday, April 26** at **3:00 pm EDT**. Dr. Kyle Bernstein will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Dr. Beth Bigman will discuss how to maintain critical diabetes care and prevention during the pandemic.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 4/26" in the subject line. The call will be recorded and posted to CDC's website here.
- MMWR Early Release: "Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021" [Attachment, Link]
    - From the summary: *"Twenty-two possible breakthrough SARS-CoV-2 infections occurred among fully vaccinated persons ≥14 days after their second dose of COVID-19 vaccine. Two thirds of persons were asymptomatic. A minority of persons with breakthrough infection experienced mild to moderate COVID-19–like symptoms; two COVID-19–related hospitalizations and one death occurred. No facility-associated secondary transmission was identified."*
- MMWR Early Release: "COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021" [Attachment, Link]
    - From the summary: *"In a COVID-19 outbreak at a Kentucky SNF involving a newly introduced variant to the region, unvaccinated residents and health care personnel (HCP) had 3.0 and 4.1 times the risk of infection as did vaccinated residents and HCP. Vaccine was 86.5% protective against symptomatic illness among residents and 87.1% protective among HCP."*

Standing Updates

- CDC Partner Update – April 21 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Updates – April 19 & 20 [Attachments]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]

- The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.

- CSTE COVID-19 Response Resource Repository [Link]
  - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
  - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
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From: Epidemiology and Laboratory Capacity for Infectious Diseases (CD (CDC) <elc@cdc.gov>
Sent: Wednesday, April 21, 2021 2:54 PM
To: Epidemiology and Laboratory Capacity for Infectious Diseases (CD (CDC) <elc@cdc.gov>
Subject: Important information regarding ELC K-12 Reopening Schools- Friday Deadline
Importance: High

This message is being sent via BCC to all ELC Governance Team members and partner organizations of ELC

Greetings,

To respond to questions we have received regarding *ELC Reopening Schools*, we wanted to provide additional clarity on the **two** deliverables due this Friday, April 23rd. These items are:

1. Validation/correction of the 'School District Weekly Reporting Template', pre-populated with school districts in your jurisdiction.
    - This list will be used for reporting starting on April 30th and every week thereafter until June 7th (when reporting requirements will be adjusted).
    - Recipients are not required to submit *any* testing data on April 23rd – just the updated/verified template.
    - The School District Weekly Reporting Template:
        - May be changed, as necessary, to reflect any corrections that need to be made. If no corrections are necessary, no adjustments are required.
        - May list all out non-public institutions separately or rolled up under the "Other" category. This choice is at the discretion of the jurisdiction.
    - To access and submit your template:
        - Go into the 'ELC Reopening Schools: COVID Award' portal;
        - In the 'ELC Reopening Schools Reporting' page;
        - In the 'Reporting Spreadsheet' section;
        - Upload the 'School District Weekly Reporting Template' into the 'Upload Current Reporting Spreadsheet Here' field.
2. A brief narrative of how you plan to partner and provide resources to the districts in your jurisdiction. We realize that everyone is at different stages and is dealing with different environments when it comes to instituting K-12 screening tests. With that in mind, please note that:
    - This narrative should be brief and may be very high-level (i.e., 1 paragraph may be sufficient to broadly describe how districts will be engaged/resourced).
    - The narrative should highlight any real or perceived barriers you anticipate as you roll out screening testing for K-12. Some challenges may be experienced state/jurisdiction-wide, or they may be isolated to particular districts. This information is important for the ELC to collate and provide to leadership.
    - This brief narrative is what is referenced in the guidance in terms of weekly reporting regarding support to school districts. The intent of the weekly reporting is to acknowledge that recipients may not have all the details of their implementation plan in the first 10 day after award issuance.

    - Weekly reporting offers recipients the opportunity to add details and/or modify their approach until the implementation plan is finalized.
    - If there are no subsequent changes, then the plan submitted on April 23rd will be automatically used to meet the weekly reporting requirement.
- To submit your narrative:
    - Go into the 'ELC Reopening Schools: COVID Award' REDCap portal;
    - In the 'ELC Reopening Schools Financial Reporting' page;
    - There are two blank, open-ended boxes for your narrative.

We do not expect that every district in every jurisdiction will be ready to adopt screening testing immediately. During Phase 2/Activity 2, we will ask you to describe your plan for working with the jurisdictions in more specific terms. Recipients will then provide more detailed plans, which can include how they will employ different approaches for different districts, for example, or specific strategies such as incentivizing test (e.g., "test to play/stay/or sway"). We will be evaluating the information we receive regularly and will implement changes to our approach as necessary. As a reminder, these funds should cover the required costs for school districts to run a screening testing program, including follow up on positives.

We may reach out directly or via our partners at CSTE, APHL, ASTHO, and NACCHO to receive input from you along the way.

We appreciate the ongoing partnership with all of you and we understand this is yet another large lift. We are here to help in whatever way we can. We will be sharing FAQs in coming days to provide additional clarity; in the meantime, please don't hesitate to reach out to your ELC Project Officer or leadership with any questions or clarifications.

All the very best,
-The ELC Team

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Monday, April 19, 2021 7:21 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 4/19

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 19, 2021:

Renewal of Determination That a Public Health Emergency Exists: As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date (April 15, 2021) and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective April 21, 2021, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, that a public health emergency exists and has existed since January 27, 2020, nationwide.

Highlights from Friday and Monday's White House COVID-19 Response Team Briefing

Andy Slavitt

- **Vaccine Availability:** Over 80 percent of seniors have had at least their first shot. Fifty percent of adults in the U.S. have had at least one shot. We now have one thing on our mind: making sure that the other 50 percent know how easy it is to get a shot. If you still think it's too difficult your vaccine, here's what you need to know: the lack of supply, the shortage of locations, the confusing rules are all in the past. That cannot be said enough. There are thousands of more people ready to help you get vaccinated. There are now millions more vaccine doses available and waiting. There are now more than 60,000 safe and convenient places for you to get your shot.
- **Expanded Vaccine Eligibility:** If you are 16 or over, it is your turn to get vaccinated no matter where you live. There's a nine out of ten chance that you are located within five miles of your vaccine shot. For those of you who can't get to a vaccine site, we're helping community-based organizations connect vulnerable Americans with shots. And now, to get resources to healthcare providers serving at-risk populations and to promote equitable distribution of vaccines, today HHS is making $150 million available to community-based healthcare providers to strengthen their efforts to get shots in arms and care for patients with COVID-19.
- **Get Vaccinated:** Join the more than 130 million Americans who have already gotten at least one shot, that's half of all adults. Here's my direct plea to everyone listening: If you haven't already made an appointment to get vaccinated, make one right now. You are eligible. Then, reach out to your family, friends, and neighbors to make sure they can make an appointment too. See what help you can offer them to help those who might need extra assistance.
- **American Rescue Plan:** We are announcing a $1.7 billion investment to bolster the ability of the CDC and state and local public health departments to monitor, track, and defeat emerging threats — whether it's COVID-19 variants today or other viruses in the future — through a process known as genomic sequencing. This significant investment, which is made possible due to the American Rescue Plan President Biden signed into law last month, is critical in our fight against the new and potentially dangerous variants of COVID-19. Right now, these variants account for nearly half of all COVID-19 cases in the United States, and we need more capacity in our public health system to identify and track these mutations. This funding will enable CDC and states to do more genomic sequencing as we activate the nation's great research capabilities to detect variants earlier and increase our visibility into emerging threats. This investment will give public health officials the chance to react more quickly to prevent and stop the spread. Today's investment also builds on the major investments in testing and genomic sequencing that we made earlier this year. That includes $10 billion of American Rescue Plan funding to support COVID-19 testing in schools, another $2.5 billion to help state and local public health agencies increase testing capacity in underserved and high-risk communities, and nearly $200 million to begin to increase genomic sequencing capacity that this investment comes on top of.

Dr. Walensky

- **Case Update:** Yesterday, CDC reported nearly 60,950 cases of COVID-19. Our seven-day average is up to over 67,440 per day. For context, one month ago, our seven-day average of cases was just over 53,000 per day. The seven-day average of hospital admissions is about 5,460. Sadly, the seven-day average of daily deaths are now increasing, with six consecutive days of increases, to about 695 deaths per day. Sunday, we again saw almost 700 deaths in a single day.
- **Vaccination Update:** So far, we have administered 209 million vaccine doses, with an average daily administration of more than 3 million doses. This brings us to 192.8 million doses in the first 100 days — 96 percent of our goal in 88 days. This means that almost 40 percent of the total population has received at least one dose of a COVID-19 vaccine, and one out of every four people is fully vaccinated. More than 65 percent of people age 65 and older and more than 25 percent of people are fully vaccinated.
- **Vaccine Effectiveness:** First, among nearly 4,000 healthcare personnel, first responders, and essential workers who received the Pfizer and Moderna vaccines, the risk of any infection, asymptomatic and symptomatic, was reduced by 90 percent after receiving the two recommended doses of the vaccine. This study was yet additional evidence that these vaccines are working. The efficacy we saw in clinical trials is now being shown in the real world. Second, last week, we released data on the number of so-called "breakthrough infections," of people who, despite being vaccinated, still tested positive for COVID-19 more than 14 days after they're getting their second vaccine dose. With any vaccine, we expect such rare cases. But so far, out of more than 84 million people who are fully vaccinated, we have only received reports of less than 6,000 breakthrough cases. Although this number is from 43 states and territories and likely an underestimate, it still makes a really important point: These vaccines are working. Of the nearly 6,000 cases, approximately 30 percent had no symptoms at all. Based on these data, here's the bottom line: Getting a vaccine will help protect you, it will help protect others, and it will help us end this pandemic.
- **Rising Cases and Variants:** Some of these increases are as a result of relaxed prevention efforts in states across the country, such as relaxed mask mandates or loosened restrictions on indoor restaurant seating. Another reason for these increases is the continued spread of highly transmissible variants — more than 50 to 70 percent more transmissible — which makes the race to stop the transmission even more challenging and threatens to overwhelm our healthcare system again in parts of this country. CDC data show that the B117 variant — the variant originally identified in the United Kingdom — represents 44 percent of the virus circulating during the week of March 27th.
- **Johnson & Johnson Update:** After the press briefing on Wednesday (4/14), the Advisory Committee on Immunization Practices — or

ACIP — met to discuss the six cases and provide recommendations. I want to thank the ACIP for their thoughtful discussion and their commitment to the science. The recommendation from this group of independent experts for a continued pause will allow additional time to review any additional cases that might come in, and for them to conduct a complete risk assessment and to evaluate the emerging science. ACIP will meet again this Friday, April 23rd, from 11:00 to 5:00 to provide further recommendations.

Dr. Fauci

- **Vaccine Efficacy in Clinical Trials:** This is work that has been done in tens of thousands of people in clinical trials, has been peer reviewed independently, and published in scientific journals. Pfizer and Moderna's efficacy are shown in the New England Journal of Medicine papers. The same holds true for J&J. All three are highly efficacious in clinical trials.
- **Vaccine Efficacy in Real-World Settings:** In over 23,000 employees at the University of Texas, the infection rate was miniscule among vaccinated employees: 0.05 percent. The CDC — looking, again, at the real-world effectiveness — showed that in almost 80,000 person-days with full immunization, 0.04 per 1,000 person-days.
- **Vaccine Safety:** We have an extraordinary capability to monitor safety, as an extremely rare adverse event of 6 individuals among 7,000 was picked up by the surveillance system. Those surveillance systems include ones that follow up on clinical trials, monitoring systems by the CDC, by the FDA, and other monitoring systems. When we say a vaccine is safe, you're talking about an exquisitely sensitive monitoring system.
- **NIH-sponsored Coronavirus Disease 2019 Treatment Guidelines Panel:** This is a panel of individuals co-chaired by Dr. Cliff Lane, who is the Deputy Director of NIAID, but also the Clinical Director of the Institute; Henry Masur, who is the Director of the Critical Care Medicine Unit at NIH; and Roy "Trip" Gulik, who is the Chief of Infectious Diseases at Weill Cornell Medicine in New York City. This panel was established to be able to work, literally in real time, updating guidelines for clinicians and healthcare providers throughout the country and the world on the latest information.

Dr. Murthy

- **American Indians and Alaska Natives:** According to a recent CDC report, American Indians and Alaska Natives were 3.5 times more likely to get COVID than a non-Hispanic, white population. Native people are also more than four times likely to be hospitalized as a result of COVID-19. Despite these challenges, our colleagues working in the Indian health system have heroically administered more than 1 million doses of COVID-19 vaccines. That is a remarkable achievement and a testament to their dedication. Today, the Biden administration is doubling down on this critical work with a — with a $4 billion investment from the American Rescue Plan to the Indian Health Service Tribal and urban Indian health programs. Specifically, these funds will support the following: expanded COVID-19 vaccinations, including mobile efforts, large-scale vaccination events, and public education and outreach campaigns; expanded testing, contact tracing, PPE access, and treatment; increased preventive health services for those at higher risk for COVID-19; and increased support for telehealth, the healthcare workforce, and the broader Indian healthcare system, which has been a hard hit during the pandemic due to lost reimbursements for care for both public and private insurance.
- **Increasing Access and Increasing Confidence:** The more people see those around and get vaccinated, particularly family and friends, the more comfortable they become with getting vaccinated themselves. The easier we make it to get vaccinated, the more people will get vaccinated, and that means more people around them would feel comfortable with getting vaccine themselves. That's why access and confidence go hand in hand, and so does safety. This brings me to the second topic. This week you've heard a lot from us about the pause with administering the Johnson & Johnson COVID-19 vaccine. These decisions are never simple, and this one was taken after a very careful assessment of the risks and benefits of calling for such a pause. However, the actions taken by CDC and the FDA this week should give Americans confidence that our safety system is working for them. For some members of the public, uncertainty about getting vaccinated stems from questions about how safe the vaccines are. This week is a reminder that safety is our top priority. Even when an extremely rare safety occurs, our scientific agencies will act with thoroughness and transparency so people can remain confident in the vaccines that are recommended to them.

Vaccine Updates

Vaccine Eligibility: CDC updated the following COVID-19 information pages to include that everyone 16 years of age and older is now eligible to get a COVID-19 vaccine: Vaccine FAQs, How Vaccines Get to You, Key Things to Know, and Vaccine Rollout Recommendations. CDC also updated the following information pages for specific communities to include the expanded eligibility of the COVID-19 vaccine: persons with disabilities, essential workers, healthcare personnel, older adults, and those high risk for severe illness. Get a COVID-19 vaccine as soon as you can. Moreover, CDC updated their general vaccination resources, including information on preparing for your vaccine.

Moderna Vaccine Update: The FDA updated their Moderna COVID-19 Vaccine Frequently Asked Questions page. On December 18, 2020, the U.S. Food and Drug Administration issued an emergency use authorization for the second vaccine for the prevention of coronavirus disease 2019 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows Moderna COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

Johnson & Johnson Update: On April 13, 2021, CDC and FDA recommended a pause in the use of Johnson & Johnson's Janssen COVID-19 Vaccine. Of the nearly 7 million doses administered so far in the United States, a small number of reports of a rare and severe type of blood clot have been reported in people after receiving the J&J/Janssen COVID-19 Vaccine. All reports occurred among women between the ages of 18 and 48, and symptoms occurred six to 13 days after vaccination. As of April 13, 2021, of the more than 180 million doses administered so far of the Pfizer-BioNTech or Moderna vaccines, no reports matching those associated with the J&J/Janssen vaccine have been received.

FEMA's J&J Update: In alignment with the recommendation from the CDC and FDA to pause the use of the Johnson & Johnson vaccine, FEMA immediately ceased administration of these doses at our federal community vaccination center pilot sites and mobile vaccine units. This pause will continue until further guidance is received from CDC and FDA. We are working with our state partners to determine the path forward and find alternative vaccine options for these sites.

FEMA Vaccination Sites: There are 31 active or temporarily closed federal community vaccination center pilot sites and 20 mobile pop-up sites in 22 states. Additionally, there are 10 mobile vaccination units deployed to eight states. These centers and units have administered more than 3.4 million vaccinations. Working with state governments FEMA will open additional federal community vaccination center pilot sites, which include federal support and supplemental vaccine allocation: this week, federal community vaccination center pilot sites are scheduled to open in Bessemer, Alabama; Tulsa, Oklahoma; and Central Point, Oregon. Last week, FEMA transitioned management of the federal community vaccination center pilot sites in Los Angeles and Oakland to the state. FEMA continues to support both sites with federal personnel. Additionally, FEMA has obligated more than $936 million to support the state's vaccination efforts. These sites administered more than 671,000 shots since they opened on Feb. 16. FEMA mobile vaccination units have begun operations. These vehicles can bring vaccinations to hard-to-reach and high-risk populations who cannot access services from fixed sites. Ten mobile vaccination units are currently deployed to Connecticut, Maine, Maryland, Nebraska, Nevada, New Mexico, Oregon and South Dakota.

DoD Response to J&J Pause: In a press briefing on Friday, Pentagon Press Secretary John F. Kirby stated that while the DoD intended to use the Johnson & Johnson vaccine to support overseas personnel and their families, the vaccine distribution planners on our COVID task force developed a plan to reallocate doses of the Moderna vaccine to our overseas commands. Each service will now direct a total of approximately 30,000 additional doses of Moderna throughout the month of May. That's around roughly 10,000 per week, beginning May 10th, to overseas locations in European Command, Indo-Pacific Command and Central Command. This will help keep the vaccination efforts right on pace to provide initial doses to over 70 percent of our overseas personnel and their families by the end of May.

COVID-19 Illness After Vaccination: CDC released information regarding what you should know about the possibility of COVID-19 illness after vaccination. COVID-19 vaccines are effective. However, a small percentage of people who are fully vaccinated will still get COVID-19 if they are exposed to the virus that causes it. These are called "vaccine breakthrough cases." This means that while people who have been vaccinated are much less likely to get sick, it may still happen. Experts continue to study how common these cases are.

CDC Weekly Review: On Friday, CDC released their weekly review on the COVID-19 pandemic, including updated numbers of reported cases, SARA-CoV-2 variants, testing, vaccinations, hospitalizations, and deaths. Nationally, COVID-19-related emergency department visits as well as both hospital admissions and current hospitalizations have risen among patients ages 18 to 64 years in recent weeks. The good news is that emergency department visits and hospitalizations among people ages 65 years and older have decreased, likely demonstrating the important role vaccination plays in protecting against COVID-19. As access to vaccines for all Americans increases, we have reason to be hopeful. However, until more of the U.S. population is fully vaccinated, consistent use of prevention strategies, such as universal and correct use of masks, social distancing, and hand washing, will help to limit the spread of SARS-CoV-2, the virus that causes COVID-19. Even if you have been fully vaccinated against COVID-19, you should keep taking these everyday precautions in public places. For more information, view the CDC's data on vaccinations, vaccination demographics, and vaccination trends.

Operational Considerations for Jurisdictions Planning to Operate COVID-19 Vaccination Clinics: CDC released guidance for jurisdictions planning to operate COVID-19 vaccinations clinics. Safe and effective COVID-19 vaccines have been developed and authorized and are being manufactured. Jurisdictions are presently vaccinating people in their target populations. Currently, vaccine is available in growing quantities, with even more vaccine slated to become available soon. Most jurisdictions can provide access to vaccination using a combination of usual vaccination providers (pharmacies and medical providers/community health centers) and a limited number of public health clinics. Many jurisdictions are planning for and operating multiple, temporary, large- and small-scale vaccination sites, both fixed location and mobile, as strategies to vaccinate more of the population rapidly. The Federal Emergency Management Agency (FEMA) is working with jurisdictions to establish Community Vaccination Centers (CVCs). These CVCs can be established as fixed facilities, drive-through facilities, or as mobile vaccination clinics based on a jurisdiction's needs.

ACIP Jurisdictions Estimated Worker Population: CDC updated their information from the Advisory Committee on Immunization Practices (ACIP) regarding vaccination data among different worker populations.

Testing and Treatment

FDA Revokes EUA for Monoclonal Antibody Bamlanivimab: On Friday, the FDA revoked the emergency use authorization (EUA) that allowed for the investigational monoclonal antibody therapy bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. Based on its ongoing analysis of emerging scientific data, specifically the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone resulting in the increased risk for treatment failure, the FDA has determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. Therefore, the agency determined that the criteria for issuance of an authorization are no longer met and has revoked the EUA. Instead of administering Bamlanivimab alone, health care providers should consider using the other authorized monoclonal antibody therapies expected to retain activity against the viral variants: Casirivimab and imdevimab, administered together, and Bamlanivimab and etesevimab, administered together.

FDA Testing Update: As of Friday, 363 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 266 molecular tests and sample collection devices, 75 antibody and other immune response tests, and 22 antigen tests. There are 46 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home tests, four over-the-counter (OTC) at-home antigen tests, and two OTC molecular tests. The FDA has authorized 7 antigen tests and 2 molecular tests for serial screening programs. The FDA has also authorized 457 revisions to EUA authorizations.

Funding

$150 Million from ARP to Support Community-Based Health Care Providers: HHS announced the availability of nearly $150 million to community-based health care providers to aid their response to COVID-19. These funds will support approximately 100 Health Center Program look-alikes to respond to and mitigate the spread of COVID-19, strengthen vaccination efforts, and enhance health care services and infrastructure in communities across the country. Health center look-alikes (LALs) are community-based health care providers that provide essential primary care services to underserved communities and vulnerable populations but are not Health Center Program grantees. This funding will be made available through the Health Resources and Services Administration (HRSA) and is part of President Biden's commitment to ensuring equity in the nation's COVID-19 response and vaccination efforts.

Biden Administration Announces $1.7 Billion Investment to Fight COVID-19 Variants: In order to improve the detection, monitoring, and mitigation of COVID-19 variants, the Biden Administration is rapidly investing $1.7 billion from the American Rescue Plan to help states and other jurisdictions more effectively fight these mutations. An essential component of the response to the emerging COVID-19 variants is increasing the country's genomic sequencing — the process by which COVID DNA is decoded and potentially deadly mutations in the virus are detected. With this funding, allocated through the Centers for Disease Control and Prevention (CDC), will help the CDC, states, and other jurisdictions more effectively detect and track variants by scaling genomic sequencing efforts. With the information from sequencing, the CDC and state and local public health leaders can implement known prevention measures to stop the spread.

Biden Administration Invests $4 Billion in ARP Funding to Combat COVID-19 in Indian Country: As part of President Biden's continued efforts to ensure the pandemic response reaches all people and all communities, the Biden Administration is announcing it will invest more than $4 billion to combat COVID-19 in Indian Country. The funding, from the American Rescue Plan, will expand COVID-19 vaccinations, testing, and treatment; increase preventive health services to American Indians and Alaska Natives at higher risk for COVID-19; expand hospitals' and health clinics' ability to serve their communities during the pandemic and beyond; and provide the Indian Health Service (IHS), tribal health programs, and urban Indian health programs with needed funding to make up for lost reimbursements experienced during the pandemic.

FEMA Funeral Assistance Funding: As of today, FEMA has received more than 101,000 funeral assistance applications. Applicants may apply by calling 844-684-6333 (TTY: 800-462-7585) from 9 a.m. to 9 p.m. ET, Monday through Friday. Multilingual services are available. Callers who use a relay service, videophone or captioned telephones should provide their specific number assigned to that service. It is important that FEMA is able to contact applicants. Please note, phone calls from FEMA may come from an unidentified number. FEMA will not contact anyone until they have called FEMA or have applied for assistance.

Reopening Guidance

Personal and Social Activities: CDC updated their information on engaging in personal and social activities. COVID-19 cases, hospitalizations, and deaths are extremely high across the United States. To decrease your chance of getting and spreading COVID-19, CDC recommends that you do not gather with people who do not live with you at this time. Attending events and gatherings increases your risk of getting and spreading COVID-19. Stay home to protect yourself and others from COVID-19.

Travel Health Notices: CDC updated their travel health notices to provide current risk assessment levels for COVID-19 in different countries.

Considerations for Casinos and Gaming Operations: As some casinos and gaming operations resume in some areas of the United States, CDC offers the following considerations for ways in which casino and gaming operators can help protect staff and customers and slow the spread of COVID-19. Casinos and gaming operations can determine, in collaboration with local, state, territorial, federal, or tribal health officials, whether and how to implement these considerations, making adjustments to meet the needs and circumstances of the local community. Implementation should be guided by what is feasible, practical, acceptable, and tailored to the needs of each community. For more information on bars and restaurants within casinos, please see CDC's Considerations for Restaurants and Bars. These considerations are meant to supplement—not replace—any local, state, territorial, federal, or tribal safety laws, rules, or regulations with which businesses must comply.

Community-Based Organizations: CDC updated their guidance for community-based organizations (CBOs). As some CBOs begin to resume or increase their level of activities, CDC offers considerations for ways these organizations can help protect individuals and communities and slow the spread of coronavirus disease 2019 (COVID-19). COVID-19 cases, hospitalizations, and deaths are extremely high across the United States. To decrease your chance of getting and spreading COVID-19, CDC recommends that you do not gather with people who do not live with you at this time. Attending events and gatherings increases your risk of getting and spreading COVID-19. Stay home to protect yourself and others from COVID-19.

Considerations for Institutions of Higher Education: CDC updated their guidance for institutions of higher education (IHEs). As some IHEs prepare to re-open or keep open in-person learning in the United States, IHEs are faced with the challenge of keeping students, faculty, staff, and volunteers safe due to the coronavirus disease 2019 (COVID-19) pandemic. CDC offers the following considerations for ways that IHEs can help protect students and employees (e.g., faculty, staff, and administrators) and slow the spread of COVID-19. This document refers only to risks related to COVID-19. IHEs may consider implementing several strategies to maintain healthy environments.

Information for Specific Populations

USDA Activities to Contain the COVID-19 Pandemic: The United States Department of Agriculture (USDA) updated their fact sheet on activities to contain the COVID-19 pandemic. USDA has deployed 1,064 disaster, public health specialists to assist with federal response.

Guidance for Large or Extended Families Living in the Same Home: CDC released guidance for large or extended families living in the same home. If you or someone in your household is at increased risk for severe illness from COVID-19, then all family members should act as if they are at increased risk. This can be difficult if space is limited for large or extended families living together. While avoiding close contact with others and isolating someone who is sick can feel lonely, these actions are necessary to reduce the spread of COVID-19 and protect yourself and your household.

DoD Force Health Protection Guidance: On Friday, the Department of Defense released the memorandum for Force Health Protection Guidance (Supplement 20) – Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic. This memorandum applies to official and unofficial travel and proves updated pre- and post-travel guidance for purposes of force health protection (FHP) for Service members, DoD family members, DoD civilian employees, and DoD contractor personnel, as well as fully vaccinated individuals.

Staffing Resources: CDC updated their staffing resources and guidance to strengthen the public health workforce. CDC updated their information regarding the number of CDC COVID-19 response staff deployed across America.

Cleaning, Disinfecting, and Ventilation: CDC updated their resources for cleaning, disinfecting, and ventilation, including an updated toolkit for school administrators on cleaning, disinfection, and hand hygiene. Reducing the risk of exposure to SARS-CoV-2, the virus that causes COVID-19, by cleaning and disinfection is an integral part of opening schools that will require careful planning.

Childhood Vaccination Toolkit for Clinicians: CDC released a toolkit for clinicians on getting children caught up on receiving recommended vaccinations. COVID-19 disrupted both in-person learning and routine well-child visits for many children over the last year. As a result, too many children have fallen behind on receiving recommended vaccines. Children need to get caught up now so that they are protected as they go back to in-person learning and summer camps. Healthcare providers can identify families whose children have missed doses and contact them to schedule appointments. Providers can also let families know what precautions are in place for safe delivery of in-person services.

Health Departments and Public Safety Partners: CDC updated their information for health departments and public health partners to help educate communities and promote COVID-19 vaccination.

Manufacturing Workers & Employers: CDC and the Occupational Safety and Health Administration (OSHA) updated their guidance for manufacturing workers and employers.

Acute Care Delivery at Home Tip Sheet: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released a tip sheet providing an overview of characteristics of various types of acute care delivery at home programs to help healthcare providers better understand this care model. Some healthcare providers and systems have been providing hospital-level care in patient's homes for years; others have implemented acute care delivery at home models in response to overcrowding at hospitals due to COVID-19.

COVID-19 and Healthcare Professional Stress and Resilience: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released Issue 12 of The Exchange, which examines the impact of COVID-19 on healthcare professionals. The issue focuses

on three categories: understanding acute and chronic stressors in the healthcare worker population, identifying at-risk employees, and promising practices in building resilience.

COVID-19 Healthcare Delivery Impacts: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) updated their tip sheet to help healthcare system planners prepare to mitigate potential healthcare delivery impacts.

Strategies to Help Combat the Coronavirus Blues: The COVID-19 Schools Task Force, FEMA Region VII, and HHS Region 7 released a document summarizing the contents of the Mind Over Matter Resource Guide. This guide can be used to support messaging for college and university campus communities to help combat COVID-19 fatigue and promote general wellness, both during and after the pandemic.

Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19: On April 2, 2021, the CDC released a declaration determining that the eviction of tenants could be detrimental to public health control measures to slow the spread of COVID-19. View the posted order, as well as eviction protection declaration forms in English and Spanish. Please visit HUD's COVID-19 Emergency Information for Housing Counselors for additional resources and information.

United States Coast Guard Vaccine FAQs: The United States Coast Guard updated their Frequently Asked Questions page about the vaccine, and specific questions related to Coast Guard administered vaccines.

Older Adults: CDC updated their information for older adults, who are at a greater risk of hospitalization or dying if diagnosed with COVID-19. The risk for severe illness with COVID-19 increases with age, with older adults at highest risk. If you have a family member or friend who lives in a nursing home, assisted living facility, or other type of senior living or retirement community, you may be concerned about COVID-19. To protect friends and family members who live in these communities, CDC has issued updated recommendations for visitations at post-acute facilities. These recommendations align with the Centers for Medicare and Medicaid Services (CMS) guidance for visitations under various circumstances.

Caring for Someone Sick: CDC updated their guidance for caregivers in non-healthcare settings. Cleaning with a household cleaner that contains soap or detergent reduces the amount of germs on surfaces and objects and decreases risk of infection from surfaces. In most situations, cleaning alone removes most virus particles on surfaces.

People at Increased Risk: CDC updated their resources available for people at increased risk, and for other people who need to take extra precautions.

Non-Emergency Transportation for Tribal Communities: CDC updated their guidance on non-emergency transportation for tribal communities. Tribal community members may need to regularly share personal vehicles with members outside of their own households. They may also need to use personal vehicles to transport people who are visibly sick. In addition, tribal organizations may provide medical transportation to their community members using non-emergency vehicles (cars or vans, for example). CDC outlines precautions that can be considered to minimize risk of spreading COVID-19 when sharing personal vehicles.

Implementing Screening and Treatment of Unhealthy Alcohol Use During COVID-19: The Agency for Healthcare Research and Quality (AHRQ) posted an article on implementing screening and treatment of unhealthy alcohol use during COVID-19. Since the onset of the COVID-19 pandemic in March 2020, alcohol sales have increased dramatically in many States across the country and rates of unhealthy alcohol use are rising in parallel. Unhealthy alcohol use, which refers to the full spectrum of alcohol misuse from risky or hazardous drinking to alcohol use disorder, is associated with adverse consequences, including poorer physical and mental health outcomes as well as negative socioeconomic effects. AHRQ's EvidenceNow: Managing Unhealthy Alcohol Use Initiative represents an important opportunity to help clinicians support many patients receive the appropriate diagnosis, counseling, and treatment for unhealthy alcohol use by implementing the best patient-centered outcomes research findings available to improve health.

Sprayers Safety Precautions: CDC updated their information regarding how to select cleaners, disinfectants, and application methods for use in facilities, businesses, and public indoor spaces to ensure that you can clean and disinfect safely and effectively. In most situations, cleaning surfaces (using soap or detergent) is enough to reduce SAR-CoV-2, the virus that causes COVID-19. Clean surfaces before disinfecting.

CMS Updates

Encouraging Latino Consumers to Enroll in Health Insurance Coverage: Today, HHS Secretary Xavier Becerra announced commitments from national organizations to support Latino outreach and enrollment efforts during the current Special Enrollment Period (SEP) made available on HealthCare.gov by President Biden due to the COVID-19 Public Health Emergency (English | Spanish). As part of the Latino Week of Action April 18 - 24, these organizations and HHS will share information with Latino consumers and use social media to encourage them to enroll in affordable, quality health plans through HealthCare.gov. Access to affordable health coverage and care is particularly important for Latinos in the US because 22% of non-elderly Latinos are uninsured, a rate almost 2.5 times that of White Americans. During this week and beyond, HHS and many organizations will send targeted messages, participate in earned media opportunities, and amplify the SEP through social media channels to raise awareness about the coverage options available through HealthCare.gov for the Latino community. The Centers for Medicare & Medicaid Services (CMS) has also launched an outreach and an educational campaign, which includes broadcast and digital advertising and educates through email and text messages in both Spanish and English.

PPE

Guidance for Wearing Masks: CDC updated their guidance for wearing masks. Masks are a simple barrier to help prevent your respiratory droplets from reaching others. Studies show that masks reduce the spray of droplets when worn over the nose and mouth. CDC also updated their information on the different types of masks. CDC recommends that N95 respirators should be prioritized for protection against COVID-19 in healthcare settings. Essential workers and workers who routinely wore respirators before the pandemic should continue wearing N95 respirators. As N95s become available they can be worn in non-healthcare settings.

Research

Large Clinical Trial to Study Repurposed Drugs to Treat COVID-19 Symptoms: The NIH will fund a large, randomized, placebo-controlled Phase 3 clinical trial to test several existing prescription and over-the-counter medications for people to self-administer to treat symptoms of COVID-19. Part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public–private partnership, the ACTIV-6 trial aims to provide evidence-based treatment options for the majority of adult patients with COVID-19 who have mild-to-moderate symptoms and are not sick enough to be hospitalized. NIH will provide an initial investment of $155 million in funding for the trial.

Experimental Antiviral for COVID-19 Effective in Hamster Study: The experimental antiviral drug MK-4482 significantly decreased levels of virus and disease damage in the lungs of hamsters treated for SARS-CoV-2 infection, according to a new study from NIH scientists. SARS-CoV-2 is the virus that causes COVID-19. MK-4482, delivered orally, is now in human clinical trials. Remdesivir, an antiviral drug already approved by the U.S. Food and Drug Administration for use against COVID-19, must be provided intravenously, making its use primarily limited to clinical settings. In their study, published in the journal *Nature Communications*, the scientists found MK-4482 treatment effective when provided up to 12 hours before or 12 hours after infecting the hamsters with SARS-CoV-2. These data suggest that MK-4482 treatment potentially could mitigate high-risk exposures to SARS-CoV-2 and might be used to treat established SARS-CoV-2 infection alone or possibly in combination with other agents.

Public Health Investigations of COVID-19 Vaccine Breakthrough Cases: CDC released a case investigation protocol on public health investigations of COVID-19 vaccine breakthrough cases. The U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for three COVID-19 vaccines. In large, randomized controlled trials, each vaccine was safe and efficacious for preventing symptomatic, laboratory-confirmed COVID-19 disease. There were no statistically significant differences in efficacy by age, gender, race, or comorbidities. Despite the high level of efficacy, a small number of breakthrough cases occurred. The phase 3 studies have not yet identified risk factors for vaccine breakthrough cases; however, approximately 44,000 people received the FDA-authorized vaccines during the clinical trials and follow-up is ongoing. This protocol can be used to guide public health investigations of COVID-19 vaccine breakthrough cases. We aim to capture both symptomatic and asymptomatic infections. Characterization of vaccine breakthrough cases could provide the first indication that a vaccine is less effective in certain demographic groups or that vaccine-induced immunity is waning, and booster doses may be needed. Clustering of cases among vaccinated persons by time, geographic area, or lot could help identify an issue in manufacturing, shipping, handling, or administration. Evaluating SARS-CoV-2 strains that cause vaccine breakthrough cases provides one way to monitor for variant strains that could result in lower vaccine efficacy.

COVID-19 and the Changing Healthcare Delivery Landscape: HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) released a study highlighting the impact of COVID-19 on healthcare delivery. The study examines supply chain, patients delaying emergency care, the delay of elective procedures, and financial impacts to the healthcare system.

COVID-19 Science Update: CDC released their weekly COVID-19 Science Update. This week's issue includes, but is not limited to, research on the following: the association of sociodemographic factors and blood group type with risk of COVID-19, increased household secondary attack rates with variants of concern**,** and the epidemiologic evidence for airborne transmission of SARS-CoV-2 during church singing.

Hospitalization and Death by Race/Ethnicity: CDC updated their information on hospitalization and death rates by race/ethnicity. Race and ethnicity are risk markers for other underlying conditions that affect health including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers.

Marvin Figueroa, Director
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U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Tuesday, April 20, 2021 6:45 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 4/20

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 20, 2021:

Case Update

New Cases (based on 7-day rolling average)
- **31,484,148** US cases
- **3% decrease** in new cases (7-day average), as of April 19; (was 8% increase last week)

Testing
- **399,891,811** tests completed (4/19)
- **6%** positive test rate as of the week of 4/13– 4/19 (was 5.5% last week)

Hospitalizations
- **2,048,742** total COVID hospital admissions
- The 7-day average (4/13-4/19) number of new confirmed COVID-19 admissions **decreased by 3%** week on week (from 5,493 to 5,341 admissions per day)

Deaths
- **564,292** total US deaths
- The 7-day average (4/13-4/19) number of reported deaths **increased by 3%** week on week (from 673 to 692 deaths per day)

Vaccines
- **211,581,309** vaccine doses **administered** (4/19)
- **39.9%** (132.3 million people) of the population has received **1 or more doses** and **25.7%** (85.4 million people) of the population have been **fully vaccinated**
- **80.1%** of adults 65 and older have received **at least 1 dose** and **64.9%** have been **fully vaccinated**

Vaccine Updates

Percent of Doses Administered: CDC updated their information on the percent of COVID-19 vaccine doses administered. The majority of U.S. states and territories have administered at or above 85% of their first vaccine doses delivered. To maintain inventory, some vaccine will always be kept in supply; so percentages are not expected to reach 100%.

Reported Adverse Events: CDC and FDA have recommended a pause in the use of Johnson & Johnson's J&J/Janssen COVID-19 Vaccine in the United States out of an abundance of caution, effective Tuesday, April 13. The Advisory Committee on Immunization Practices (ACIP) will hold its second emergency meeting to discuss J&J/Janssen COVID-19 Vaccine on April 23, 2021. People who have received the J&J/Janssen COVID-19 Vaccine within the past three weeks who develop severe headache, abdominal pain, leg pain, or shortness of breath should seek medical care right away.

ACIP Meeting Recording: CDC released the recording of the Advisory Committee on Immunization Practices (ACIP) meeting that was held on April 14, 2021 following the pause of the Johnson & Jonson COVID-19 vaccine. The meeting provides an overview of safety with Janssen's COVID-19 vaccine (Ad26.COV2.S), an update on thromboembolic events, an update on COVID-19 vaccines safety surveillance, VaST assessments, and work group interpretations.

V-safe Pregnancy Registry: CDC updated their information on the v-safe pregnancy registry. As of April 19, 2021, more than 94 thousand v-safe participants have indicated they were pregnant at the time they received COVID-19 vaccination. CDC is currently enrolling eligible participants and analyzing data to better understand how COVID-19 vaccination affects pregnant people. As CDC learns more about the effects of vaccination during pregnancy, data will be presented at the Advisory Committee on Immunization Practices (ACIP) meetings, which are open to the public, and in published reports.

COVID-19 Community Corps: The HHS COVID-19 public education campaign is a national initiative to increase public confidence in and uptake of COVID-19 vaccines while reinforcing basic prevention measures such as mask wearing and social distancing. Specifically, the COVID-19 Community Corps works to engage with a broad range of groups and individuals, including trusted community organizations, local leaders, and others sharing the goal of increasing vaccine confidence and uptake. Join the COVID-19 Community Corps here, and view their resources, toolkits, and information on how to communicate with others about protecting themselves and their communities.

Testing and Treatment

FDA Testing Update: As of today, 367 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 269 molecular tests and sample collection devices, 75 antibody and other immune response tests, and 23 antigen tests. There are 49 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home tests, four over-the-counter (OTC) at-home antigen tests, and two OTC molecular tests. The FDA has authorized 8 antigen tests and 2 molecular tests for serial screening programs. The FDA has also authorized 462 revisions to EUA authorizations.

Funding

$12.7 Million to Programs Enhancing Health Care Delivery to Rural Underserved Populations: Today, the Health Resources and Services Administration (HRSA) announced more than $12.7 million in funding to 61 public, private and non-profit entities across 35 states to serve rural

communities and address rural health disparities as part of its community-based Rural Health Care Services Outreach Program (Outreach Program). The Outreach Program expands and improves health services for rural residents by supporting innovative and evidence-based approaches tailored to the specific needs of local communities. For the first time, funds will go toward supporting the Healthy Rural Hometown Initiative (HRHI) to address underlying factors that drive rural health disparities related to the five leading causes of avoidable death (heart disease, cancer, unintentional injury, chronic lower respiratory disease, and stroke).

Reopening Guidance

Personal and Social Activities: CDC updated their information on how to safely go about personal and social activities . The page outlines guidance for visiting a restaurant or bar, hosting gatherings or cook-outs, attending an event or gathering, using gyms or fitness centers, going to a nail salon, visiting a library, traveling overnight, and visiting parks. Attending events and gatherings increases your risk of getting and spreading COVID-19. Stay home to protect yourself and others from COVID-19.

Safer Travel Ideas: CDC recommends delaying travel until you are able to get fully vaccinated. Even if you are fully vaccinated, choose safer travel options to protect yourself, your loved ones, and others from COVID-19.

Communication Resources for Travelers: CDC's public health messaging system offers up-to-date messages to travelers at specific airports, seaports, and land borders where most international travelers enter or leave the United States.

Crew Disembarkations Through Commercial Travel: CDC is committed to helping cruise lines provide for the safety and well-being of their crew members while onboard cruise ships and as they disembark. CDC is allowing crew members to disembark from all cruise ships in U.S. waters with certain precautions. Cruise lines with complete and accurate response plans are able to use commercial travel to disembark crew members from certain ships if the ships meet certain criteria set by CDC. Criteria include no confirmed cases of coronavirus disease 2019 (COVID-19) or COVID-19-like illness onboard the ship within the last 14 days. These ships are also able to lessen certain social distancing restrictions onboard. Cruise lines with complete and accurate COVID-19 response plans but not meeting the above criteria will still be able to disembark their crew members using noncommercial travel. Cruise lines must have measures in place to ensure those involved in transport are not exposed to the virus that causes COVID-19 and follow all CDC requirements to prevent interaction of disembarking crew with the public. Additionally, CDC recommends that all eligible port personnel and travelers (passengers and crew) get a COVID-19 vaccine when one is available to them.

Information for Specific Populations

DoD COVID-19 Vaccine Availability: As of yesterday, any adult in DoD can get a COVID-19 vaccine if they want one. That includes military personnel, adult dependents, retirees and civilians. To help ensure military personnel and their families stationed overseas are taken care of, the military services are getting an additional 31,500 doses of the Moderna vaccine for use at locations within the U.S. European Command. On the other side of the globe, an additional 30,000 doses of the Moderna vaccine are targeted at locations within both the U.S. Indo-Pacific Command and the U.S. Central Command. Pentagon Press Secretary Kirby said that by the end of May, over 80% of overseas personnel should have received initial doses of the COVID-19 vaccine. The Defense Department has outpaced the national average in administration of the vaccine it's received. Of the more than 3 million doses of vaccines it's received, more than 2.5 million have been administered.

DLA Prepared to Increase Overseas Vaccine Distribution: The Defense Logistics Agency (DLA) is helping military health officials prepare for a surge in COVID-19 vaccinations available to the Defense Department starting this month. The department expects to begin receiving about 390,000 doses weekly — up from an average of 155,500 a week — with DLA continuing to receive, pack, ship and track vaccines for individuals outside the continental U.S. or deployed with the Navy.

Considerations for Retirement Communities and Independent Living Facilities: CDC offers considerations for ways in which administrators of retirement communities and independent living facilities can help protect residents, workers, visitors, and communities and slow the spread of COVID-19. These considerations are for administrators of retirement communities and independent living facilities that are not healthcare facilities. Learn more about guidance for long-term care facilities (LTCFs) that offer medical services (e.g., nursing homes, skilled nursing facilities, assisted living facilities, day care programs for older adults).

Talking to Your Close Contacts if You Have COVID-19: CDC updated their information on how to talk to you close contacts if you have COVID-19. People diagnosed with COVID-19 can still spread the virus even if they don't have any symptoms. If you have COVID-19, stay home, wear a mask and socially distance in your home, and notify your close contacts.

People at Increased Risk: CDC updated their guidance for people at increased risk, and other people who need to take extra precautions. Some people are more likely than others to become severely ill. Severe illness means that a person with COVID-19 may need hospitalization, intensive care, a ventilator to help them breathe or they may even die. People at increased risk, and those who live or visit with them, need to take precautions to protect themselves from getting COVID-19.

Elections and Voting: CDC updated their guidance for election polling locations and voters. Specifically, CDC updated their information on cleaning and disinfecting. Cleaning with products containing soap or detergent reduces germs on surfaces and objects by removing contaminants and may also weaken or damage some of the virus particles, which decreases risk of infection from surfaces. Cleaning high touch surfaces and shared objects once a day is usually enough to sufficiently remove virus that may be on surfaces unless someone with confirmed or suspected COVID-19 has been in your facility. For more information on cleaning your facility regularly and cleaning your facility when someone is sick, see Cleaning and Disinfecting Your Facility.

Research

New Streamlined Approach for Serial Testing Programs: Today, the FDA took steps to further facilitate the authorization of molecular tests for screening asymptomatic individuals using pooled anterior nasal respiratory specimens in serial testing programs. The FDA issued an amendment for many molecular diagnostic COVID-19 tests that had received an emergency use authorization (EUA). If a test developer has self-certified it has validated its test for pooling, FDA will add that test to a list of tests that can be used for pooling nasal specimens as part of a serial testing program. Pooling, the process of combining multiple specimens together to more quickly test groups of people for SARS-CoV-2, can be an efficient approach for a serial testing program that tests many people on a routine basis. The flexibility that the FDA has provided developers continues to be a hallmark of our approach to the COVID-19 pandemic and we will continue to prioritize authorization for tests with the ability to increase testing accessibility or to significantly increase testing capacity. The FDA is committed to assisting our schools, workplaces, communities and other entities with establishing effective testing programs as the national response to the COVID-19 pandemic continues to evolve.

One in Ten Healthcare Workers with Mild COVID Have Lasting Symptoms: NIH Director Dr. Francis Collins comments on a recent *JAMA* study which found that just over 1 in 10 healthcare workers who had what at first seemed to be a relatively mild bout of COVID-19 were still coping with at least one moderate to severe symptom eight months later. Those symptoms—most commonly including loss of smell and taste, fatigue, and breathing problems—also negatively affected the work and/or personal lives of these individuals. Their findings show that 26 percent of those who had mild COVID-19 reported at least one moderate to severe symptom that lasted more than two months. That's compared to 9 percent of participants without COVID-19. What's more, 11 percent of the individuals with mild COVID-19 had at least one debilitating symptom that lasted for at least eight months. In the group without COVID-19, any symptoms of feeling unwell resolved relatively quickly.

Lab Publications: CDC updated their collection of lab publications. The publications cover the following topics: diagnostics, epidemiology, research, serology, and treatment.

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Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

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COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021

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Although COVID-19 mRNA vaccines demonstrated high efficacy in clinical trials (*1*), they were not 100% efficacious. Thus, some infections postvaccination are expected. Limited data are available on effectiveness in skilled nursing facilities (SNFs) and against emerging variants. The Kentucky Department for Public Health (KDPH) and a local health department investigated a COVID-19 outbreak in a SNF that occurred after all residents and health care personnel (HCP) had been offered vaccination. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received 2 vaccine doses. Twenty-six residents and 20 HCP received positive test results for SARS-CoV-2, the virus that causes COVID-19, including 18 residents and four HCP who had received their second vaccine dose >14 days before the outbreak began. An R.1 lineage variant was detected with whole genome sequencing (WGS). Although the R.1 variant has multiple spike protein mutations, vaccinated residents and HCP were 87% less likely to have symptomatic COVID-19 compared with those who were unvaccinated. Vaccination of SNF populations, including HCP, is critical to reduce the risk for SARS-CoV-2 introduction, transmission, and severe outcomes in SNFs. An ongoing focus on infection prevention and control practices is also essential.

Investigation and Epidemiologic Findings

The SNF conducted vaccination clinics using Pfizer-BioNTech mRNA vaccine on January 10, January 31, and February 21, 2021. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received two vaccine doses. All vaccinated residents and HCP were vaccinated on-site, the majority on January 10 and 31. Four residents and five HCP received their second dose during the third clinic, which was <14 days before the outbreak onset.

Before and during the outbreak, SARS-CoV-2 testing was used for evaluating symptomatic illness in residents and HCP. Symptom screening of residents and HCP had been ongoing since March 2020, and twice-weekly screening testing of all HCP had been occurring since November 2020. A COVID-19 case was defined as a positive SARS-CoV-2 antigen or reverse transcription–polymerase chain reaction (RT-PCR) test result. Possible reinfection was defined as a positive SARS-CoV-2 test result >90 days after a previous laboratory-confirmed infection.

The outbreak was identified during routine HCP antigen testing on March 1.* This was 8 days after the third vaccination clinic. The index case occurred in an unvaccinated, symptomatic HCP. Once the outbreak was identified, daily rapid point-of-care antigen testing of all residents, regardless of symptoms, was added to the twice-weekly HCP testing. Additional specimens were collected the same day for RT-PCR confirmation of positive antigen test results. One week after the outbreak was identified, resident antigen testing was reduced to three times weekly, then to twice weekly after no additional cases were identified for 1 week.

The local health department interviewed HCP and facility staff members to collect information about the cases. Vaccination status was ascertained through immunization registry review and facility interviews. COVID-19–related hospitalizations and deaths were confirmed by medical records reviews. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.†

Relative risks (RRs) were calculated comparing unvaccinated and vaccinated residents and HCP; vaccine effectiveness (VE [1–RR of vaccinated versus unvaccinated x 100]) was

* https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
† 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. 241(d); 5 U.S.C. 552a; 44 U.S.C. 3501 et seq.

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Centers for Disease Control and Prevention

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calculated for the following outcomes: SARS-CoV-2 infection, symptomatic COVID-19, hospitalization, and death. Persons who received their second vaccine dose ≥14 days before the outbreak began were considered vaccinated, consistent with CDC postvaccination guidance[§] and breakthrough case definition. Ten persons who had received at least 1 dose but had not received a second vaccine dose ≥14 days before the outbreak were excluded from analyses.

A sensitivity analysis was conducted using a 7-day threshold to classify persons as vaccinated, consistent with the Pfizer-BioNTech vaccine clinical trials (*1*). Four residents and five HCP who received their second vaccine dose 8 days before outbreak identification were classified as vaccinated in this sensitivity analysis. One HCP who received a single vaccine dose remained excluded (Supplementary Table https://stacks.cdc.gov/view/cdc/105235).

KDPH Division of Laboratory Services performed WGS (*2*). Genomes were assembled using the StaPH-B Monroe pipeline,[¶] followed by Nextclade[**] for clade assignment and mutation calling, Pangolin[††] for lineage assignment, and Nextstrain for phylogenetic analysis (*3*).

During the outbreak, 46 COVID-19 cases were identified, including cases in 26 residents (18 fully vaccinated) and 20 HCP (four vaccinated) (Figure) (Table). Two cases occurred in residents who had received their second vaccine dose within 14 days; these two cases were excluded from the primary analysis. Vaccinated residents and HCP were less likely to be infected than were unvaccinated persons. Attack rates in unvaccinated residents (75.0%) were 3 times as high as those in vaccinated residents (25.4%; RR = 3.0; 95% confidence interval [CI] = 1.7–5.2) and in unvaccinated HCP (29.6%) were 4.1 times as high as those in vaccinated HCP (7.1%; RR = 4.1; 95% CI = 1.5–11.6). The estimated VE against SARS-CoV-2 infection among residents was 66.2% (95% CI = 40.5%–80.8%) and among HCP was 75.9% (95% CI = 32.5%–91.4%).

VE against symptomatic COVID-19 was 86.5% (95% CI = 65.6%–94.7%) among residents and 87.1% (95% CI = 46.4%–96.9%) among HCP. VE against hospitalization was 94.4% (95% CI = 73.9%–98.8%) among residents; no HCP were hospitalized. Three residents died, two of whom were unvaccinated (VE = 94.4%; 95% CI = 44.6%–99.4%).

Four possible reinfections were identified (one resident and three HCP); of these, one HCP was vaccinated. All four persons experienced symptomatic illness. One resident was infected 300 days earlier and had nine consecutive negative RT-PCR tests before reinfection, including two within 30 days of the outbreak. This resident was hospitalized and died.

Laboratory and Bioinformatics Findings

WGS was performed for 28 specimens (27 persons, including one who was reinfected); all had >97% genome coverage at a depth of >30x, therefore passing required quality control matrices.[§§] Examination of phylogeny revealed 28 clustered sequences sharing 14 amino acid mutations not present in the reference Wuhan-1 genome: ORF1a:A2584T, ORF1b:P314L, ORF1b:G1362R, ORF1b:P1936H, S:E484K, S:D614G, S:G769V, S:W152L, M:F28L, N:M1X, N:S187L, N:R203K, N:G204R, and N:Q418H. This cluster aligns with the R.1 lineage, which had not previously been identified in Kentucky. Whereas the 28 sequences share spike protein mutations E484K, D614G, G769V, and W152L with the R.1 root, the mutation ORF1a:A2584T places the cluster in a separate group on the phylogenetic tree.

Public Health Response

The local health department, along with the KDPH regional epidemiologist and regional infection preventionist, provided guidance on implementation of infection prevention strategies. These included the use of transmission-based precautions and hand hygiene, ongoing testing to identify new cases, exclusion of symptomatic HCP from work, isolation and quarantine of HCP, and provision of dedicated and separate spaces for care of infected and exposed residents, regardless of vaccination status.[¶¶]

Discussion

In a SNF with 90.4% of residents vaccinated, an outbreak of COVID-19 occurred after introduction from an unvaccinated, symptomatic HCP. WGS identified an R.1 lineage variant, characterized by E484K and other mutations within the spike protein. Attack rates were three to four times as high among unvaccinated residents and HCP as among those who were vaccinated; vaccinated persons were significantly less likely to experience symptoms or require hospitalization.

Although the R.1 variant is not currently identified as a CDC variant of concern or interest,[***] it does have several mutations of importance. The D614G mutation demonstrates evidence

[§] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html
[¶] https://staph-b.github.io/staphb_toolkit/workflow_docs/monroe/
[**] https://clades.nextstrain.org/
[††] https://github.com/cov-lineages/pangolin

[§§] Percentage of coverage and depth of coverage are metrics computed during genome assembly that correspond with data quality. The data quality threshold used by the Association of Public Health Laboratories is ≥90% and 10X depth for Illumina sequencing technology. https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARS-CoV-2-Sequencing.pdf
[¶¶] https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html
[***] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

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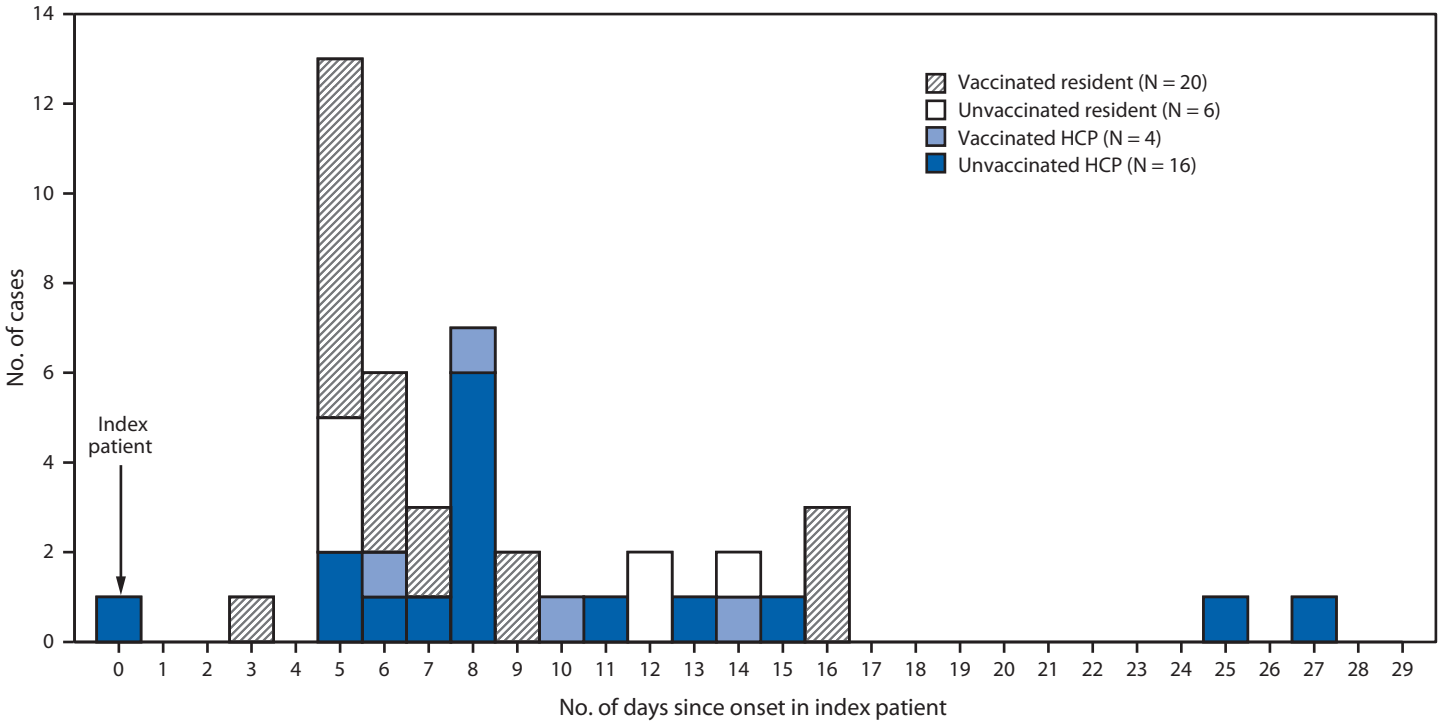
FIGURE. SARS-CoV-2 illness onset* among residents and health care personnel (HCP) in a skilled nursing facility, relative to onset in the index patient, by vaccination status† — Kentucky, March 2021



* Symptom onset date or specimen collection date, if asymptomatic.
† Persons who received 2 doses of Pfizer-BioNTech vaccine are indicated as vaccinated; unvaccinated persons received no vaccine doses. Persons who received a second dose of vaccine <14 days before outbreak onset (four residents and five HCP) and those who received only a single dose of vaccine (one HCP) were excluded from the primary analysis; this resulted in exclusion of two cases that occurred in residents.

of increasing virus transmissibility (*4*). The E484K mutation, found within the receptor-binding domain of the spike protein, is also seen in the variants of concern B.1.351 and P.1, which show evidence of reduced neutralization by convalescent and postvaccination sera (*5*,*6*). Mutation W152L might reduce the effectiveness of neutralizing antibodies (*7*). Although vaccination was associated with decreased likelihood of infection and symptomatic illness, 25.4% of vaccinated residents and 7.1% of vaccinated HCP were infected, supporting concerns about potential reduced protective immunity to R.1. In addition, four possible reinfections were identified, providing some evidence of limited or waning natural immunity to this variant.

Point estimates for VE against SARS-CoV-2 infections were lower than were those reported from Israel's national vaccination program (*8*). Whereas this could reflect reduced protection against R.1, other factors to consider include the smaller sample size in this study and the higher exposure risk associated with an outbreak in a congregate setting. In addition, testing, regardless of symptoms, was performed with high frequency for both residents and HCP, which contrasts with VE studies that use a primary reliance on individual test-seeking behavior. Such differences could influence VE estimates for infection; therefore, caution is urged when comparing these studies. Regardless of VE differences in SARS-CoV-2 infection, the estimated VE for COVID-19 symptom prevention (86.5% for residents; 87.1% for HCP) demonstrates a strong protective effect of vaccination.

The risk for poor outcomes among unvaccinated SNF residents is highlighted by the hospitalization of four of the six unvaccinated, infected residents, and two subsequent deaths, including in one previously infected resident. This underscores the importance of the Advisory Committee on Immunization Practices' recommendation that all persons, including those who have recovered from COVID-19, be vaccinated.†††

Low acceptance of vaccination among SNF HCP might increase the likelihood of SARS-CoV-2 introduction and transmission within a facility. Nationally, a median of 37.5% of HCP working in long-term care facilities had received at least 1 dose of vaccine by mid-January 2021 (*9*). Although the vaccination rate in this SNF surpassed this early national rate, approximately one half of HCP were vaccinated. To protect

††† https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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TABLE. Relative risk and estimated vaccine effectiveness for prevention of SARS-CoV-2 infection, symptomatic COVID-19, hospitalization, and death for fully vaccinated persons compared with unvaccinated persons during a COVID-19 outbreak in a skilled nursing facility (SNF) — Kentucky, 2021

Population and outcome	No. (% attack rate)		Unvaccinated versus vaccinated RR (95% CI)	Vaccine effectiveness[§] (95% CI)
	Vaccinated*	Unvaccinated†		
Total SNF population[¶]	**(n = 127)**	**(n = 62)**	—	—
SARS-CoV-2 infection	22 (17.3)	22 (35.5)	—	—
Symptomatic	8 (6.3)	20 (32.3)	—	—
Hospitalization	2 (1.6)	4 (6.5)	—	—
Death	1 (0.8)	2 (3.2)	—	—
Residents	**(n = 71)**	**(n = 8)**	—	—
SARS-CoV-2 infection	18 (25.4)	6 (75.0)	3.0 (1.7–5.2)	66.2 (40.5–80.8)
Symptomatic	6 (8.5)	5 (62.5)	7.4 (2.9–18.8)	86.5 (65.6–94.7)
Hospitalization	2 (2.8)	4 (50.0)	17.8 (3.8–82.1)	94.4 (73.9–98.8)
Death	1 (1.4)	2 (25.0)	17.8 (1.8–174.7)	94.4 (44.6–99.4)
Health care personnel	**(n = 56)**	**(n = 54)**	—	—
SARS-CoV-2 infection	4 (7.1)	16 (29.6)	4.1 (1.5–11.6)	75.9 (32.5–91.4)
Symptomatic	2 (3.6)	15 (27.8)	7.8 (1.9–32.4)	87.1 (46.4–96.9)
Hospitalization	0 (—)	0 (—)	—	—
Death	0 (—)	0 (—)	—	—

Abbreviations: CI = confidence interval; RR = relative risk.

* Receipt of 2 doses of Pfizer-BioNTech vaccine ≥14 days before identification of the SNF outbreak; persons who received a second dose of vaccine <14 days before the outbreak (four residents and five health care personnel) and those who received a single dose of vaccine (one health care worker) were excluded, which resulted in exclusion of two resident cases.

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¶ Includes residents and health care personnel.

SNF residents, it is imperative that HCP, as well as SNF residents, be vaccinated. A continued emphasis on strategies for prevention of disease transmission, even among vaccinated populations, is also critical. Timely implementation of infection control strategies after outbreak identification likely contributed to the rapid decline in new cases during the second week of the outbreak.

The findings in this report are subject to at least three limitations. First, the health status of residents who declined vaccination might have differed from those who consented to vaccination. Thus, hospitalization and death outcomes might be biased when comparing the groups without controlling for underlying health conditions. Second, underlying health status and advance directives might affect decisions for resident hospitalization; therefore, association of vaccination with hospitalization in this SNF population might have limited generalizability. Finally, because of the reduced sensitivity of antigen testing in asymptomatic populations,[§§§] it is possible that some asymptomatic cases were not identified. If this introduced differential bias for identification of cases in either the vaccinated or unvaccinated groups, actual VE for the prevention of SARS-CoV-2 infections could differ from measured effectiveness.

[§§§] https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Summary

What is already known about this topic?

COVID-19 vaccines have demonstrated high efficacy in clinical trials. Limited data are available on effectiveness in skilled nursing facilities (SNFs) and against emerging variants.

What is added by this report?

In a COVID-19 outbreak at a Kentucky SNF involving a newly introduced variant to the region, unvaccinated residents and health care personnel (HCP) had 3.0 and 4.1 times the risk of infection as did vaccinated residents and HCP. Vaccine was 86.5% protective against symptomatic illness among residents and 87.1% protective among HCP.

What are the implications for public health practice?

Vaccination of SNF residents and HCP is essential to reduce the risk for symptomatic COVID-19, as is continued focus on infection prevention and control practices.

An R.1 lineage variant, not previously detected in Kentucky, was identified in a SNF outbreak where 46 residents and HCP were infected. Compared with unvaccinated persons, vaccinated persons had reduced risk for SARS-CoV-2 infection and symptomatic COVID-19. A continued emphasis on vaccination of SNF populations, including HCP, is essential to reduce the risk for SARS-CoV-2 introduction, transmission, and severe outcomes in SNFs. An ongoing focus on infection prevention and control practices is also critical.

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Acknowledgments

Patients and health care personnel described in this report; local public health partners; Suzanne Beavers, CDC.

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COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021

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Although COVID-19 mRNA vaccines demonstrated high efficacy in clinical trials (*1*), they were not 100% efficacious. Thus, some infections postvaccination are expected. Limited data are available on effectiveness in skilled nursing facilities (SNFs) and against emerging variants. The Kentucky Department for Public Health (KDPH) and a local health department investigated a COVID-19 outbreak in a SNF that occurred after all residents and health care personnel (HCP) had been offered vaccination. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received 2 vaccine doses. Twenty-six residents and 20 HCP received positive test results for SARS-CoV-2, the virus that causes COVID-19, including 18 residents and four HCP who had received their second vaccine dose >14 days before the outbreak began. An R.1 lineage variant was detected with whole genome sequencing (WGS). Although the R.1 variant has multiple spike protein mutations, vaccinated residents and HCP were 87% less likely to have symptomatic COVID-19 compared with those who were unvaccinated. Vaccination of SNF populations, including HCP, is critical to reduce the risk for SARS-CoV-2 introduction, transmission, and severe outcomes in SNFs. An ongoing focus on infection prevention and control practices is also essential.

Investigation and Epidemiologic Findings

The SNF conducted vaccination clinics using Pfizer-BioNTech mRNA vaccine on January 10, January 31, and February 21, 2021. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received two vaccine doses. All vaccinated residents and HCP were vaccinated on-site, the majority on January 10 and 31. Four residents and five HCP received their second dose during the third clinic, which was <14 days before the outbreak onset.

Before and during the outbreak, SARS-CoV-2 testing was used for evaluating symptomatic illness in residents and HCP. Symptom screening of residents and HCP had been ongoing since March 2020, and twice-weekly screening testing of all HCP had been occurring since November 2020. A COVID-19 case was defined as a positive SARS-CoV-2 antigen or reverse transcription–polymerase chain reaction (RT-PCR) test result. Possible reinfection was defined as a positive SARS-CoV-2 test result >90 days after a previous laboratory-confirmed infection.

The outbreak was identified during routine HCP antigen testing on March 1.* This was 8 days after the third vaccination clinic. The index case occurred in an unvaccinated, symptomatic HCP. Once the outbreak was identified, daily rapid point-of-care antigen testing of all residents, regardless of symptoms, was added to the twice-weekly HCP testing. Additional specimens were collected the same day for RT-PCR confirmation of positive antigen test results. One week after the outbreak was identified, resident antigen testing was reduced to three times weekly, then to twice weekly after no additional cases were identified for 1 week.

The local health department interviewed HCP and facility staff members to collect information about the cases. Vaccination status was ascertained through immunization registry review and facility interviews. COVID-19–related hospitalizations and deaths were confirmed by medical records reviews. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.†

Relative risks (RRs) were calculated comparing unvaccinated and vaccinated residents and HCP; vaccine effectiveness (VE [1–RR of vaccinated versus unvaccinated x 100]) was

* https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
† 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. 241(d); 5 U.S.C. 552a; 44 U.S.C. 3501 et seq.

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calculated for the following outcomes: SARS-CoV-2 infection, symptomatic COVID-19, hospitalization, and death. Persons who received their second vaccine dose ≥14 days before the outbreak began were considered vaccinated, consistent with CDC postvaccination guidance[§] and breakthrough case definition. Ten persons who had received at least 1 dose but had not received a second vaccine dose ≥14 days before the outbreak were excluded from analyses.

A sensitivity analysis was conducted using a 7-day threshold to classify persons as vaccinated, consistent with the Pfizer-BioNTech vaccine clinical trials (*1*). Four residents and five HCP who received their second vaccine dose 8 days before outbreak identification were classified as vaccinated in this sensitivity analysis. One HCP who received a single vaccine dose remained excluded (Supplementary Table https://stacks.cdc.gov/view/cdc/105235).

KDPH Division of Laboratory Services performed WGS (*2*). Genomes were assembled using the StaPH-B Monroe pipeline,[¶] followed by Nextclade[**] for clade assignment and mutation calling, Pangolin[††] for lineage assignment, and Nextstrain for phylogenetic analysis (*3*).

During the outbreak, 46 COVID-19 cases were identified, including cases in 26 residents (18 fully vaccinated) and 20 HCP (four vaccinated) (Figure) (Table). Two cases occurred in residents who had received their second vaccine dose within 14 days; these two cases were excluded from the primary analysis. Vaccinated residents and HCP were less likely to be infected than were unvaccinated persons. Attack rates in unvaccinated residents (75.0%) were 3 times as high as those in vaccinated residents (25.4%; RR = 3.0; 95% confidence interval [CI] = 1.7–5.2) and in unvaccinated HCP (29.6%) were 4.1 times as high as those in vaccinated HCP (7.1%; RR = 4.1; 95% CI = 1.5–11.6). The estimated VE against SARS-CoV-2 infection among residents was 66.2% (95% CI = 40.5%–80.8%) and among HCP was 75.9% (95% CI = 32.5%–91.4%).

VE against symptomatic COVID-19 was 86.5% (95% CI = 65.6%–94.7%) among residents and 87.1% (95% CI = 46.4%–96.9%) among HCP. VE against hospitalization was 94.4% (95% CI = 73.9%–98.8%) among residents; no HCP were hospitalized. Three residents died, two of whom were unvaccinated (VE = 94.4%; 95% CI = 44.6%–99.4%).

Four possible reinfections were identified (one resident and three HCP); of these, one HCP was vaccinated. All four persons experienced symptomatic illness. One resident was infected 300 days earlier and had nine consecutive negative RT-PCR tests before reinfection, including two within 30 days of the outbreak. This resident was hospitalized and died.

Laboratory and Bioinformatics Findings

WGS was performed for 28 specimens (27 persons, including one who was reinfected); all had >97% genome coverage at a depth of >30x, therefore passing required quality control matrices.[§§] Examination of phylogeny revealed 28 clustered sequences sharing 14 amino acid mutations not present in the reference Wuhan-1 genome: ORF1a:A2584T, ORF1b:P314L, ORF1b:G1362R, ORF1b:P1936H, S:E484K, S:D614G, S:G769V, S:W152L, M:F28L, N:M1X, N:S187L, N:R203K, N:G204R, and N:Q418H. This cluster aligns with the R.1 lineage, which had not previously been identified in Kentucky. Whereas the 28 sequences share spike protein mutations E484K, D614G, G769V, and W152L with the R.1 root, the mutation ORF1a:A2584T places the cluster in a separate group on the phylogenetic tree.

Public Health Response

The local health department, along with the KDPH regional epidemiologist and regional infection preventionist, provided guidance on implementation of infection prevention strategies. These included the use of transmission-based precautions and hand hygiene, ongoing testing to identify new cases, exclusion of symptomatic HCP from work, isolation and quarantine of HCP, and provision of dedicated and separate spaces for care of infected and exposed residents, regardless of vaccination status.[¶¶]

Discussion

In a SNF with 90.4% of residents vaccinated, an outbreak of COVID-19 occurred after introduction from an unvaccinated, symptomatic HCP. WGS identified an R.1 lineage variant, characterized by E484K and other mutations within the spike protein. Attack rates were three to four times as high among unvaccinated residents and HCP as among those who were vaccinated; vaccinated persons were significantly less likely to experience symptoms or require hospitalization.

Although the R.1 variant is not currently identified as a CDC variant of concern or interest,[***] it does have several mutations of importance. The D614G mutation demonstrates evidence

[§] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html
[¶] https://staph-b.github.io/staphb_toolkit/workflow_docs/monroe/
[**] https://clades.nextstrain.org/
[††] https://github.com/cov-lineages/pangolin

[§§] Percentage of coverage and depth of coverage are metrics computed during genome assembly that correspond with data quality. The data quality threshold used by the Association of Public Health Laboratories is ≥90% and 10X depth for Illumina sequencing technology. https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARS-CoV-2-Sequencing.pdf
[¶¶] https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html
[***] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

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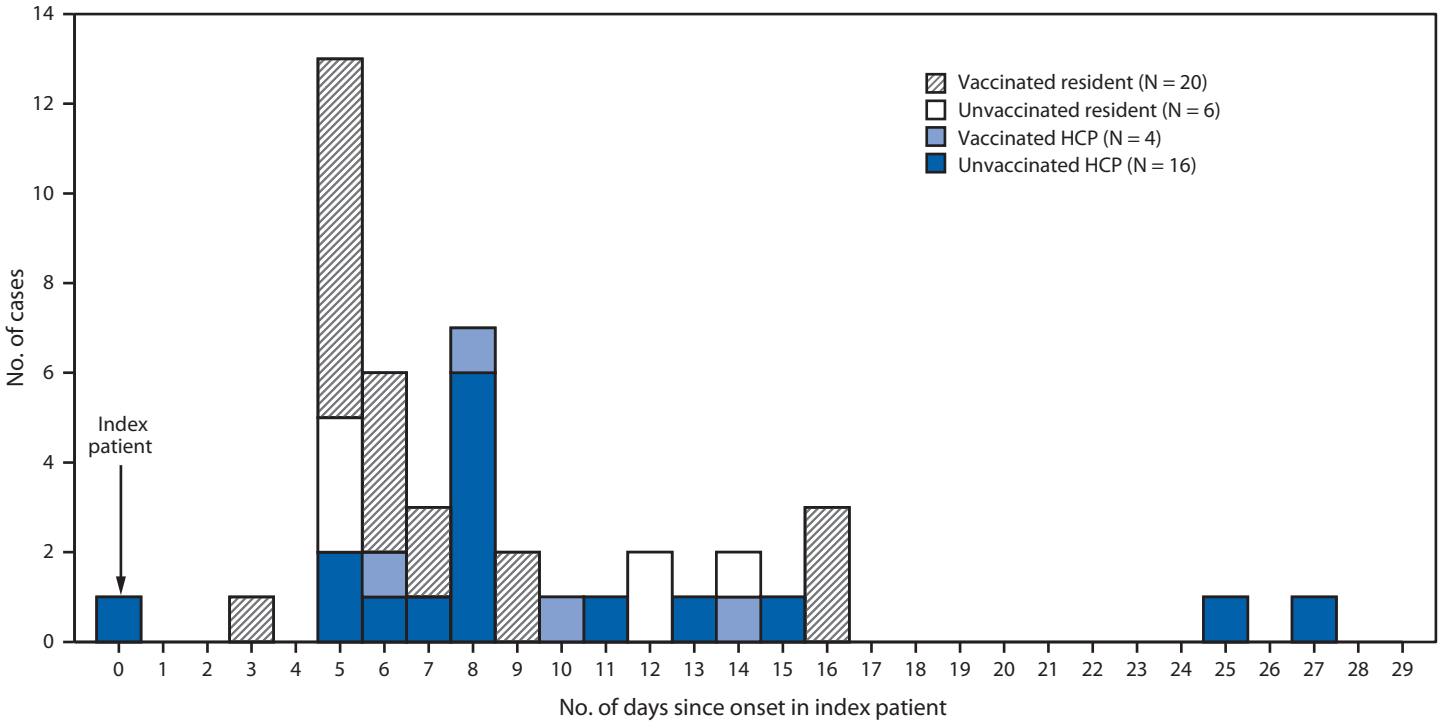
FIGURE. SARS-CoV-2 illness onset* among residents and health care personnel (HCP) in a skilled nursing facility, relative to onset in the index patient, by vaccination status† — Kentucky, March 2021



* Symptom onset date or specimen collection date, if asymptomatic.
† Persons who received 2 doses of Pfizer-BioNTech vaccine are indicated as vaccinated; unvaccinated persons received no vaccine doses. Persons who received a second dose of vaccine <14 days before outbreak onset (four residents and five HCP) and those who received only a single dose of vaccine (one HCP) were excluded from the primary analysis; this resulted in exclusion of two cases that occurred in residents.

of increasing virus transmissibility (*4*). The E484K mutation, found within the receptor-binding domain of the spike protein, is also seen in the variants of concern B.1.351 and P.1, which show evidence of reduced neutralization by convalescent and postvaccination sera (*5*,*6*). Mutation W152L might reduce the effectiveness of neutralizing antibodies (*7*). Although vaccination was associated with decreased likelihood of infection and symptomatic illness, 25.4% of vaccinated residents and 7.1% of vaccinated HCP were infected, supporting concerns about potential reduced protective immunity to R.1. In addition, four possible reinfections were identified, providing some evidence of limited or waning natural immunity to this variant.

Point estimates for VE against SARS-CoV-2 infections were lower than were those reported from Israel's national vaccination program (*8*). Whereas this could reflect reduced protection against R.1, other factors to consider include the smaller sample size in this study and the higher exposure risk associated with an outbreak in a congregate setting. In addition, testing, regardless of symptoms, was performed with high frequency for both residents and HCP, which contrasts with VE studies that use a primary reliance on individual test-seeking behavior. Such differences could influence VE estimates for infection; therefore, caution is urged when comparing these studies. Regardless of VE differences in SARS-CoV-2 infection, the estimated VE for COVID-19 symptom prevention (86.5% for residents; 87.1% for HCP) demonstrates a strong protective effect of vaccination.

The risk for poor outcomes among unvaccinated SNF residents is highlighted by the hospitalization of four of the six unvaccinated, infected residents, and two subsequent deaths, including in one previously infected resident. This underscores the importance of the Advisory Committee on Immunization Practices' recommendation that all persons, including those who have recovered from COVID-19, be vaccinated.†††

Low acceptance of vaccination among SNF HCP might increase the likelihood of SARS-CoV-2 introduction and transmission within a facility. Nationally, a median of 37.5% of HCP working in long-term care facilities had received at least 1 dose of vaccine by mid-January 2021 (*9*). Although the vaccination rate in this SNF surpassed this early national rate, approximately one half of HCP were vaccinated. To protect

††† https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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TABLE. Relative risk and estimated vaccine effectiveness for prevention of SARS-CoV-2 infection, symptomatic COVID-19, hospitalization, and death for fully vaccinated persons compared with unvaccinated persons during a COVID-19 outbreak in a skilled nursing facility (SNF) — Kentucky, 2021

Population and outcome	No. (% attack rate)		Unvaccinated versus vaccinated RR (95% CI)	Vaccine effectiveness[§] (95% CI)
	Vaccinated*	Unvaccinated†		
Total SNF population[¶]	**(n = 127)**	**(n = 62)**	—	—
SARS-CoV-2 infection	22 (17.3)	22 (35.5)	—	—
Symptomatic	8 (6.3)	20 (32.3)	—	—
Hospitalization	2 (1.6)	4 (6.5)	—	—
Death	1 (0.8)	2 (3.2)	—	—
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Abbreviations: CI = confidence interval; RR = relative risk.

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[§§§] https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

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Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021

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Early studies suggest that COVID-19 vaccines protect against severe illness (*1*); however, postvaccination SARS-CoV-2 infections (i.e., breakthrough infections) can occur because COVID-19 vaccines do not offer 100% protection (*2*,*3*). Data evaluating the occurrence of breakthrough infections and impact of vaccination in decreasing transmission in congregate settings are limited. Skilled nursing facility (SNF) residents and staff members have been disproportionately affected by SARS-CoV-2, the virus that causes COVID-19 (*4*,*5*), and were prioritized for COVID-19 vaccination (*6*,*7*). Starting December 28, 2020, all 78 Chicago-based SNFs began COVID-19 vaccination clinics over several weeks through the federal Pharmacy Partnership for Long-Term Care Program (PPP).† In February 2021, through routine screening, the Chicago Department of Public Health (CDPH) identified a SARS-CoV-2 infection in a SNF resident >14 days after receipt of the second dose of a two-dose COVID-19 vaccination series. SARS-CoV-2 cases, vaccination status, and possible vaccine breakthrough infections were identified by matching facility reports with state case and vaccination registries. Among 627 persons with SARS-CoV-2 infection across 75 SNFs since vaccination clinics began, 22 SARS-CoV-2 infections were identified among 12 residents and 10 staff members across 15 facilities ≥14 days after receiving their second vaccine dose (i.e., breakthrough infections in fully vaccinated persons). Nearly two thirds (14 of 22; 64%) of persons with breakthrough infections were asymptomatic; two residents were hospitalized because of COVID-19, and one died. No facility-associated secondary transmission occurred. Although few SARS-CoV-2 infections in fully vaccinated persons were observed, these cases demonstrate the need for SNFs to follow recommended routine infection prevention and control practices and promote high vaccination coverage among SNF residents and staff members.

CDPH monitors SNF SARS-CoV-2 infections using a data triangulation method that matches the SARS-CoV-2 test results from nucleic acid amplification tests (NAATs, such as reverse transcription–polymerase chain reaction [RT-PCR]) and antigen tests reported to the Illinois' National Electronic Disease Surveillance System with facility-reported line lists of SARS-CoV-2 test results from routine screening testing.§ In February 2021, CDPH began matching records to Illinois' Comprehensive Automated Immunization Registry Exchange to identify breakthrough infections. After identifying SARS-CoV-2 infection in a SNF resident 16 days after receipt of a second vaccine dose, CDPH initiated an investigation to quantify breakthrough infections across all facilities, evaluate symptoms and clinical outcomes, and assess potential secondary transmission. Vaccine effectiveness was not evaluated.

* These authors contributed equally to this report.

† A public-private partnership among CDC; CVS Pharmacy; Managed Health Care Associates, Inc.; and Walgreens to provide on-site COVID-19 vaccination of residents and staff members at enrolled long-term care facilities, including SNFs. https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html

§ CDPH advises facilities to routinely test residents at least monthly. Staff members were also required to receive testing routinely, with frequency determined based on community positivity rate and other metrics of interest. Staff members at all Chicago-based SNFs were tested at least twice weekly (until February 4, 2021), then weekly (during February 4–March 18, 2021), then biweekly (from March 18, 2021 through the end of investigation period). In response to a facility outbreak (i.e., a resident or staff member with a case within the past 14 days), all staff members and residents (excluding those who received a positive SARS-CoV-2 test <90 days previously) are required to receive testing at least every 3–7 days until no new cases occur for at least 14 days. At the time a breakthrough infection was identified, frequency of resident testing at the 15 SNFs ranged from monthly to twice per week; frequency of staff member testing ranged from weekly to twice weekly.

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Summary

What is already known about this topic?

Residents and staff members of skilled nursing facilities (SNFs) are recommended to receive COVID-19 vaccine as a priority group.

What is added by this report?

Twenty-two possible breakthrough SARS-CoV-2 infections occurred among fully vaccinated persons ≥14 days after their second dose of COVID-19 vaccine. Two thirds of persons were asymptomatic. A minority of persons with breakthrough infection experienced mild to moderate COVID-19–like symptoms; two COVID-19–related hospitalizations and one death occurred. No facility-associated secondary transmission was identified.

What are the implications for public health practice?

SNFs should prioritize vaccination and follow recommended COVID-19 infection prevention and control practices, including following work restrictions, isolation, quarantine, testing of residents and staff members, and use of personal protective equipment.

A facility's investigation period started on its first vaccination clinic date and ended March 31, 2021.[¶] A confirmed case of SARS-CoV-2 infection was defined as a positive SARS-CoV-2 NAAT or antigen test result from a respiratory specimen collected from a resident or staff member during the investigation period. Consistent with CDC guidance, a vaccine breakthrough infection in a resident or staff member was defined as a receipt of a positive SARS-CoV-2 NAAT or antigen test result from a respiratory specimen collected ≥14 days after completing the two-dose COVID-19 vaccination series.[**] Infection prevention specialists conducted case investigations to assess symptoms, clinical outcomes, and close contact information.

SARS-CoV-2 incidence during the investigation period was assessed across four groups based on vaccination status at the time a positive respiratory specimen was collected: 1) unvaccinated (never received a COVID-19 vaccine dose); 2) partially vaccinated (received one dose of a two-dose series); 3) vaccinated but not immune (received two doses of a two-dose series but <14 days had elapsed since the second dose); and 4) fully vaccinated (received two doses of a two-dose series and ≥14 days had elapsed since the second dose). In addition to routine facility follow-up, CDPH actively monitored facilities with breakthrough infections for 28 days to identify whether any new cases occurred in close contacts of the person with breakthrough infection.[††] Analyses were completed using SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[§§]

During the investigation period, an estimated 7,931 SNF residents and 6,834 staff members received two doses of COVID-19 vaccine. A total of 627 confirmed SARS-CoV-2 infections were identified across 75 of the 78 Chicago-based SNFs, including 353 (56%) among residents and 274 (44%) among staff members during the investigation period (Table 1). Three facilities had no confirmed SARS-CoV-2 infections after their first vaccination clinic. Approximately one half (47%) of resident cases occurred in men, 42% were in non-Hispanic Black persons, and the median age was 71 years. More than two thirds (72%) of staff member cases were in women, 38% were in non-Hispanic Black persons, and the median age was 42 years. Among the 627 cases, 447 (71%) occurred in unvaccinated persons, 145 (23%) in partially vaccinated persons, 13 (2%) in vaccinated but not immune persons, and 22 (4%) in fully vaccinated persons (Figure). These breakthrough infections occurred in 12 residents and 10 staff members and accounted for 16% (22 of 136) of SNF-associated cases occurring across all facilities ≥14 days after the second vaccination clinic at the respective facilities. No demographic or clinical differences were observed by vaccination status.

Among the 22 breakthrough infections, 18 (82%) were detected in persons who received testing as part of routine screening, and four (18%) occurred in residents who received testing before a hospital admission or procedure. Among the 18 breakthrough infections identified during routine screening, 14 were detected (across 10 facilities) while residents were receiving weekly testing from the facilities; staff members at all facilities were receiving testing at least weekly. The median interval from second dose to collection of a positive SARS-CoV-2 specimen was 29 days (interquartile range [IQR] = 23–42 days). The median interval between most recent positive NAAT result and last known negative test result was 7 days (IQR = 7–14 days).

[¶] First round vaccination clinics occurred during December 28, 2020–January 18, 2021. Persons were included in the study if infection occurred between the first clinic date at their respective facility and March 31, 2021. Moderna COVID-19 vaccination was exclusively administered at Chicago-based SNFs through the federal PPP. Six residents and two staff members received Pfizer-BioNTech COVID-19 vaccine through Chicago-based vaccine providers not participating in the federal PPP or facilities outside the city of Chicago.

[**] CDC breakthrough infection guidance: https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html. Residents and staff members were excluded from the investigation if they had received 1) a positive SARS-CoV-2 test result from December 28 through the date of their facility's first vaccination clinic or 2) a known initial positive SARS-CoV-2 test result <90 days before their most recent SARS-CoV-2 test result.

[††] For residents, close contact was defined as being within 6 ft of a person for ≥15 minutes over a 24-hour period, regardless of personal protective equipment used. For staff members, close contact was defined as being within 6 ft of a person for ≥15 minutes over a 24-hour period when one or both persons were unmasked.

[§§] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect.552a; 44 U.S.C. Sect.3501 et seq.

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TABLE 1. Number and percentage of skilled nursing facility residents and staff members with a positive confirmed SARS-CoV-2 test result, by demographic and clinical characteristics and vaccination status — Chicago, Illinois, December 2020–March 2021

Characteristic	Vaccination status of residents and staff members with SARS-CoV-2 infections, no. (column %)				
	Total (n = 627)	Unvaccinated* (n = 447)	Partially vaccinated* (n = 145)	Vaccinated but not immune* (n = 13)	Fully vaccinated with breakthrough infection* (n = 22)
Median age (IQR)	60.0 (43.0–73.0)	57.0 (39.0–71.0)	65.0 (50.0–79.0)	66.0 (58.0–79.0)	61.5 (41.0–73.0)
Sex					
Female	376 (60.0)	265 (59.3)	89 (61.4)	7 (53.9)	15 (68.2)
Male	237 (37.8)	168 (37.6)	56 (38.6)	6 (46.2)	7 (31.8)
Unknown	14 (2.2)	14 (3.1)	0 (—)	0 (—)	0 (—)
Race/Ethnicity					
Hispanic/Latino	58 (9.3)	37 (8.3)	16 (11.0)	1 (7.7)	4 (18.2)
Asian, non-Hispanic	24 (3.8)	11 (2.5)	9 (6.2)	1 (7.7)	3 (13.6)
Black, non-Hispanic	252 (40.2)	193 (43.2)	44 (30.3)	7 (53.9)	8 (36.4)
White, non-Hispanic	144 (23.0)	79 (17.7)	55 (37.9)	3 (23.1)	7 (31.8)
Other,† non-Hispanic	16 (2.6)	12 (2.7)	4 (2.8)	0 (—)	0 (—)
Unknown	133 (21.2)	115 (25.7)	17 (11.7)	1 (7.7)	0 (—)
Role					
Resident	353 (56.3)	235 (52.6)	97 (66.9)	9 (69.2)	12 (54.6)
Staff member	274 (43.7)	212 (47.4)	48 (33.1)	4 (30.8)	10 (45.5)
Symptoms§					
Yes	92 (14.7)	62 (13.9)	21 (14.5)	1 (7.7)	8 (36.4)
No	34 (5.4)	15 (3.4)	5 (3.5)	0 (—)	14 (63.6)
Unknown	501 (79.9)	370 (82.8)	119 (82.1)	12 (92.3)	0 (—)
Hospitalizations					
Yes	123 (19.6)	90 (20.1)	27 (18.6)	2 (15.4)	4 (18.2)¶
No	504 (80.4)	357 (79.9)	118 (81.4)	11 (84.6)	18 (81.8)
Deaths					
Yes	21 (3.4)	14 (3.1)	6 (4.1)	0 (—)	1 (4.6)
No	606 (96.7)	433 (96.9)	139 (95.9)	13 (100.0)	21 (95.5)
Previous positive SARS-CoV-2 result					
Yes	41 (6.5)	22 (4.9)	9 (6.2)	4 (30.8)	6 (27.3)
No	586 (93.5)	425 (95.1)	136 (93.8)	9 (69.2)	16 (72.7)

Abbreviations: I-NEDSS = Illinois' National Electronic Disease Surveillance System; IQR = interquartile range.

* Unvaccinated: received no COVID-19 vaccine doses; partially vaccinated: received one dose; vaccinated but not immune: received two doses but <14 days had elapsed since receipt of second dose; and fully vaccinated with breakthrough infection: received two doses and then received a positive SARS-CoV-2 test result ≥14 days after receipt of the second dose.

† Persons with the following races listed in I-NEDSS as American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, other, or multiracial were categorized as non-Hispanic other.

§ Data on symptoms were extracted from I-NEDSS for unvaccinated, partially vaccinated, and vaccinated but not immune persons. Most COVID-19 case reports are entered into I-NEDSS through electronic laboratory reporting and provide minimal information (e.g., name, date of birth, and laboratory test and results) needed to meet reporting requirements. Data on symptoms in persons with breakthrough infections were supplemented with details from case investigations, which were not completed for nonbreakthrough cases. Symptom status for many persons with nonbreakthrough infection cases is unknown.

¶ Two residents were hospitalized for COVID-19–related reasons. Two additional residents were hospitalized for non-COVID-19–related reasons.

Two-dose vaccination coverage among residents and staff members at facilities with breakthrough infections ranged from 62% to 96% and 18% to 85%, respectively. Among the 15 facilities with breakthrough cases, attack rates[¶¶] for unvaccinated and vaccinated residents were 15% (89 of 604) and 0.8% (15 of 1,781), respectively. Among staff members, attack rates for unvaccinated and vaccinated persons were 6% (62 of 992) and 1% (12 of 1,135), respectively. Eleven facilities reported a total of 41 confirmed cases within 28 days after initial breakthrough infection at a facility (Table 2).[***] No facility-associated secondary transmission was determined to have occurred because the new cases that occurred after the initial breakthrough infection were not close contacts of the persons with breakthrough infections.

[¶¶] To calculate attack rates, residents and staff members who had never received COVID-19 vaccine (i.e., unvaccinated persons) and those who had received one COVID-19 vaccine dose of a two-dose series (i.e., partially vaccinated persons) were categorized as unvaccinated. Residents and staff members who had received two COVID-19 vaccine doses of a two-dose series and <14 days or ≥14 days had elapsed (i.e., vaccinated but not immune and fully vaccinated persons, respectively) were categorized as vaccinated. Aggregate vaccination data were only available for residents and staff members who received two doses of COVID-19 vaccine and did not have a SARS-CoV-2 infection. In the denominator, differentiation between persons who received two doses <14 days or ≥14 days was not possible.

[***] Cases identified within a 28-day monitoring window from the date of specimen collection for the breakthrough infection. For facilities with multiple breakthrough infections, 28-day monitoring windows might overlap, and new facility cases might be listed multiple times. As of April 12, 2021, nine of the 41 cases were breakthrough infections; seven of which are listed (see Table 2) and occurred during the investigation period.

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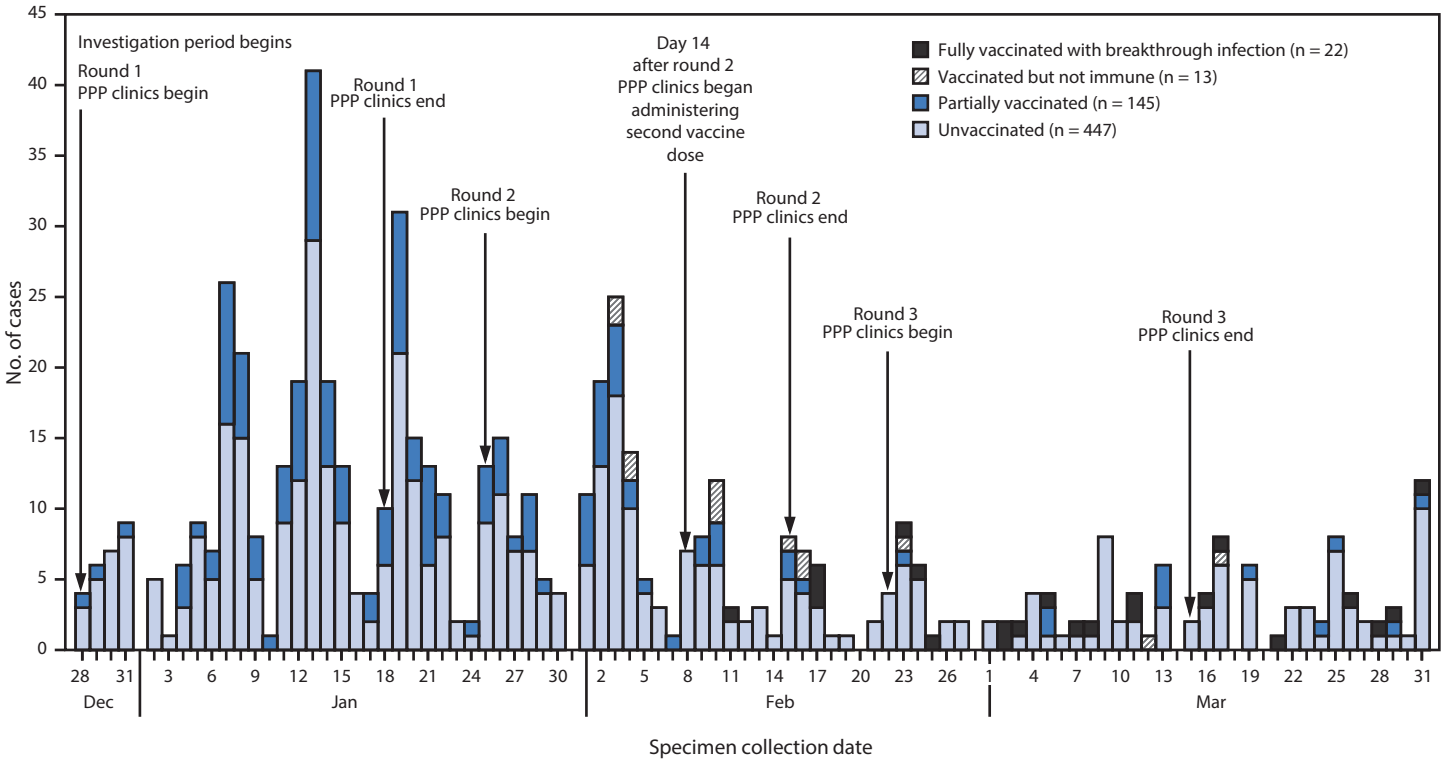
FIGURE. Confirmed SARS-CoV-2 infections (n = 627) among residents and staff members at 75* skilled nursing facilities, by specimen collection date and vaccination status† — Chicago, Illinois, December 2020–March 2021



Abbreviation: PPP = Federal Pharmacy Partnership for Long-Term Care Program.

* Among 78 Chicago-based facilities. Three facilities had no confirmed SARS-CoV-2 infections.

† Unvaccinated: received no COVID-19 vaccine doses; partially vaccinated: received one dose; vaccinated but not immune: received two doses but <14 days had elapsed since receipt of second dose; fully vaccinated with breakthrough infection: received two doses and then received a positive SARS-CoV-2 test result ≥14 days after receipt of the second dose.

Among the 22 persons with breakthrough infections, 14 (64%; eight residents and six staff members) were asymptomatic (Table 2). Three symptomatic persons (B3, E10, and G13) had mild, nonspecific symptoms; two (E8 and G12) had mild, specific symptoms; and three (A1, D6, and O22) had diagnosed pneumonia.††† Four residents were hospitalized: two (D6 and O22) for COVID-19–related reasons and two (A1 and D5) for reasons unrelated to COVID-19; one resident (O22) died.

Resident A1 received a diagnosis of pneumonia 9 days after receiving the second COVID-19 vaccine dose and 7 days before receiving a positive SARS-CoV-2 test result (Table 2). Although the timing of the patient's positive SARS-CoV-2 test result met the definition of a breakthrough infection, the clinical history indicated that the infection likely occurred <14 days after the second dose. Resident D6 was hospitalized for weakness and loss of appetite in association with pneumonia. Resident O22 experienced fatigue and respiratory symptoms and received a diagnosis of pneumonia. This patient had a positive SARS-CoV-2 test result on hospital admission and had concomitant group B β-hemolytic streptococcal bacteremia and a *Pseudomonas* urinary tract infection and died 7 days after hospital admission. The death certificate listed complications of COVID-19 infection as primary cause of death; underlying conditions were hypertension, diabetes mellitus, and chronic kidney disease.

Among 12 available specimens from seven patients with breakthrough infections, RT-PCR cycle threshold values were >28, indicating low levels of detectable virus. Six persons with breakthrough infections had a previous positive SARS-CoV-2 test result >90 days before the most recent test, including five persons who had negative test results (range = 1–43 tests) between the positive results (Supplementary Figure, https://stacks.cdc.gov/view/cdc/105130) and at least one negative NAAT result <14 days before the postvaccination positive test result. Five persons were asymptomatic during the second infection. Paired specimens for sequence comparison were unavailable.

††† Symptoms were categorized as nonspecific, mild, or moderate based on the National Notifiable Diseases Surveillance System and Council of State and Territorial Epidemiologists definition of symptomatic COVID-19. https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/08/05/

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TABLE 2. Skilled nursing facility residents and staff members with SARS-CoV-2 breakthrough infections,* by facility and clinical characteristics — Chicago, Illinois, December 2020–March 2021

		Residents and staff members with breakthrough infection										Facilities	
Facility	Patient	Sex, age (yrs)	Role	Symptoms	Hospitalized	Death	No. of days between second vaccine dose and positive specimen collection	Ct value†	Previous positive SARS-CoV-2 test result	No. of days between initial and most recent positive test result	No. of days between last negative SARS-CoV-2 test result and postvaccination positive test	No. of facility cases occurring after breakthrough infection§	No. of cases considered close contacts¶
A	1	F, 75	Resident	Pneumonia, seizure	Yes, not COVID-19 related**	No	16	—	No	—	23	3	0
B	2	F, 63	Staff	None	No	No	21	—	No	—	6	3	0
	3	F, 36	Staff	HA, fatigue	No	No	29	—	No	—	7	2	0
C	4	F, 83	Resident	None	No	No	18	26.2	No	—	7	2	0
D	5	M, 64	Resident	None	Yes, not COVID-19 related††	No	15	—	Yes	96	106	2	0
	6	M, 73	Resident	Pneumonia, weakness	Yes, COVID-19 related§§	No	21	—	No	—	112	2	0
	7	F, 70	Resident	None	No	No	42	28.8	No	—	7	4	0
E	8	F, 82	Resident	Fatigue, cough	No	No	19	26.9	No	—	29	9	0
	9	F, 95	Resident	None	No	No	28	—	Yes	303	9	5	0
	10	F, 29	Staff	HA	No	No	34	50.0¶¶	No	—	7	1	0
F	11	F, 46	Resident	None	No	No	29	—	Yes	112	8	0	NA
G	12	F, 36	Staff	Chills, myalgia, HA, sore throat, fatigue, cough, loss of taste or smell	No	No	27	29.9	No	—	4	2	0
	13	F, 46	Staff	Sore throat, nausea, diarrhea	No	No	51	27.7	No	—	10	2	0
H	14	M, 41	Staff	None	No	No	29	32.6	Yes	214	7	1	0
I	15	F, 37	Staff	None	No	No	39	28.6	No	—	5	1	0
J	16	M, 60	Resident	None	No	No	31	38.5	No	—	7	1	0
	17	M, 26	Staff	None	No	No	53	—	No	—	14	1	0
K	18	F, 57	Staff	None	No	No	27	28.3	No	—	7	7	0
L	19	F, 49	Staff	None	No	No	42	16.9	No	—	7	0	NA
M	20	M, 77	Resident	None	No	No	45	20.5	No	—	220	0	NA
N	21	F, 70	Resident	None	No	No	56	—	Yes	137	7	4	0
O	22	M, 66	Resident	Pneumonia, fatigue, cough, SOB, difficulty breathing	Yes, COVID-19 related***	Yes***	46	—	Yes	152	13	0	NA

See table footnotes on the next page.

Discussion

Twelve SNF residents and 10 staff members had positive SARS-CoV-2 test results ≥14 days after receiving a second COVID-19 vaccine dose (breakthrough infections). Fourteen (64%) were asymptomatic, available RT-PCR cycle threshold values suggest low viral loads, and no facility-associated secondary transmission was detected. Two residents with breakthrough infections experienced COVID-related hospitalizations, one of whom died because of multiple concurrent infections. Although rare, postvaccination breakthrough infection can occur because COVID-19 vaccines do not offer 100% protection (*2*,*3*). Early studies suggest that COVID-19 vaccines protect against severe illness and might be effective at preventing infection (*1*); however, data on the impact of vaccination on transmission in congregate settings are limited. In addition, some persons whose infections met the case definition of a breakthrough infection might have had persistently positive

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TABLE 2. (*Continued*) Skilled nursing facility residents and staff members with SARS-CoV-2 breakthrough infections,* by facility and clinical characteristics — Chicago, Illinois, December 2020–March 2021

Abbreviations: Ct = cycle threshold; F = female; HA = headache; M = male; NA = not applicable; NAAT = nucleic acid amplification test; SOB = shortness of breath.

* Receipt of a positive SARS-CoV-2 NAAT (e.g., reverse transcription–polymerase chain reaction) or antigen test result from a respiratory specimen collected ≥14 days after completing the two-dose COVID-19 vaccination series.

† Missing Ct values are for specimens that were discarded by the laboratory and unavailable for sequencing.

§ Cases identified within a 28-day monitoring window from the date of specimen collection for the breakthrough infection. For facilities with multiple breakthrough infections, 28-day monitoring windows might overlap, and new facility cases might be listed multiple times.

¶ When a new case in a facility was identified, infection prevention specialists determined whether the person with the case met criteria to be considered a close contact of the person with the breakthrough infection. Data in this column represent the number of cases in persons that met the definition of a close contact and occurred after identification of the breakthrough infection as of April 12, 2021.

** Resident A1 had a positive SARS-CoV-2 test result 16 days after receiving the second dose of COVID-19 vaccine, which was an incidental finding when admitted to the hospital for new onset of seizures. The positive result might have been related to an episode of pneumonia diagnosed 9 days after the second dose. COVID-19 testing was not associated with compatible symptoms, and this resident was included because the resident's case met the laboratory-based breakthrough infection definition. This resident likely did not experience a breakthrough infection because previous pneumonia onset is suggestive of SARS-CoV-2 infection before full immunization.

†† Resident D5 had a positive preprocedural SARS-CoV-2 test result and was subsequently hospitalized for non-COVID-19–related reasons, including multiple falls and a bloodstream infection related to a midline catheter.

§§ Resident D6 was hospitalized for COVID-19-related reasons because of weakness and loss of appetite in association with pneumonia diagnosed at hospital admission.

¶¶ Based on the symptomatic disease case definition outlined by the Council of State and Territorial Epidemiologists, patient E10 had nonspecific COVID-19 symptoms. Previous testing history was examined using the Illinois' National Electronic Disease Surveillance System. No known previous positive SARS-CoV-2 were identified for this patient.

*** Resident O22 was hospitalized for COVID-19-related reasons because of fatigue, cough, SOB, and difficulty breathing. SARS-CoV-2 test result was positive, and resident received a diagnosis of pneumonia requiring hospital admission and intubation in the intensive care unit for hypoxic respiratory failure. Concomitant infections including group B streptococcal bacteremia and *Pseudomonas* urinary tract infection were also identified. The resident died 7 days after hospital admission.

NAAT results after initial infection; however, most had multiple confirmed negative interim test results. Additional data are needed to differentiate breakthrough infections from sequelae of previous infections and to determine whether persons with breakthrough infections can transmit virus.

The results in this report highlight the importance of COVID-19 vaccination in high-risk congregate settings such as SNFs; most fully vaccinated persons were not infected, did not have COVID-19–like symptoms, and did not have severe illness. Despite the identification of positive NAAT results during the investigation period, breakthrough infections did not lead to secondary transmission at these facilities.

Expanded testing of residents and staff members in these settings in response to clusters or outbreak investigations is also important, regardless of vaccination status, because these persons might have asymptomatic infections.§§§ A previous study found that vaccination has an estimated effectiveness of 63% against SARS-CoV-2 infection among SNF residents >14 days after the first dose through 7 days after the second dose (*8*). Additional studies are needed to assess the impact of full vaccination in SNFs and to understand how vaccination in settings that include older adults, immunocompromised persons, and persons with known history of SARS-CoV-2 infection compares with clinical trial efficacy data. Whether vaccinated asymptomatic persons can transmit SARS-CoV-2 is also unknown; therefore, facilities should continue to require residents to quarantine after close contact with an infected person.¶¶¶

Vaccine effectiveness estimates for prevention of SARS-CoV-2 infection and COVID-19 were not calculated because CDPH does not have access to SNF electronic medical records, limiting the ability to obtain individual-level data from facilities on all residents and staff members and to calculate person-time among vaccinated and unvaccinated persons who were not infected. Facilities did not have the capacity to provide line lists and vaccination information for noninfected residents and staff members.

The findings in this report are subject to at least four limitations. First, confirming whether patients with a breakthrough infection and a previous positive SARS-CoV-2 test result had a true reinfection or represented persons with prolonged shedding from previous infection was not possible. Intermittent prolonged SARS-CoV-2 shedding is well described (*9*). In addition to two SARS-CoV-2 tests ≥90 days apart, paired respiratory specimens are needed so that their genetic sequences can be compared.**** Data such as epidemiologic links to confirmed cases and clinical course can provide supporting evidence for reinfection but do not definitively identify reinfection events. Second, vaccination data in this report are limited to Chicago residents and persons vaccinated in Chicago; data were unavailable for staff members who were not Chicago residents and were vaccinated outside Chicago. Third, data entry errors or delayed surveillance reporting might prevent record matching, leading to an underestimate of breakthrough infections. Finally, although some specimens were submitted for genotyping to evaluate possible variant strains, results are pending and not yet available.

SNFs should continue to follow recommended infection prevention and control practices,†††† including work restrictions, isolation of persons with confirmed cases, quarantine of residents who have had close contact with persons with confirmed cases,

§§§ https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html

¶¶¶ https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html

**** https://www.cdc.gov/coronavirus/2019-ncov/php/invest-criteria.html

†††† https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html

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routine and outbreak testing of residents and staff members, and use of personal protective equipment, regardless of vaccination status. Maintaining high vaccination coverage among residents and staff members is also important to reduce opportunities for transmission within facilities and exposure among persons who might not have achieved protective immunity after vaccination.

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Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021

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Early studies suggest that COVID-19 vaccines protect against severe illness (*1*); however, postvaccination SARS-CoV-2 infections (i.e., breakthrough infections) can occur because COVID-19 vaccines do not offer 100% protection (*2*,*3*). Data evaluating the occurrence of breakthrough infections and impact of vaccination in decreasing transmission in congregate settings are limited. Skilled nursing facility (SNF) residents and staff members have been disproportionately affected by SARS-CoV-2, the virus that causes COVID-19 (*4*,*5*), and were prioritized for COVID-19 vaccination (*6*,*7*). Starting December 28, 2020, all 78 Chicago-based SNFs began COVID-19 vaccination clinics over several weeks through the federal Pharmacy Partnership for Long-Term Care Program (PPP).† In February 2021, through routine screening, the Chicago Department of Public Health (CDPH) identified a SARS-CoV-2 infection in a SNF resident >14 days after receipt of the second dose of a two-dose COVID-19 vaccination series. SARS-CoV-2 cases, vaccination status, and possible vaccine breakthrough infections were identified by matching facility reports with state case and vaccination registries. Among 627 persons with SARS-CoV-2 infection across 75 SNFs since vaccination clinics began, 22 SARS-CoV-2 infections were identified among 12 residents and 10 staff members across 15 facilities ≥14 days after receiving their second vaccine dose (i.e., breakthrough infections in fully vaccinated persons). Nearly two thirds (14 of 22; 64%) of persons with breakthrough infections were asymptomatic; two residents were hospitalized because of COVID-19, and one died. No facility-associated secondary transmission occurred. Although few SARS-CoV-2 infections in fully vaccinated persons were observed, these cases demonstrate the need for SNFs to follow recommended routine infection prevention and control practices and promote high vaccination coverage among SNF residents and staff members.

CDPH monitors SNF SARS-CoV-2 infections using a data triangulation method that matches the SARS-CoV-2 test results from nucleic acid amplification tests (NAATs, such as reverse transcription–polymerase chain reaction [RT-PCR]) and antigen tests reported to the Illinois' National Electronic Disease Surveillance System with facility-reported line lists of SARS-CoV-2 test results from routine screening testing.§ In February 2021, CDPH began matching records to Illinois' Comprehensive Automated Immunization Registry Exchange to identify breakthrough infections. After identifying SARS-CoV-2 infection in a SNF resident 16 days after receipt of a second vaccine dose, CDPH initiated an investigation to quantify breakthrough infections across all facilities, evaluate symptoms and clinical outcomes, and assess potential secondary transmission. Vaccine effectiveness was not evaluated.

* These authors contributed equally to this report.

† A public-private partnership among CDC; CVS Pharmacy; Managed Health Care Associates, Inc.; and Walgreens to provide on-site COVID-19 vaccination of residents and staff members at enrolled long-term care facilities, including SNFs. https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html

§ CDPH advises facilities to routinely test residents at least monthly. Staff members were also required to receive testing routinely, with frequency determined based on community positivity rate and other metrics of interest. Staff members at all Chicago-based SNFs were tested at least twice weekly (until February 4, 2021), then weekly (during February 4–March 18, 2021), then biweekly (from March 18, 2021 through the end of investigation period). In response to a facility outbreak (i.e., a resident or staff member with a case within the past 14 days), all staff members and residents (excluding those who received a positive SARS-CoV-2 test <90 days previously) are required to receive testing at least every 3–7 days until no new cases occur for at least 14 days. At the time a breakthrough infection was identified, frequency of resident testing at the 15 SNFs ranged from monthly to twice per week; frequency of staff member testing ranged from weekly to twice weekly.

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Summary

What is already known about this topic?

Residents and staff members of skilled nursing facilities (SNFs) are recommended to receive COVID-19 vaccine as a priority group.

What is added by this report?

Twenty-two possible breakthrough SARS-CoV-2 infections occurred among fully vaccinated persons ≥14 days after their second dose of COVID-19 vaccine. Two thirds of persons were asymptomatic. A minority of persons with breakthrough infection experienced mild to moderate COVID-19–like symptoms; two COVID-19–related hospitalizations and one death occurred. No facility-associated secondary transmission was identified.

What are the implications for public health practice?

SNFs should prioritize vaccination and follow recommended COVID-19 infection prevention and control practices, including following work restrictions, isolation, quarantine, testing of residents and staff members, and use of personal protective equipment.

A facility's investigation period started on its first vaccination clinic date and ended March 31, 2021.[¶] A confirmed case of SARS-CoV-2 infection was defined as a positive SARS-CoV-2 NAAT or antigen test result from a respiratory specimen collected from a resident or staff member during the investigation period. Consistent with CDC guidance, a vaccine breakthrough infection in a resident or staff member was defined as a receipt of a positive SARS-CoV-2 NAAT or antigen test result from a respiratory specimen collected ≥14 days after completing the two-dose COVID-19 vaccination series.[**] Infection prevention specialists conducted case investigations to assess symptoms, clinical outcomes, and close contact information.

SARS-CoV-2 incidence during the investigation period was assessed across four groups based on vaccination status at the time a positive respiratory specimen was collected: 1) unvaccinated (never received a COVID-19 vaccine dose); 2) partially vaccinated (received one dose of a two-dose series); 3) vaccinated but not immune (received two doses of a two-dose series but <14 days had elapsed since the second dose); and 4) fully vaccinated (received two doses of a two-dose series and ≥14 days had elapsed since the second dose). In addition to routine facility follow-up, CDPH actively monitored facilities with breakthrough infections for 28 days to identify whether any new cases occurred in close contacts of the person with breakthrough infection.[††] Analyses were completed using SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[§§]

During the investigation period, an estimated 7,931 SNF residents and 6,834 staff members received two doses of COVID-19 vaccine. A total of 627 confirmed SARS-CoV-2 infections were identified across 75 of the 78 Chicago-based SNFs, including 353 (56%) among residents and 274 (44%) among staff members during the investigation period (Table 1). Three facilities had no confirmed SARS-CoV-2 infections after their first vaccination clinic. Approximately one half (47%) of resident cases occurred in men, 42% were in non-Hispanic Black persons, and the median age was 71 years. More than two thirds (72%) of staff member cases were in women, 38% were in non-Hispanic Black persons, and the median age was 42 years. Among the 627 cases, 447 (71%) occurred in unvaccinated persons, 145 (23%) in partially vaccinated persons, 13 (2%) in vaccinated but not immune persons, and 22 (4%) in fully vaccinated persons (Figure). These breakthrough infections occurred in 12 residents and 10 staff members and accounted for 16% (22 of 136) of SNF-associated cases occurring across all facilities ≥14 days after the second vaccination clinic at the respective facilities. No demographic or clinical differences were observed by vaccination status.

Among the 22 breakthrough infections, 18 (82%) were detected in persons who received testing as part of routine screening, and four (18%) occurred in residents who received testing before a hospital admission or procedure. Among the 18 breakthrough infections identified during routine screening, 14 were detected (across 10 facilities) while residents were receiving weekly testing from the facilities; staff members at all facilities were receiving testing at least weekly. The median interval from second dose to collection of a positive SARS-CoV-2 specimen was 29 days (interquartile range [IQR] = 23–42 days). The median interval between most recent positive NAAT result and last known negative test result was 7 days (IQR = 7–14 days).

[¶] First round vaccination clinics occurred during December 28, 2020–January 18, 2021. Persons were included in the study if infection occurred between the first clinic date at their respective facility and March 31, 2021. Moderna COVID-19 vaccination was exclusively administered at Chicago-based SNFs through the federal PPP. Six residents and two staff members received Pfizer-BioNTech COVID-19 vaccine through Chicago-based vaccine providers not participating in the federal PPP or facilities outside the city of Chicago.

[**] CDC breakthrough infection guidance: https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html. Residents and staff members were excluded from the investigation if they had received 1) a positive SARS-CoV-2 test result from December 28 through the date of their facility's first vaccination clinic or 2) a known initial positive SARS-CoV-2 test result <90 days before their most recent SARS-CoV-2 test result.

[††] For residents, close contact was defined as being within 6 ft of a person for ≥15 minutes over a 24-hour period, regardless of personal protective equipment used. For staff members, close contact was defined as being within 6 ft of a person for ≥15 minutes over a 24-hour period when one or both persons were unmasked.

[§§] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect.552a; 44 U.S.C. Sect.3501 et seq.

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TABLE 1. Number and percentage of skilled nursing facility residents and staff members with a positive confirmed SARS-CoV-2 test result, by demographic and clinical characteristics and vaccination status — Chicago, Illinois, December 2020–March 2021

Characteristic	Vaccination status of residents and staff members with SARS-CoV-2 infections, no. (column %)				
	Total (n = 627)	Unvaccinated* (n = 447)	Partially vaccinated* (n = 145)	Vaccinated but not immune* (n = 13)	Fully vaccinated with breakthrough infection* (n = 22)
Median age (IQR)	60.0 (43.0–73.0)	57.0 (39.0–71.0)	65.0 (50.0–79.0)	66.0 (58.0–79.0)	61.5 (41.0–73.0)
Sex					
Female	376 (60.0)	265 (59.3)	89 (61.4)	7 (53.9)	15 (68.2)
Male	237 (37.8)	168 (37.6)	56 (38.6)	6 (46.2)	7 (31.8)
Unknown	14 (2.2)	14 (3.1)	0 (—)	0 (—)	0 (—)
Race/Ethnicity					
Hispanic/Latino	58 (9.3)	37 (8.3)	16 (11.0)	1 (7.7)	4 (18.2)
Asian, non-Hispanic	24 (3.8)	11 (2.5)	9 (6.2)	1 (7.7)	3 (13.6)
Black, non-Hispanic	252 (40.2)	193 (43.2)	44 (30.3)	7 (53.9)	8 (36.4)
White, non-Hispanic	144 (23.0)	79 (17.7)	55 (37.9)	3 (23.1)	7 (31.8)
Other,† non-Hispanic	16 (2.6)	12 (2.7)	4 (2.8)	0 (—)	0 (—)
Unknown	133 (21.2)	115 (25.7)	17 (11.7)	1 (7.7)	0 (—)
Role					
Resident	353 (56.3)	235 (52.6)	97 (66.9)	9 (69.2)	12 (54.6)
Staff member	274 (43.7)	212 (47.4)	48 (33.1)	4 (30.8)	10 (45.5)
Symptoms§					
Yes	92 (14.7)	62 (13.9)	21 (14.5)	1 (7.7)	8 (36.4)
No	34 (5.4)	15 (3.4)	5 (3.5)	0 (—)	14 (63.6)
Unknown	501 (79.9)	370 (82.8)	119 (82.1)	12 (92.3)	0 (—)
Hospitalizations					
Yes	123 (19.6)	90 (20.1)	27 (18.6)	2 (15.4)	4 (18.2)¶
No	504 (80.4)	357 (79.9)	118 (81.4)	11 (84.6)	18 (81.8)
Deaths					
Yes	21 (3.4)	14 (3.1)	6 (4.1)	0 (—)	1 (4.6)
No	606 (96.7)	433 (96.9)	139 (95.9)	13 (100.0)	21 (95.5)
Previous positive SARS-CoV-2 result					
Yes	41 (6.5)	22 (4.9)	9 (6.2)	4 (30.8)	6 (27.3)
No	586 (93.5)	425 (95.1)	136 (93.8)	9 (69.2)	16 (72.7)

Abbreviations: I-NEDSS = Illinois' National Electronic Disease Surveillance System; IQR = interquartile range.

* Unvaccinated: received no COVID-19 vaccine doses; partially vaccinated: received one dose; vaccinated but not immune: received two doses but <14 days had elapsed since receipt of second dose; and fully vaccinated with breakthrough infection: received two doses and then received a positive SARS-CoV-2 test result ≥14 days after receipt of the second dose.

† Persons with the following races listed in I-NEDSS as American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, other, or multiracial were categorized as non-Hispanic other.

§ Data on symptoms were extracted from I-NEDSS for unvaccinated, partially vaccinated, and vaccinated but not immune persons. Most COVID-19 case reports are entered into I-NEDSS through electronic laboratory reporting and provide minimal information (e.g., name, date of birth, and laboratory test and results) needed to meet reporting requirements. Data on symptoms in persons with breakthrough infections were supplemented with details from case investigations, which were not completed for nonbreakthrough cases. Symptom status for many persons with nonbreakthrough infection cases is unknown.

¶ Two residents were hospitalized for COVID-19–related reasons. Two additional residents were hospitalized for non-COVID-19–related reasons.

Two-dose vaccination coverage among residents and staff members at facilities with breakthrough infections ranged from 62% to 96% and 18% to 85%, respectively. Among the 15 facilities with breakthrough cases, attack rates[¶¶] for unvaccinated and vaccinated residents were 15% (89 of 604) and 0.8% (15 of 1,781), respectively. Among staff members, attack rates for unvaccinated and vaccinated persons were 6% (62 of 992) and 1% (12 of 1,135), respectively. Eleven facilities reported a total of 41 confirmed cases within 28 days after initial breakthrough infection at a facility (Table 2).[***] No facility-associated secondary transmission was determined to have occurred because the new cases that occurred after the initial breakthrough infection were not close contacts of the persons with breakthrough infections.

[¶¶] To calculate attack rates, residents and staff members who had never received COVID-19 vaccine (i.e., unvaccinated persons) and those who had received one COVID-19 vaccine dose of a two-dose series (i.e., partially vaccinated persons) were categorized as unvaccinated. Residents and staff members who had received two COVID-19 vaccine doses of a two-dose series and <14 days or ≥14 days had elapsed (i.e., vaccinated but not immune and fully vaccinated persons, respectively) were categorized as vaccinated. Aggregate vaccination data were only available for residents and staff members who received two doses of COVID-19 vaccine and did not have a SARS-CoV-2 infection. In the denominator, differentiation between persons who received two doses <14 days or ≥14 days was not possible.

[***] Cases identified within a 28-day monitoring window from the date of specimen collection for the breakthrough infection. For facilities with multiple breakthrough infections, 28-day monitoring windows might overlap, and new facility cases might be listed multiple times. As of April 12, 2021, nine of the 41 cases were breakthrough infections; seven of which are listed (see Table 2) and occurred during the investigation period.

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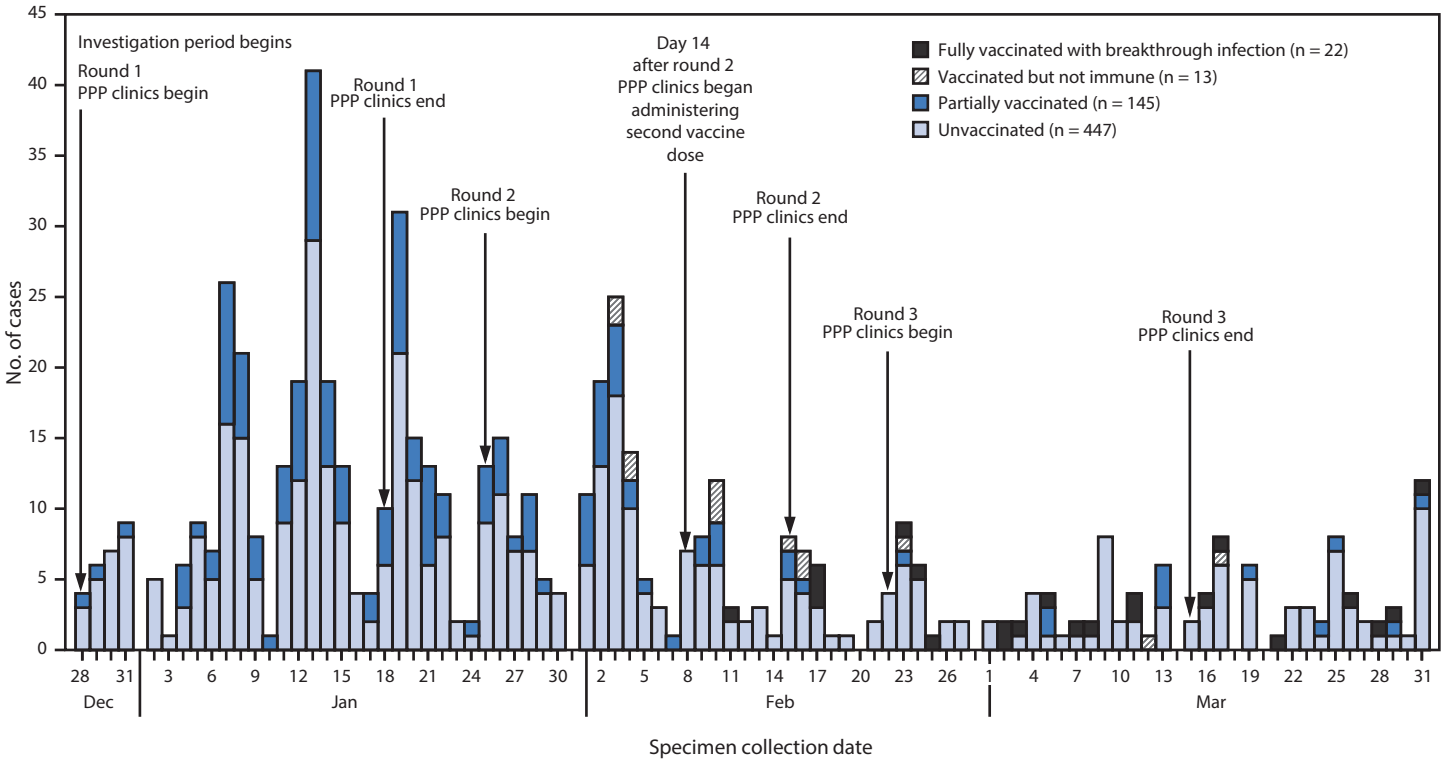
FIGURE. Confirmed SARS-CoV-2 infections (n = 627) among residents and staff members at 75* skilled nursing facilities, by specimen collection date and vaccination status† — Chicago, Illinois, December 2020–March 2021



Abbreviation: PPP = Federal Pharmacy Partnership for Long-Term Care Program.
* Among 78 Chicago-based facilities. Three facilities had no confirmed SARS-CoV-2 infections.
† Unvaccinated: received no COVID-19 vaccine doses; partially vaccinated: received one dose; vaccinated but not immune: received two doses but <14 days had elapsed since receipt of second dose; fully vaccinated with breakthrough infection: received two doses and then received a positive SARS-CoV-2 test result ≥14 days after receipt of the second dose.

Among the 22 persons with breakthrough infections, 14 (64%; eight residents and six staff members) were asymptomatic (Table 2). Three symptomatic persons (B3, E10, and G13) had mild, nonspecific symptoms; two (E8 and G12) had mild, specific symptoms; and three (A1, D6, and O22) had diagnosed pneumonia.††† Four residents were hospitalized: two (D6 and O22) for COVID-19–related reasons and two (A1 and D5) for reasons unrelated to COVID-19; one resident (O22) died.

Resident A1 received a diagnosis of pneumonia 9 days after receiving the second COVID-19 vaccine dose and 7 days before receiving a positive SARS-CoV-2 test result (Table 2). Although the timing of the patient's positive SARS-CoV-2 test result met the definition of a breakthrough infection, the clinical history indicated that the infection likely occurred <14 days after the second dose. Resident D6 was hospitalized for weakness and loss of appetite in association with pneumonia. Resident O22 experienced fatigue and respiratory symptoms and received a diagnosis of pneumonia. This patient had a positive SARS-CoV-2 test result on hospital admission and had concomitant group B β-hemolytic streptococcal bacteremia and a *Pseudomonas* urinary tract infection and died 7 days after hospital admission. The death certificate listed complications of COVID-19 infection as primary cause of death; underlying conditions were hypertension, diabetes mellitus, and chronic kidney disease.

Among 12 available specimens from seven patients with breakthrough infections, RT-PCR cycle threshold values were >28, indicating low levels of detectable virus. Six persons with breakthrough infections had a previous positive SARS-CoV-2 test result >90 days before the most recent test, including five persons who had negative test results (range = 1–43 tests) between the positive results (Supplementary Figure, https://stacks.cdc.gov/view/cdc/105130) and at least one negative NAAT result <14 days before the postvaccination positive test result. Five persons were asymptomatic during the second infection. Paired specimens for sequence comparison were unavailable.

††† Symptoms were categorized as nonspecific, mild, or moderate based on the National Notifiable Diseases Surveillance System and Council of State and Territorial Epidemiologists definition of symptomatic COVID-19. https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/08/05/

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TABLE 2. Skilled nursing facility residents and staff members with SARS-CoV-2 breakthrough infections,* by facility and clinical characteristics — Chicago, Illinois, December 2020–March 2021

		Residents and staff members with breakthrough infection										Facilities	
Facility	Patient	Sex, age (yrs)	Role	Symptoms	Hospitalized	Death	No. of days between second vaccine dose and positive specimen collection	Ct value†	Previous positive SARS-CoV-2 test result	No. of days between initial and most recent positive test result	No. of days between last negative SARS-CoV-2 test result and postvaccination positive test	No. of facility cases occurring after breakthrough infection§	No. of cases considered close contacts¶
A	1	F, 75	Resident	Pneumonia, seizure	Yes, not COVID-19 related**	No	16	—	No	—	23	3	0
B	2	F, 63	Staff	None	No	No	21	—	No	—	6	3	0
	3	F, 36	Staff	HA, fatigue	No	No	29	—	No	—	7	2	0
C	4	F, 83	Resident	None	No	No	18	26.2	No	—	7	2	0
D	5	M, 64	Resident	None	Yes, not COVID-19 related††	No	15	—	Yes	96	106	2	0
	6	M, 73	Resident	Pneumonia, weakness	Yes, COVID-19 related§§	No	21	—	No	—	112	2	0
	7	F, 70	Resident	None	No	No	42	28.8	No	—	7	4	0
E	8	F, 82	Resident	Fatigue, cough	No	No	19	26.9	No	—	29	9	0
	9	F, 95	Resident	None	No	No	28	—	Yes	303	9	5	0
	10	F, 29	Staff	HA	No	No	34	50.0¶¶	No	—	7	1	0
F	11	F, 46	Resident	None	No	No	29	—	Yes	112	8	0	NA
G	12	F, 36	Staff	Chills, myalgia, HA, sore throat, fatigue, cough, loss of taste or smell	No	No	27	29.9	No	—	4	2	0
	13	F, 46	Staff	Sore throat, nausea, diarrhea	No	No	51	27.7	No	—	10	2	0
H	14	M, 41	Staff	None	No	No	29	32.6	Yes	214	7	1	0
I	15	F, 37	Staff	None	No	No	39	28.6	No	—	5	1	0
J	16	M, 60	Resident	None	No	No	31	38.5	No	—	7	1	0
	17	M, 26	Staff	None	No	No	53	—	No	—	14	1	0
K	18	F, 57	Staff	None	No	No	27	28.3	No	—	7	7	0
L	19	F, 49	Staff	None	No	No	42	16.9	No	—	7	0	NA
M	20	M, 77	Resident	None	No	No	45	20.5	No	—	220	0	NA
N	21	F, 70	Resident	None	No	No	56	—	Yes	137	7	4	0
O	22	M, 66	Resident	Pneumonia, fatigue, cough, SOB, difficulty breathing	Yes, COVID-19 related***	Yes***	46	—	Yes	152	13	0	NA

See table footnotes on the next page.

Discussion

Twelve SNF residents and 10 staff members had positive SARS-CoV-2 test results ≥14 days after receiving a second COVID-19 vaccine dose (breakthrough infections). Fourteen (64%) were asymptomatic, available RT-PCR cycle threshold values suggest low viral loads, and no facility-associated secondary transmission was detected. Two residents with breakthrough infections experienced COVID-related hospitalizations, one of whom died because of multiple concurrent infections. Although rare, postvaccination breakthrough infection can occur because COVID-19 vaccines do not offer 100% protection (*2*,*3*). Early studies suggest that COVID-19 vaccines protect against severe illness and might be effective at preventing infection (*1*); however, data on the impact of vaccination on transmission in congregate settings are limited. In addition, some persons whose infections met the case definition of a breakthrough infection might have had persistently positive

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TABLE 2. (*Continued*) Skilled nursing facility residents and staff members with SARS-CoV-2 breakthrough infections,* by facility and clinical characteristics — Chicago, Illinois, December 2020–March 2021

Abbreviations: Ct = cycle threshold; F = female; HA = headache; M = male; NA = not applicable; NAAT = nucleic acid amplification test; SOB = shortness of breath.

* Receipt of a positive SARS-CoV-2 NAAT (e.g., reverse transcription–polymerase chain reaction) or antigen test result from a respiratory specimen collected ≥14 days after completing the two-dose COVID-19 vaccination series.

† Missing Ct values are for specimens that were discarded by the laboratory and unavailable for sequencing.

§ Cases identified within a 28-day monitoring window from the date of specimen collection for the breakthrough infection. For facilities with multiple breakthrough infections, 28-day monitoring windows might overlap, and new facility cases might be listed multiple times.

¶ When a new case in a facility was identified, infection prevention specialists determined whether the person with the case met criteria to be considered a close contact of the person with the breakthrough infection. Data in this column represent the number of cases in persons that met the definition of a close contact and occurred after identification of the breakthrough infection as of April 12, 2021.

** Resident A1 had a positive SARS-CoV-2 test result 16 days after receiving the second dose of COVID-19 vaccine, which was an incidental finding when admitted to the hospital for new onset of seizures. The positive result might have been related to an episode of pneumonia diagnosed 9 days after the second dose. COVID-19 testing was not associated with compatible symptoms, and this resident was included because the resident's case met the laboratory-based breakthrough infection definition. This resident likely did not experience a breakthrough infection because previous pneumonia onset is suggestive of SARS-CoV-2 infection before full immunization.

†† Resident D5 had a positive preprocedural SARS-CoV-2 test result and was subsequently hospitalized for non-COVID-19–related reasons, including multiple falls and a bloodstream infection related to a midline catheter.

§§ Resident D6 was hospitalized for COVID-19-related reasons because of weakness and loss of appetite in association with pneumonia diagnosed at hospital admission.

¶¶ Based on the symptomatic disease case definition outlined by the Council of State and Territorial Epidemiologists, patient E10 had nonspecific COVID-19 symptoms. Previous testing history was examined using the Illinois' National Electronic Disease Surveillance System. No known previous positive SARS-CoV-2 were identified for this patient.

*** Resident O22 was hospitalized for COVID-19-related reasons because of fatigue, cough, SOB, and difficulty breathing. SARS-CoV-2 test result was positive, and resident received a diagnosis of pneumonia requiring hospital admission and intubation in the intensive care unit for hypoxic respiratory failure. Concomitant infections including group B streptococcal bacteremia and *Pseudomonas* urinary tract infection were also identified. The resident died 7 days after hospital admission.

NAAT results after initial infection; however, most had multiple confirmed negative interim test results. Additional data are needed to differentiate breakthrough infections from sequelae of previous infections and to determine whether persons with breakthrough infections can transmit virus.

The results in this report highlight the importance of COVID-19 vaccination in high-risk congregate settings such as SNFs; most fully vaccinated persons were not infected, did not have COVID-19–like symptoms, and did not have severe illness. Despite the identification of positive NAAT results during the investigation period, breakthrough infections did not lead to secondary transmission at these facilities.

Expanded testing of residents and staff members in these settings in response to clusters or outbreak investigations is also important, regardless of vaccination status, because these persons might have asymptomatic infections.§§§ A previous study found that vaccination has an estimated effectiveness of 63% against SARS-CoV-2 infection among SNF residents >14 days after the first dose through 7 days after the second dose (*8*). Additional studies are needed to assess the impact of full vaccination in SNFs and to understand how vaccination in settings that include older adults, immunocompromised persons, and persons with known history of SARS-CoV-2 infection compares with clinical trial efficacy data. Whether vaccinated asymptomatic persons can transmit SARS-CoV-2 is also unknown; therefore, facilities should continue to require residents to quarantine after close contact with an infected person.¶¶¶

Vaccine effectiveness estimates for prevention of SARS-CoV-2 infection and COVID-19 were not calculated because CDPH does not have access to SNF electronic medical records, limiting the ability to obtain individual-level data from facilities on all residents and staff members and to calculate person-time among vaccinated and unvaccinated persons who were not infected. Facilities did not have the capacity to provide line lists and vaccination information for noninfected residents and staff members.

The findings in this report are subject to at least four limitations. First, confirming whether patients with a breakthrough infection and a previous positive SARS-CoV-2 test result had a true reinfection or represented persons with prolonged shedding from previous infection was not possible. Intermittent prolonged SARS-CoV-2 shedding is well described (*9*). In addition to two SARS-CoV-2 tests ≥90 days apart, paired respiratory specimens are needed so that their genetic sequences can be compared.**** Data such as epidemiologic links to confirmed cases and clinical course can provide supporting evidence for reinfection but do not definitively identify reinfection events. Second, vaccination data in this report are limited to Chicago residents and persons vaccinated in Chicago; data were unavailable for staff members who were not Chicago residents and were vaccinated outside Chicago. Third, data entry errors or delayed surveillance reporting might prevent record matching, leading to an underestimate of breakthrough infections. Finally, although some specimens were submitted for genotyping to evaluate possible variant strains, results are pending and not yet available.

SNFs should continue to follow recommended infection prevention and control practices,†††† including work restrictions, isolation of persons with confirmed cases, quarantine of residents who have had close contact with persons with confirmed cases,

§§§ https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html

¶¶¶ https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html

**** https://www.cdc.gov/coronavirus/2019-ncov/php/invest-criteria.html

†††† https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html

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routine and outbreak testing of residents and staff members, and use of personal protective equipment, regardless of vaccination status. Maintaining high vaccination coverage among residents and staff members is also important to reduce opportunities for transmission within facilities and exposure among persons who might not have achieved protective immunity after vaccination.

Acknowledgments

Allison Arwady, Isaac Ghinai, Marielle Fricchione; Massimo Pacilli, Hira Adil, Shane Zelencik, Adebola Hassan, Winter Viverette, Amy Hanson, Daniel Galanto, Franziska Andonopoulos, Shemenia Ladd; residents and staff members of all Chicago-based skilled nursing facilities, including the administrative, medical, nursing, and infection prevention staff at the facilities with breakthrough infections.

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[1]Epidemic Intelligence Service, CDC; [2]Communicable Disease Program, Chicago Department of Public Health, Illinois; [3]Immunization Program, Chicago Department of Public Health, Illinois.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

References

1. Thompson MG, Burgess JL, Naleway AL, et al. Interim estimates of vaccine effectiveness of BNT162b2 and mRNA-1273 COVID-19 vaccines in preventing SARS-CoV-2 infection among health care personnel, first responders, and other essential and frontline workers—eight U.S. locations, December 2020–March 2021. MMWR Morb Mortal Wkly Rep 2021;70:495–500. PMID:33793460 https://doi.org/10.15585/mmwr.mm7013e3
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Readers who have difficulty accessing this PDF file may access the HTML file at https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e1.htm?s_cid=mm7017e1_w. Address all inquiries about the *MMWR* Series, including material to be considered for publication, to Editor, *MMWR* Series, Mailstop V25-5, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30329-4027 or to mmwrq@cdc.gov.

MS-DOH-21-1816-A-001721

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Wednesday, April 21, 2021 3:27 PM EDT
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Mueller, Trisha (CDC/DDNID/NCCDPHP/DRH) <czj5@cdc.gov>; Sager, Catherine R. (CDC/DDPHSIS/CGH/OD) <vtt4@cdc.gov>; Harris Sharpe, Bria (CDC/DDNID/NCBDDD/DBDID) <qov0@cdc.gov>
Subject: Partner Update: April 21,2021

Good afternoon partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov. Thank you for your partnership.

Best,
Bria Harris-Sharpe

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
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April 21, 2021

CDC Resources

- **Self- testing guidance:** Community members have the option of either a self-collection kit or a self-test for COVID testing. Self-collection kits and self-tests can be performed at home or anywhere else. These self-collection kits and tests are available either by prescription or over the counter in a pharmacy or retail store without a prescription. Currently available self-collection kits and tests are used for the detection of current infection.
- **Guide for community partners:** CDC created a complementary resource specific to community-based organizations, the Guide for Community Partners. This guide can help organizations with community-level reach with racial and ethnic minority groups — or other under-resourced communities — get connected to COVID-19 vaccination confidence and access efforts and resources. The Guide includes practical ways to get involved, best practices, one-pagers, linked resources, data, and more to help guide organizations' efforts.
- **COVID-19 vaccine equity:** CDC released a short two-pager, COVID-19 Vaccine Equity: Best Practices for Community and Faith-Based Organizations. This resource provides an overview of strategies and interventions detailed in the Guide. Specifically, it provides best practices and examples for information and materials to disseminate, methods and platforms to use, useful and accessible venues and locations to conduct outreach and vaccination sites, trusted and influential messengers to engage, and vaccination appointment and site logistics to consider
- **New vaccine resources:**
  - Recommendation to Pause Use of Johnson & Johnson's Janssen COVID-19 Vaccine
  - How to Enroll as a COVID-19 Vaccination Provider
  - What Long-Term Care Facility Residents Need to Know About COVID-19 Vaccination
  - U.S. COVID-19 Vaccination Program: Vaccine Channel Portfolio by Jurisdiction
  - General Public User (Vaccine Recipient)
  - Resources for Jurisdictions, Clinics, and Organizations
- **CDC COVID-19 Home Page:** CDC's COVID-19 Home Page provides communities with COVID-19 related information and resources.

Morbidity and Mortality Weekly Report (MMWR)

- **April 21, 2021: Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021.** Early studies suggest that COVID-19 vaccines protect against severe illness; however, postvaccination SARS-CoV-2 infections can occur because COVID-19 vaccines do not offer 100% protection. Data evaluating the occurrence of breakthrough infections and impact of vaccination in decreasing transmission in congregate settings are limited. Skilled nursing facility (SNF) residents and staff members have been disproportionately affected by SARS-CoV-2 and were prioritized for COVID-19 vaccination through the federal Pharmacy Partnership for Long-Term Care Program. Routine health department screening has identified possible breakthrough SARS-CoV-2 infections occurring among fully vaccinated person 14 days or more after their second dose of COVID-19 vaccine.
- **April 21, 2021: COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021.** The Kentucky Department for Public Health (KDPH) and a local health department investigated a COVID-19 outbreak in a SNF that occurred after all residents and health care personnel (HCP) had been offered vaccination.

Upcoming Meetings

- **Emergency Advisory Committee on Immunization Practices (ACIP):** Friday, April 23, 11:00 AM- 5:00 PM EDT ACIP A virtual emergency meeting will be held to discuss Janssen (Johnson & Johnson) COVID-19 vaccine.
- **COVID-19 Partner Update April 26, 2021: Keeping up With Critical Diabetes Care and Prevention During COVID-19:** 3:00-4:00 PM EDT, Monday, April 26, 2021. Join CDC's weekly partner call for updates on the COVID-19 response, including new resources for the private sector and the general public. Register for the event here. For Q&A, please email eocevent337@cdc.gov with "Partner Call 4/26" in the subject line. This call will be recorded andposted with previous Partner Update webinars.
- **Global, Regional, and Local Approaches to COVID-19 Vaccine Equity: Sharing lessons for World Immunization Week:** 3:00 PM EDT, Tuesday, April 27, 2021. In celebration of World Immunization Week, the NACCHO Immunization and Global Health teams are hosting a webinar that will connect global, regional and local experiences related to COVID-19 immunization equity. Register for the event here.

Additional Resources

- **Diagnosis and Management of Suspected Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT):** Tuesday, April 20, CDC and the American Society of Hematology hosted a webinar to address the rare cases of thrombosis with thrombocytopenia have been reported following vaccination with the Johnson & Johnson/Janssen COVID-19 vaccine. The recording of this webinar can be found here.

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 6 (incl. Early MMWR, School-based Screening Webinar, COVID-19 Genomic Epidemiology Focus Group, and more)
Date:	Tuesday, April 6, 2021 2:52:48 PM
Attachments:	image001.png image002.png MMWR ER - Community Transmission of SARS-CoV-2 Associated with Local Bar - February, 2021.pdf ELC Reopening Schools webinar_2021 04 01.pdf COVID-19 Partner Updates April 5 2021.msg HHS COVID-19 Update - 45.msg

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- MMWR Early Release: "Community Transmission of SARS-CoV-2 Associated with a Local Bar Opening Event – Illinois, February 2021" [Attachment, Link]
    - From the summary: *"Forty-six cases of COVID-19 were linked to an indoor bar opening event that occurred during February 2021 in a rural Illinois county. Event patrons were linked to secondary cases among household, long-term care facility, and school contacts, resulting in one hospitalization and one school closure affecting 650 students."*
- Partner Alert: Community of Practice webinar "School-based Screening Testing" [Link]
    - This week's CDC Community of Practice call is on **Thursday**, **April 8** at **2:00 pm ET**. The webinar will focus on the importance of the partnership between public health and education in establishing COVID-19 K-12 screening testing programs and provide information on assistance being offered to support these programs. You may join the call here or dial in using the call-in line below:
        - Zoom Dial-in: 1 646-828-7666
          Meeting ID: 161 148 9877
          Passcode: 66625007
- ELC webinar slides and recording of "Reopening Schools" held Thursday, April 1* [Attachment, Link]

On **Thursday**, **April 1**, ELC hosted a webinar regarding its newest supplemental funding package "ELC Reopening Schools" to review Reopening Schools guidance, subject matter expert perspectives, and a Q&A session. The slides from the webinar are attached, and a link to the recording is available here. ***Please note: the recording is a large file download.**

- COVID-19 Genomic Epidemiology Toolkit Follow Up & Focus Group [Link]
    - Thanks to all who have tried the **COVID-19 Genomic Epidemiology Toolkit**! The Toolkit modules, created by CDC with state and local partners, provide easy-to-use training materials for applying genomic epidemiology to SARS-CoV-2 surveillance and outbreak investigations. Please visit the COVID-19 Genomic Epidemiology Toolkit page as we continue to add new videos and resource links. In an effort to improve the Toolkit, we plan to host a **focus group** to gather feedback. We are looking for volunteers and would appreciate your participation. The focus group will entail an hour-long zoom call with other participants. The only requirements are that you have used the toolkit and are willing to discuss your feedback. To volunteer or to ask any questions, please email GenEpiToolkit@cdc.gov.
- CDC Partner Update Call: "Contact Tracing for COVID-19: Do we still need it? (You bet we do!) Ask an Expert – Q&A with a CDC Expert on Current COVID-19 Guidance" [Link]
    - CDC will host the next installment of its weekly partner call **Monday, April 12** at **3:00 pm ET**. Dr. Kyle Bernstein will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Then, Dr. Melanie Taylor will discuss contact tracing and why it is still important during the COVID-19 Response.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 4/12" in the subject line. The call will be recorded and posted to CDC's website here.
- CDC Media Statement: "CDC Issues Next Phase of the Conditional Sail Order for Cruise Ship Operators" [Link]
    - On **Friday**, **April 2**, CDC issued the next phase of technical guidance under the Framework for Conditional Sailing Order (CSO). From the statement: *[this phase requires]* "cruise lines to establish agreements at ports where they intend to operate, implement routine testing of crew, and develop plans incorporating vaccination strategies to reduce the risk of introduction and spread of COVID-19 by crew and passengers. Read the full statement here.

Standing Updates

- Webinar: White House COVID-19 Response Team w/ State & Local Health Officials [Link]
    - The White House COVID-19 Team will host a webinar **TODAY**, Tuesday, **April 6** at **6:00 pm EST**. Advance registration is required. After registering, you will receive a confirmation email with full call info.

    - Registration link: https://pitc.zoomgov.com/webinar/register/WN_IJV5E1zNRL2QmyyXrpki6Q
- CDC Partner Update – April 5 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – April 5 [Attachment]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
    - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Monday, April 05, 2021 4:07 PM EDT
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Mueller, Trisha (CDC/DDNID/NCCDPHP/DRH) <czj5@cdc.gov>
Subject: COVID-19 Partner Updates: April 5, 2021

Good afternoon partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov. Thank you for your partnership.

Best,
Jordan Moody

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
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1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

April 5, 2021

CDC Resources

- **Science Brief: SARS-CoV-2 and surface (fomite) transmission for indoor community environments:** A new science brief describes the latest science of SARS-CoV-2 surface (fomite) transmission. The main way people are infected with COVID-19 is through close, person-to-person contact, typically between people who are near each other (within about 6 feet). People can be infected with the virus that causes COVID-19 through contact with contaminated surfaces and objects. However, the risk is considered to be low. In most situations, cleaning surfaces using soap or detergent is enough to reduce the chances of spread from surfaces.
- **Revised guidance on SARS-CoV-2 and surface transmission:** CDC released updated guidance on cleaning and disinfecting at home and on cleaning and disinfecting facilities in community settings. In most situations at home and in the community, cleaning with soap or detergent is enough to remove virus particles on surfaces well enough to keep spaces clean. This guidance is not intended for healthcare settings or for other facilities where specific regulations or practices for cleaning and disinfection may apply.
- **Technical instructions for mitigation of COVID-19 among cruise ship crew:** This guidance was updated to add routine COID-19 laboratory screening testing of all crew section, the procedures for embarking contractors and visitors overnight, and the procedures for embarking day contractors and visitors. Surveillance reporting requirements and the color-coding system were also updated. All CDC quarantine and isolation guidance for cruise ships can be found here.
- **COVID-19 Science Update**: Released on April 2, 2021, the Science Update provides summaries of prevention, mitigation, and intervention strategies; vaccination in health care workers; detection, burden, and impact of SARS-CoV-2; transmission of SARS-CoV-2; the B.1.1.7 variant; the natural history of SARS-CoV-2 infection; social, behavioral, and communication science.
- **COVID Data Tracker Weekly Review:** Released on April 2, 2021, the Weekly Review provides an interpretive summary of last week's key data from CDC's COVID Data Tracker.

Morbidity and Mortality Weekly Report (MMWR)

- **Early Release MMWR, April 5, 2021: Community Transmission of SARS-CoV-2 Associated with a Local Bar Opening Event – Illinois, February 2021.** Forty-six cases of COVID-19 were linked to an indoor bar opening event that occurred in February 2021 in a rural Illinois county. Event patrons were linked to secondary cases among household, long-term care facility, and school contacts, resulting in one hospitalization and one school closure affecting 650 students. Opening up settings such as bars, where mask wearing and physical distancing are challenging, can affect the community.

Upcoming Meetings

- **CDC COVID-19 Partner Update: When to clean, when to disinfect, and what science says about SARS-CoV-2 on surface:** Monday, April 19, 2021: 3:00-4:00 PM EDT. CDC invites partners to a presentation on a new science brief and

updated guidance documents regarding cleaning and disinfection. Register for the webinar in advance.

- **NACCHO webinar on the federal response to COVID-19:** Tuesday, April 6, 2021: 3:00-4:00 PM EDT. The National Association of County and City Health Officials invite local health department leadership and staff to participate in this webinar to hear from FEMA, HHS, and CDC on the role of each agency in the COVID-19 response. To join the call, please register here (only registered participants will be able to join).

COVID-19 Special Project:

ELC Reopening Schools

Support for screening testing to reopen schools and keep them operating safely

April 1, 2021

Welcome

Henry Walke, MPH, MD

Incident Manager, CDC COVID-19 Response

Director, Division of Preparedness and Emerging Infections

Agenda

- Overview
- ELC Reopening Schools
  - Activities
  - Workplans & budgets
  - Timeline and reporting dates
- CDC school SMEs
- Representatives from the field
- Questions

Overview

- The *American Rescue Plan Act of 2021*

  Provided approximately $12 billion to recipients for:

  - Testing in underserved populations ($2.25B)
  - **School-based COVID-19 screening testing for teachers, staff and students to assist schools in reopening safely for in-person instruction ($10B)**

ELC Reopening Schools

- Supports comprehensive screening testing for K-12 schools (public and private) in April 2021, extending through the end of the school year and into summer/subsequent school year, as funds allow.
- Maintains integral role of public health in the testing ecosystem.
- Ensures a holistic assessment and monitoring of disease burden within any given community.

ELC Reopening Schools

- $10B awarded to all 64 recipients according to a population-based formula.
- 85% of the recipient award must be allocated to support school districts to conduct screening testing.
- 16-month funding period (April 1, 2021 – July 31, 2022)

Budgets

- Spending is permitted as soon as funds are available. Costs must align with guidance.
- Funds cannot be used to cover costs incurred before the date of award.
- Revised budget due sixty (60) days after the award is issued
  - Submit as a 'budget revision amendment' in GrantSolutions.
  - Courtesy copy in REDCap REDCap ‘ELC Reopening Schools: COVID Award’ portal under the ‘ELC Reopening Schools Financial Reporting’ page.
- For contractual agreements for school district support, submit contract details via Grant Note until revised budget finalized.

Financial Reporting

Starting thirty (30) days from award issuance, monthly financial reporting.

- Due on the 5th day of the month for the prior month financials
- Expenditures and unliquidated obligations (ULOs)
- Reported in the REDCap
  - In 'ELC Reopening Schools: COVID Award' portal
  - Under the 'ELC Reopening Schools Financial Reporting' page

Workplans

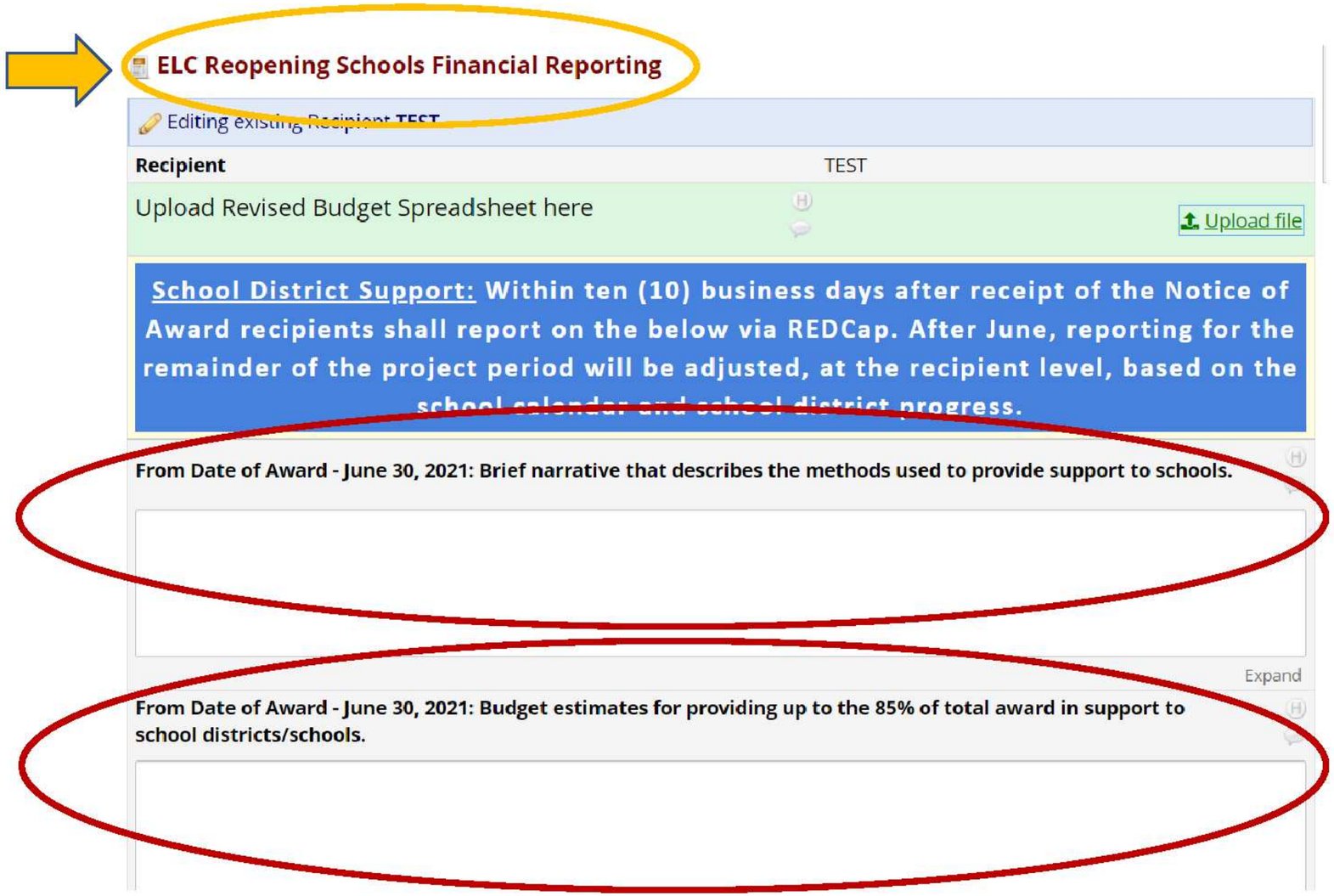
- Workplans are streamlined for this award
- Three required activities:

1. Rapid deployment of screening testing resources for the current school year.
   Estimated timeframe: April through June
2. Development of K-12 screening testing implementation plan.
   Estimated timeframe: June and July
3. Implementation of screening testing action plan for the following school year.

Required Activity 1

Rapid deployment of screening testing resources for the current school year

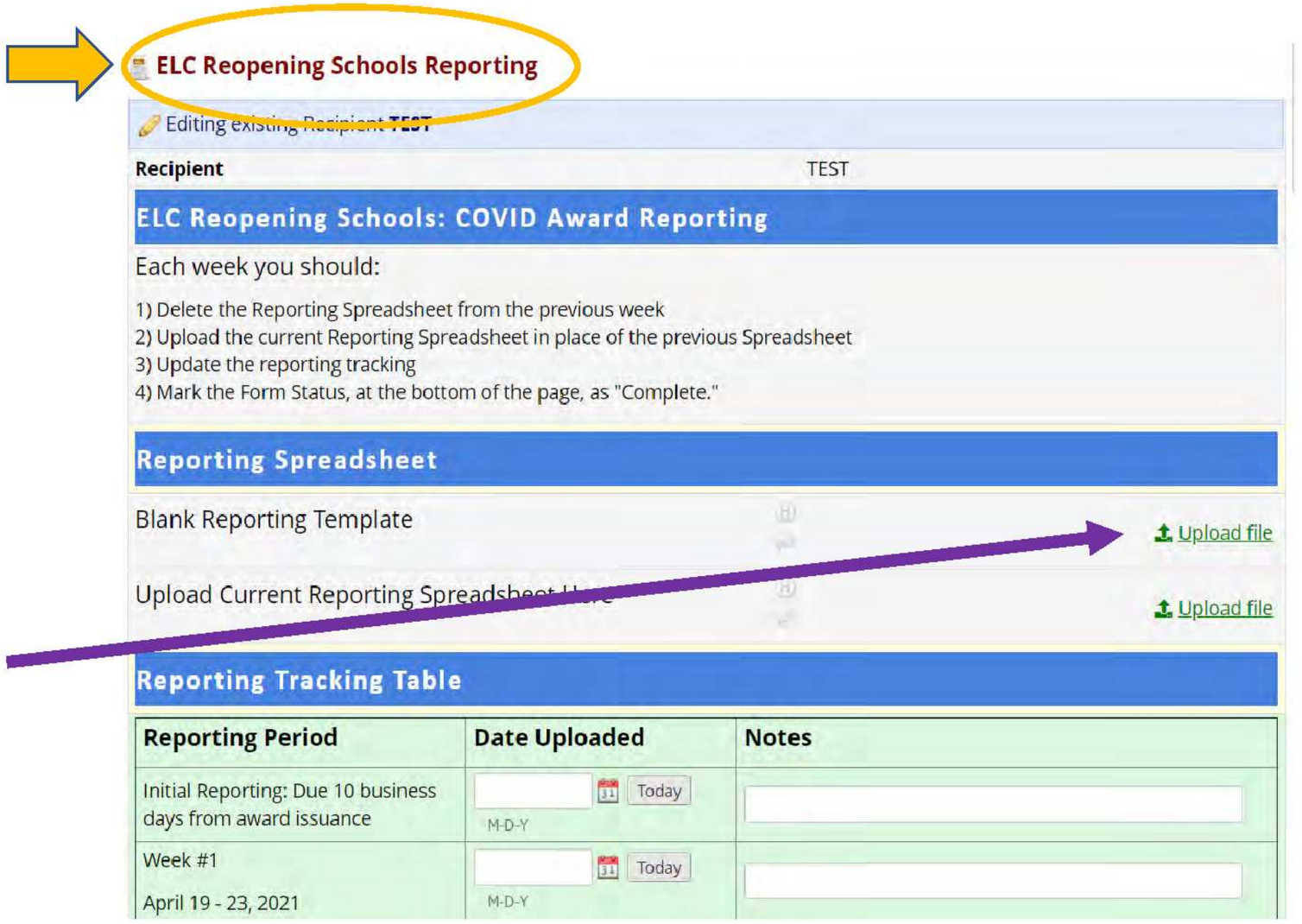
- Complete the narrative and estimates for School District Support
- Update weekly, as needed, through end of June 2021



Required Activity 1

Rapid deployment of screening testing resources for the current school year

You can find the 'Blank Reporting Template' here



- To reduce burden on recipients, ELC is creating individualized reporting templates that list school districts
- Plan is to make available through REDCap early next week (April 5 or 6)
- Review 'Blank Reporting Template' to ensure school districts are all listed

CK19-1904: ELC Reopening Schools COVID Award - Alabama - April 12 - April 16

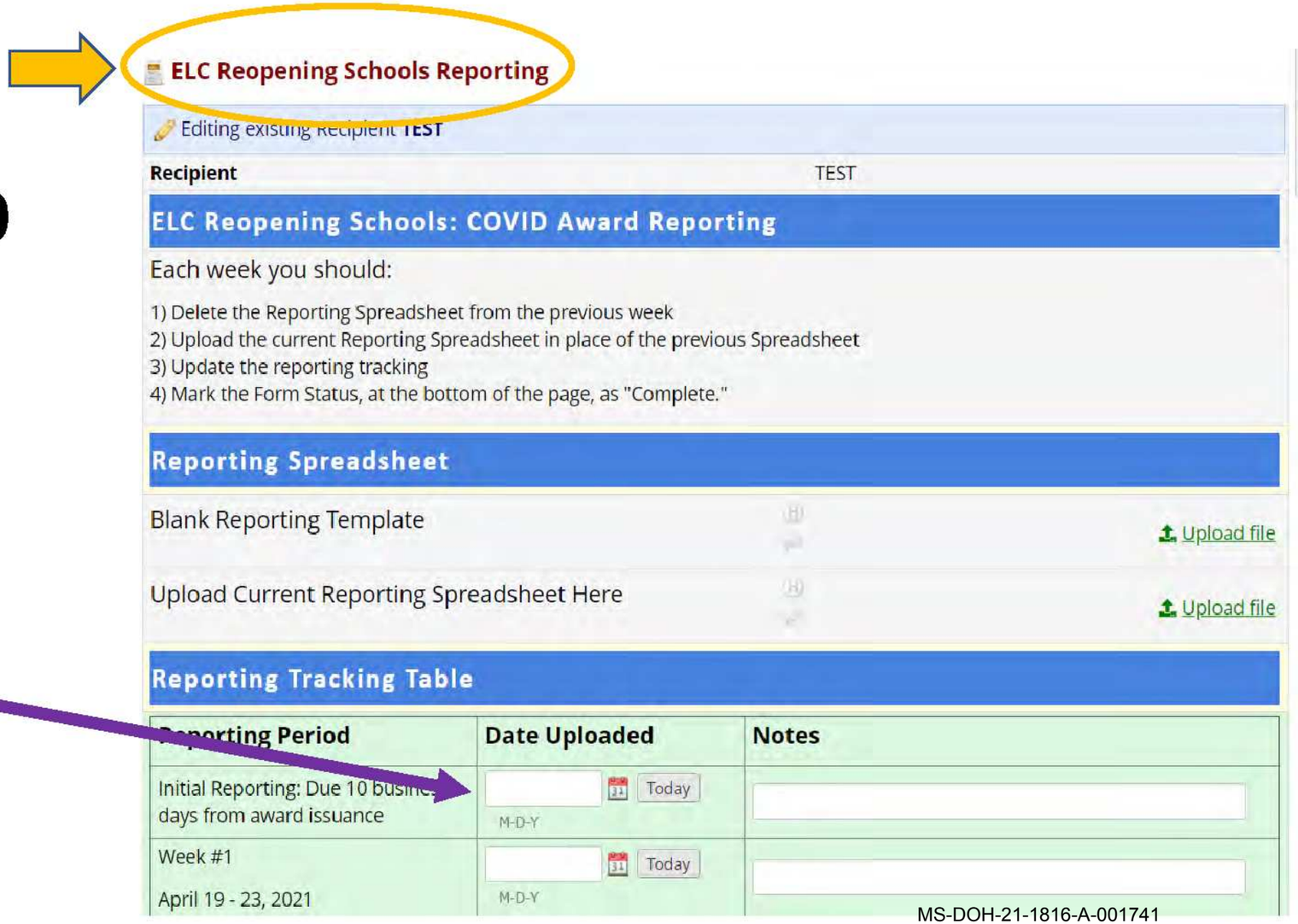
Place Holder

County	School District Name	Week	Total Enrollment	Tests Conducted: PCR	Tests Conducted: Antigen	Positive Cases (All test types)	Notes
Autauga County	Autauga County	April 12 - April 16					
Baldwin County	Baldwin County	April 12 - April 16					
Barbour County	Barbour County	April 12 - April 16					
Barbour County	Eufaula City	April 12 - April 16					
Bibb County	Bibb County	April 12 - April 16					
Blount County	Blount County	April 12 - April 16					
Blount County	Oneonta City	April 12 - April 16					
Bullock County	Bullock County	April 12 - April 16					
Butler County	Butler County	April 12 - April 16					
Calhoun County	Anniston City	April 12 - April 16					

April 12 - April 16 | April 19 - April 23 | April 26 - April 30 | May 3 - May 7 | May 10 - May 14 | ...

Weekly Reporting Requirement

- Submit in 'Initial Reporting' slot within **10 business days from award issuance**
- Mark date file is uploaded



Weekly Reporting Requirement

- Starts fifteen (15) days after the award issuance
- Report:
    1. The number of tests conducted by school districts and private/charter schools
    2. Test type
    3. Cases identified

CK19-1904: ELC Reopening Schools COVID Award - Alabama - April 12 - April 16

Place Holder

County	School District Name	Week	Total Enrollment	Tests Conducted: PCR	Tests Conducted: Antigen	Positive Cases (All test types)	Notes
Autauga County	Autauga County	April 12 - April 16					
Baldwin County	Baldwin County	April 12 - April 16					
Barbour County	Barbour County	April 12 - April 16					
Barbour County	Eufaula City	April 12 - April 16					
Bibb County	Bibb County	April 12 - April 16					
Blount County	Blount County	April 12 - April 16					
Blount County	Oneonta City	April 12 - April 16					
Bullock County	Bullock County	April 12 - April 16					
Butler County	Butler County	April 12 - April 16					
Calhoun County	Anniston City	April 12 - April 16					

April 12 - April 16 | April 19 - April 23 | April 26 - April 30 | May 3 - May 7 | May 10 - May 14 | ...

Weekly Reporting Requirement

Reporting Tracking Table

Reporting Period	Date Uploaded	Notes
Initial Reporting: Due 10 business days from award issuance	M-D-Y Today	test
Week #1 April 19 - 23, 2021	M-D-Y Today	
Week #2 April 26 - 30, 2021	M-D-Y Today	
Week #3 May 3 - 7, 2021	M-D-Y Today	
Week #4 May 10 - 14, 2021	M-D-Y Today	
Week #5 May 17 - 21, 2021	M-D-Y Today	
Week #6 May 24 - 28, 2021	M-D-Y Today	
Week #7 May 31 - June 4, 2021	M-D-Y Today	
Week #8 June 7 - 11, 2021	M-D-Y Today	
Week #9	M-D-Y Today	

- Reporting continues weekly until the end of June
- Mark date file is uploaded

Performance Measures

- Submitted through REDCap
- [Weekly/monthly] reporting schedule
- Number of screening tests performed
- Types of screening tests performed
- [Count/percent positive]

Timeline

Within 5 days after NOA	Authorized Official acknowledges receipt of this guidance by submitting a Grant Note in GrantSolutions *Letter template provided in guidance*.
10 days after NOA	Brief narrative on school support; budget estimates for up to 85% of award for school support; school list; estimated number enrolled for your support; & frequency of testing
15 days after NOA, weekly until 6/30/21	Performance measures: number of tests conducted by school district, test type, and cases identified
Beginning 5/1/21	Monthly financial reports in REDCap & GrantSolutions
6/1/21	Revised budget due in REDCap
After June	Performance reporting schedules will be adjusted individually for recipients

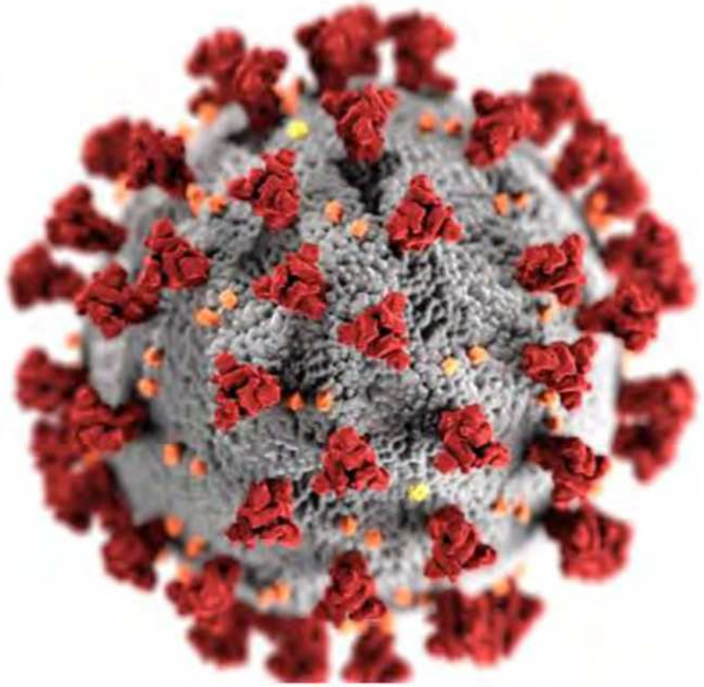
School Subject Matter Experts

Jessica Gross

Lisa Barrios

K-12 School Testing

- Purpose
- CDC Guidance
- Working with Schools
- Program Design
- Tools and Resources



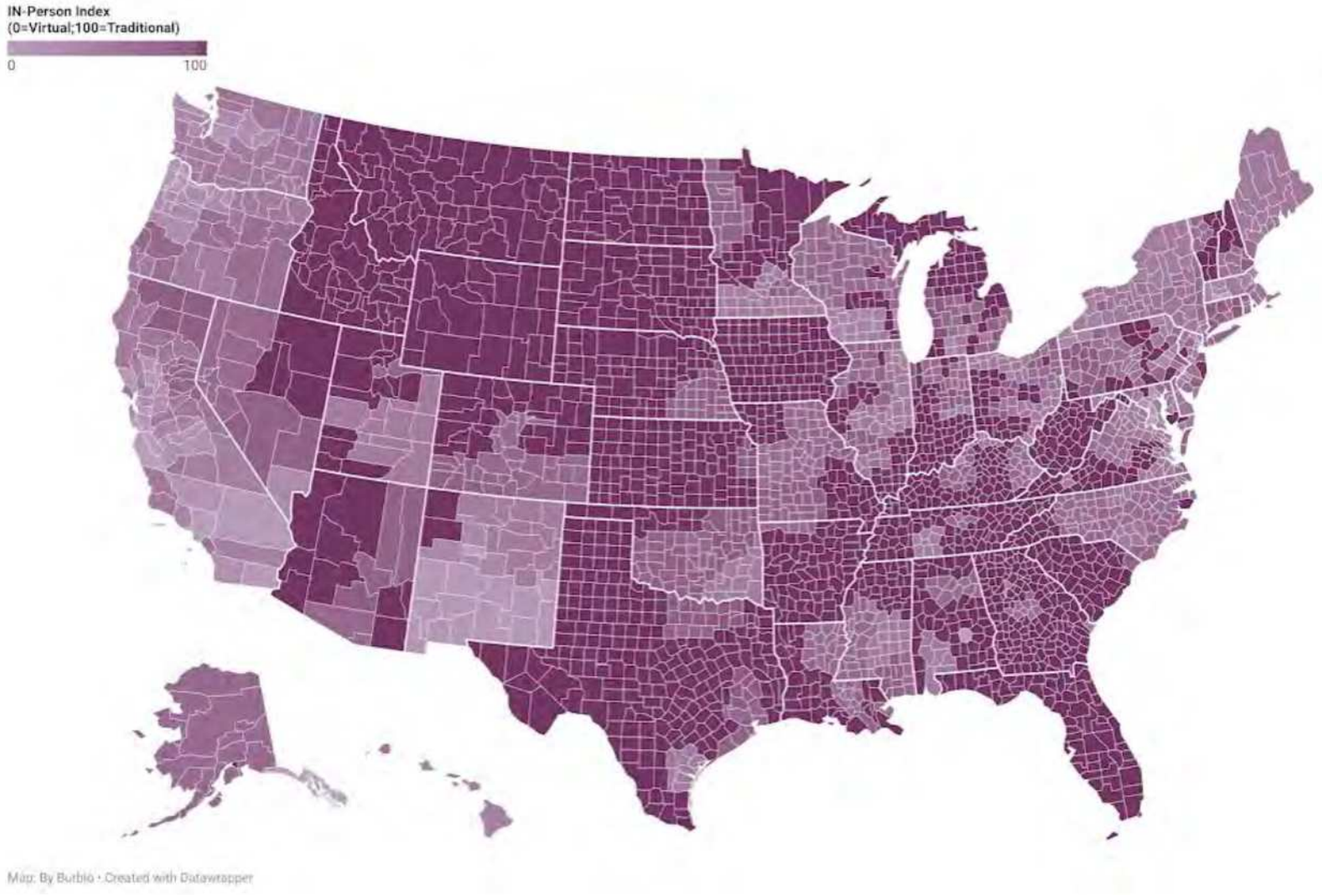
Open and Safe Schools

Photo Credit: COVID-19 Testing in K-12 Schools: Insights from Early Adopters, RAND Corporation, 2021: https://www.rand.org/pubs/research_reports/RRA1103-1.html

What's the *purpose* of testing in K-12 schools?

- **Reopening Schools**
  - virtual → hybrid
  - hybrid → in-person

- **Building Confidence**
  - teachers, staff and parents
  - schools are safe
  - transparent



Source: CNN according to data compiled by Education Week:
https://www.cnn.com/interactive/2020/health/coronavirus-schools-reopening/

Source: Burbio K-12 School Opening Tracker, estimates as of March 31, 2021

What's the *purpose* of testing in K-12 schools?

- **Layering Prevention**
  - testing (additional layer of prevention)
  - identify cases
- **Improving Mitigation**
  - identify in-school transmission
  - address root causes
- **Evolving Purpose**
  - diagnostic, screening, surveillance

Photo Credit (top): The COVID-19 Educational Testing Toolkit, Shah Family Foundation: https://covidedtesting.com/

Photo Credit (bottom): COVID-19 Testing in K-12 Schools: Insights from Early Adopters, RAND Corporation, 2021: https://www.rand.org/pubs/research_reports/RRA1103-1.html

Funding Landscape: K-12 School Testing

$550M HHS: Increased Community Access to Testing (ICATT)

HHS Continues Community Based Testing Sites for COVID-19

Today, the Department of Health and Human Services (HHS) announced the extension of the Community Based Testing Site program for COVID-19 testing, through partnership with national pharmacy and retail chains CVS, Rite-Aid, Walgreens, Quest (through services at Walmart) and service provider eTrueNorth (through services at Health Mart and Topco locations). The partnership has resulted in establishing more than 3,300 COVID-19 testing locations in all 50 states, the District of Columbia, and Puerto Rico. To date, more than 5.6 million tests have been conducted as a result of this partnership.

The Community Based Testing Site program began in the spring of 2020 and includes a large percentage - over 70% - of testing sites located in communities with moderate-to-high social vulnerability, as evidenced by their racial and ethnic composition, their household composition, their socioeconomic status, and similar considerations.

$10B CDC to 64 Jurisdictions (State Departments of Health)

Support COVID-19 screening testing to help schools reopen: Consistent with the American Rescue Plan (P.L. 117-2), the Centers for Disease Control and Prevention (CDC) will provide $10 billion to states to support COVID-19 screening testing for teachers, staff and students to assist schools in reopening safely for in-person instruction. CDC's *Operational Strategy for K-12 Schools through Phased Mitigation*, released in February 2021, makes clear that screening testing is a tool schools can utilize to help reopen safely as part of a comprehensive COVID-19 mitigation approach. Using existing funding mechanisms, this funding will be able to be deployed quickly as part of a strategy to help get schools open in the remaining months of this school year. In addition to ensuring diagnostic testing of symptomatic and exposed individuals, serial screening testing will help schools identify infected individuals without symptoms who may be contagious so that prompt action can be taken to prevent further transmission. With this ARP funding, states can support the critical testing and testing supports

$50M NIH for RADx-UP for Implementation Science

Research Opportunity Title: RADx-UP Return to School Diagnostic Testing Approaches (OT2 Clinical Trial Optional)

OTA-21-004

Participating Organization(s): National Institutes of Health

Components: This Other Transaction Research Opportunity Announcement (OT ROA) is part of the Rapid Acceleration of Diagnostics℠ for Underserved Populations (RADx-UP℠) Program. The research opportunity will be administered by the Office of the Director on behalf of RADx-UP.

Funding Instrument: The funding instrument is the Other Transaction (OT) Award mechanism.

OT awards are not grants, cooperative agreements, or contracts, and uses Other Transaction Authority, provided by Congress. Policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the recipient and details specific terms and conditions for that award.

$650M HHS/DOD for Operation ET (Expanding Testing)

Launching a pilot program to expand COVID-19 testing for schools and underserved populations through coordinating centers. HHS, in partnership with the Department of Defense (DOD), is investing $650 million to expand testing opportunities for K-8 schools and underserved congregate settings, such as homeless shelters, directly through new regional coordinating centers. These coordinating centers will organize the distribution of COVID-19 testing supplies and partner with laboratories across the country, including universities and commercial labs, to collect specimens, perform tests, and report results to the relevant public health agencies. These coordinating centers will identify existing testing capacity, match it up to an area of need, and fund that testing.

CDC Guidance

Photo Credit: COVID-19 Testing in K-12 Schools: Insights from Early Adopters, RAND Corporation, 2021: https://www.rand.org/pubs/research_reports/RRA1103-1.html

Essential Elements of Safe In-person Learning

1. **Consistent** implementation of **layered prevention strategies** to reduce transmission of SARS-CoV-2 in schools
2. **Indicators of community transmission** to reflect level of risk
3. **Phased prevention**

Additional layers of COVID-19 prevention

- **Testing** to identify individuals with SARS-CoV-2 infection
- **Vaccination** for teachers and school staff

Levels of Community Transmission

Indicator[1]	Low Transmission Blue	Moderate Transmission Yellow	Substantial Transmission Orange	High Transmission Red
Total new cases per 100,000 persons in the past 7 days[2]	0-9	10-49	50-99	≥100
Percentage of NAATs that are positive during the past 7 days[3]	<5.0%	5.0%-7.9%	8.0%-9.9%	≥10.0%

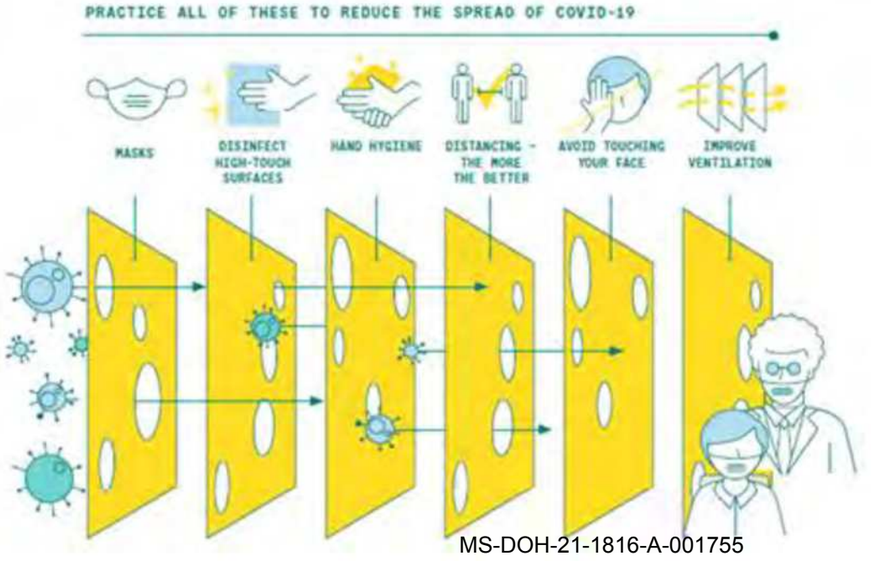
[1]If the two indicators suggest different levels, the actions corresponding to the higher threshold should be chosen. County-level data on total new cases in the past 7 days and test percent positivity are available on the County View tab in CDC's COVID Data Tracker.

[2]Total number of new cases per 100,000 persons within the last 7 days is calculated by adding the number of new cases in the county/community in the last 7 days divided by the population in the county and multiplying by 100,000.

[3]Percentage of positive diagnostic and screening nucleic acid amplification tests (NAATs) during the last 7 days is calculated by dividing the number of positive tests in the county during the last 7 days by the total number of tests resulted over the last 7 days. Additional information can be found on the Calculating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Laboratory Test Percent Positivity: CDC Methods and Considerations for Comparisons and Interpretation webpage.

Testing Identifies Individuals with SAR-COV-2 Infection and Limits Outbreaks

- In the K-12 Operational Strategy, testing is framed as additional COVID-19 prevention in schools, along with vaccination.
- Diagnostic testing: **all schools** should offer referrals to any student, teacher, staff member who has symptoms at school and those who were exposed.
- Screening testing: **some schools** may elect to use screening testing as a strategy to identify cases and prevent secondary transmission.
  - Added layer of mitigation—it doesn't replace other mitigation strategies
  - At schools that offer screening testing: weekly testing recommended for teachers (all levels), students (moderate, substantial, high levels)



MS-DOH-21-1816-A-001755

Figure Credit: COVID-19 Testing in K-12 Settings: A Playbook for Educators and Leaders, Rockefeller Foundation: https://www.rockefellerfoundation.org/wp-content/uploads/2021/02/The-RockefellerFoundation-Covid-19-K-12-Testing-Playbook-for-Educators-and-Leaders.pdf

Testing Recommendations: K-12 Schools Operational Strategy

Low Transmission Blue	Moderate Transmission Yellow	Substantial Transmission Orange	High Transmission Red
All schools implement 5 key prevention strategies: masks required; physical distancing; handwashing and respiratory etiquette; cleaning and maintaining healthy facilities; contact tracing in combination with quarantine and isolation **Diagnostic testing:**[1] symptomatic students, teachers, and staff and close contacts referred for diagnostic testing			
Screening testing[2]			
Screening testing of teachers and staff offered at least once per week			
No screening testing for students	**Screening testing for students** offered at least once per week[3]		
Testing for high-risk sports: testing recommended at least once per week[4] **Testing for low and intermediate-risk sports:** testing recommended at least once per week		**Testing for high-risk sports:** testing recommended twice per week **Testing for low and intermediate-risk sports:** testing recommended at least once per week	

[1]Diagnostic testing for SARS-CoV-2 is intended to identify occurrence of SARS-CoV-2 infection at the individual level and is performed when there is a reason to suspect that an individual may be infected, such as having symptoms or suspected recent exposure.

[2]Screening testing is intended to identify infected asymptomatic individuals who may be contagious so that measures can be taken to prevent further transmission.

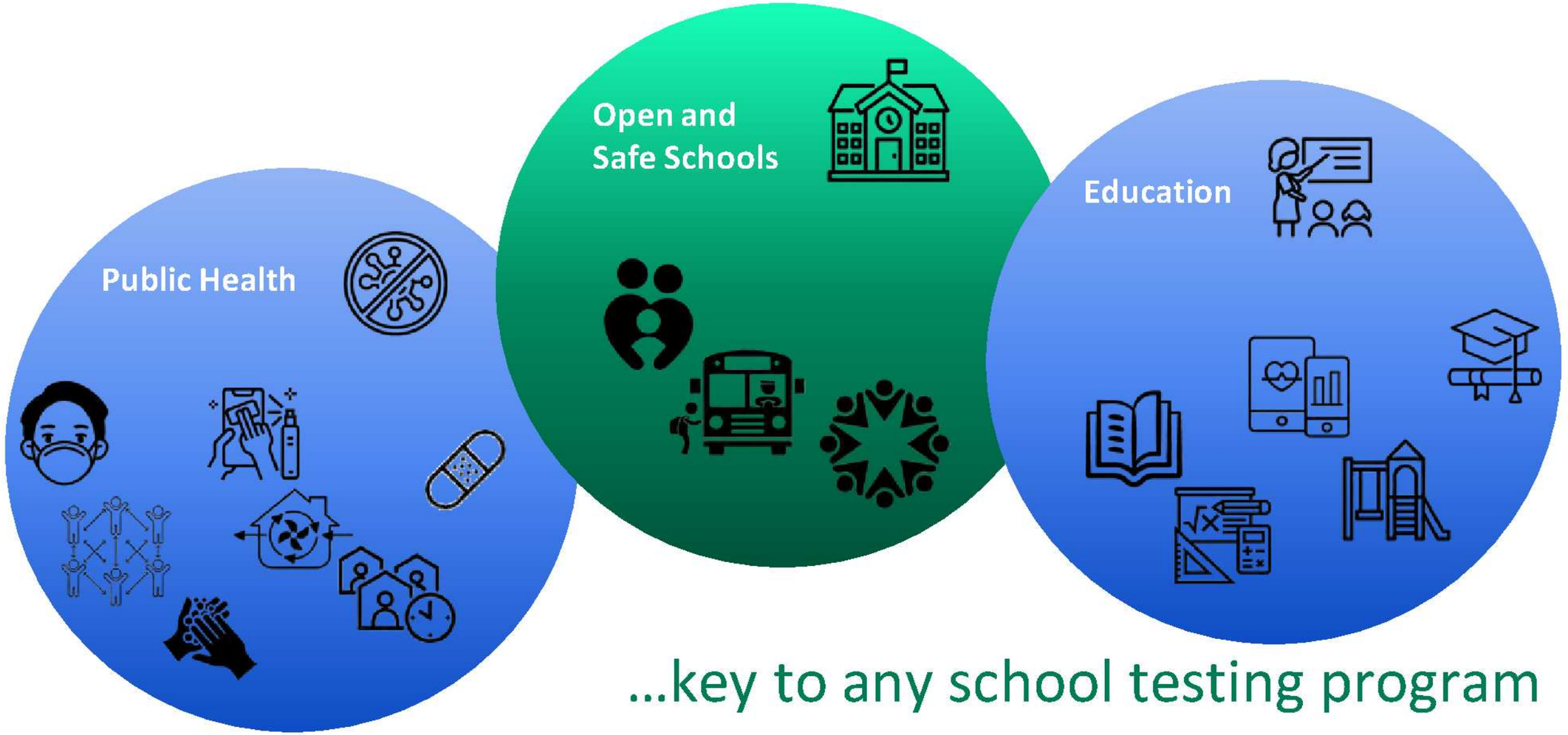
[3]Schools may ***consider testing a random sample of at least 10% of students or may conduct pooled testing of cohorts/pods for screening testing in areas of moderate and substantial community transmission***.

[4]Schools may consider using screening testing for student athletes and adults (e.g., coaches, teacher advisors) who support these activities to facilitate safe participation and reduce risk of transmission. For an example risk stratification for sports, see NCAA Transmission Risk Summary.

Working with Schools

Photo Credit: COVID-19 Testing in K-12 Schools: Insights from Early Adopters, RAND Corporation, 2021: https://www.rand.org/pubs/research_reports/RRA1103-1.html

Common ground and shared priorities…



…key to any school testing program

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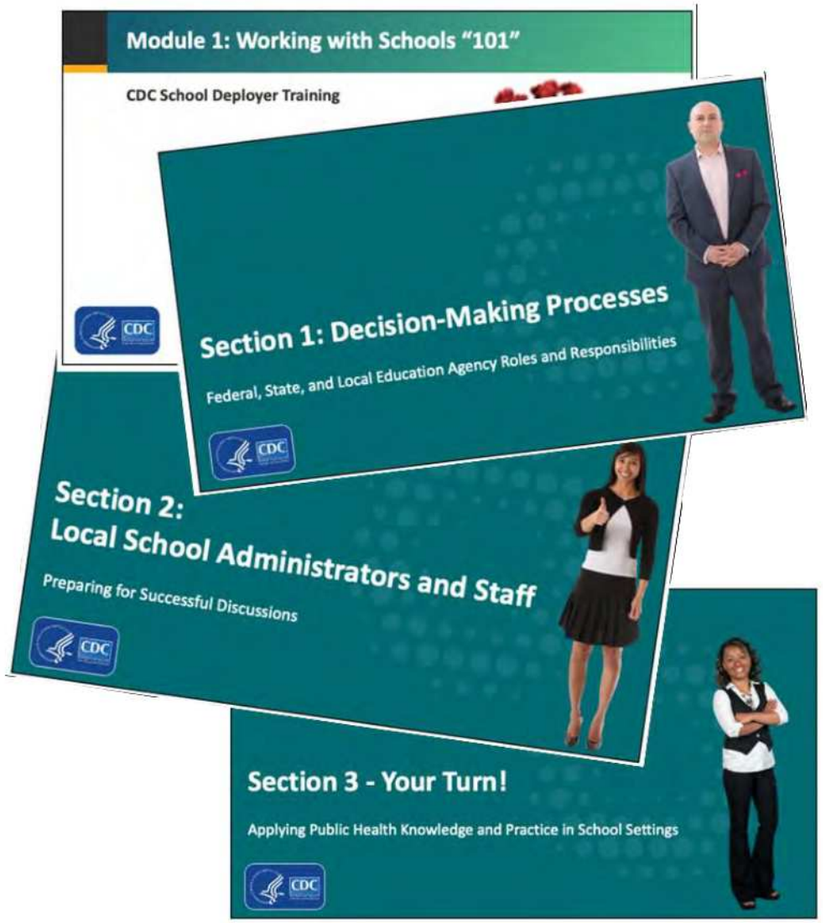
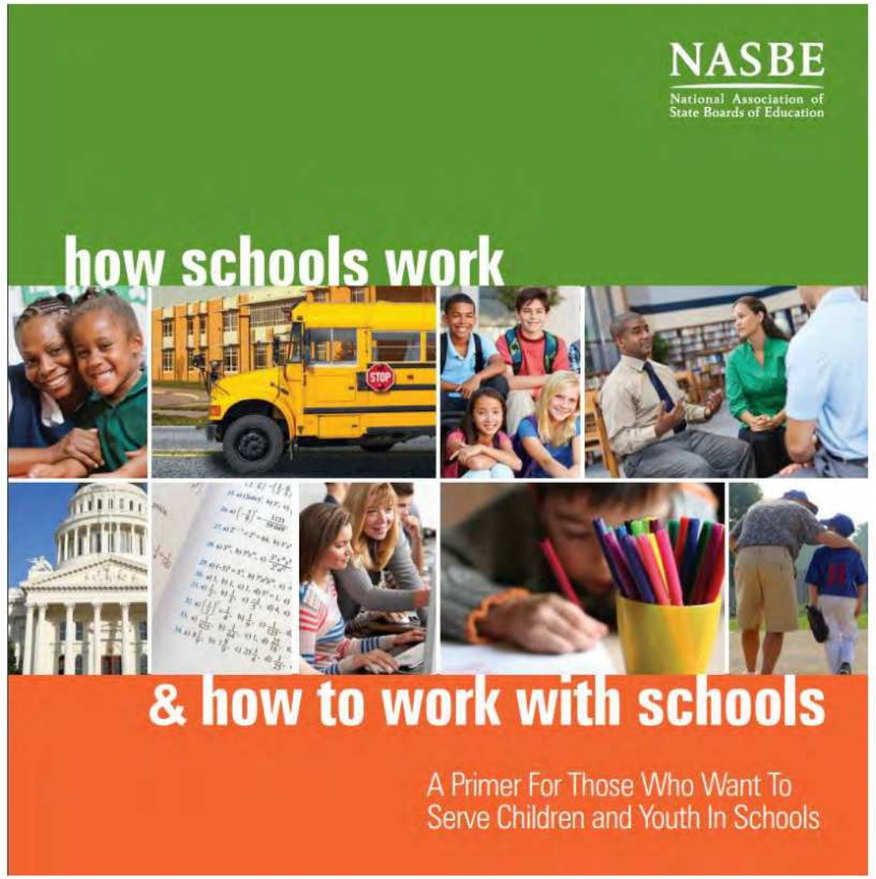
Photo Credit: COVID-19 Testing in K-12 Settings: A Playbook for Educators and Leaders, Rockefeller Foundation:

How to work with Schools



https://www.train.org/main/course/1096902/



https://nasbe.nyc3.digitaloceanspaces.com/2020/01/How-Schools-Work-2014.pdf

Guiding Principles

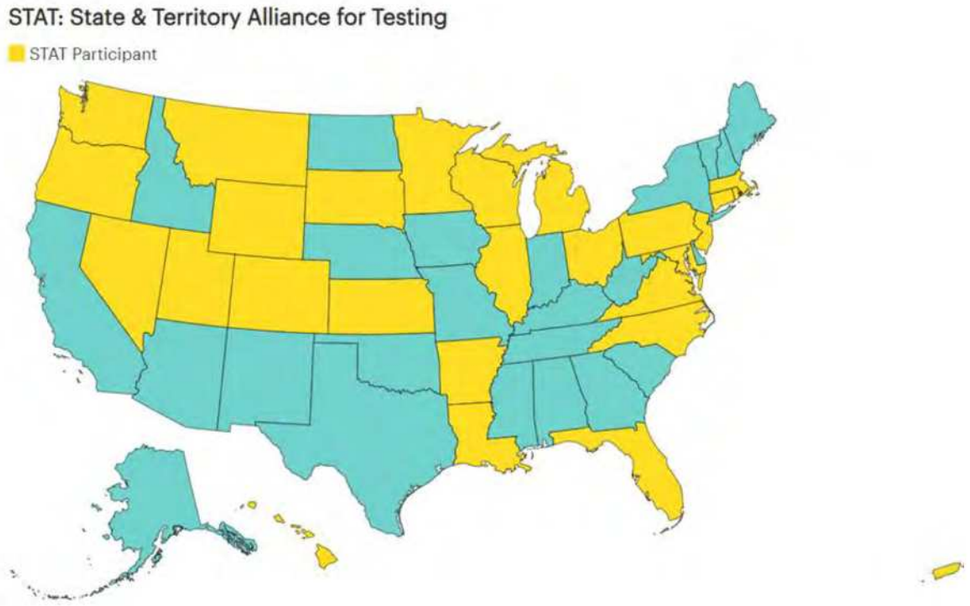
- Education's **primary goal** is to educate students
- Health, safety, development and well-being may be **secondary priorities**
- Concerns about **safety**, in particular, can affect access to some schools
- Schools are **busy** places; plan your involvement carefully
- School leaders and personnel have **multiple responsibilities and priorities**
- The **needs of schools** differ from district to district
- Education **decision-making is diffused** and variable
- **Multiple people or groups** are usually involved in the decision-making program
- **Several levels of review** before decisions are made
- Education leaders cannot address all of their **needs** alone
- Education has its own **acronyms** and **terminology**

Source: Working with Schools 101, CDC Train: https://www.train.org/main/course/1096902/

State and Local School Engagement

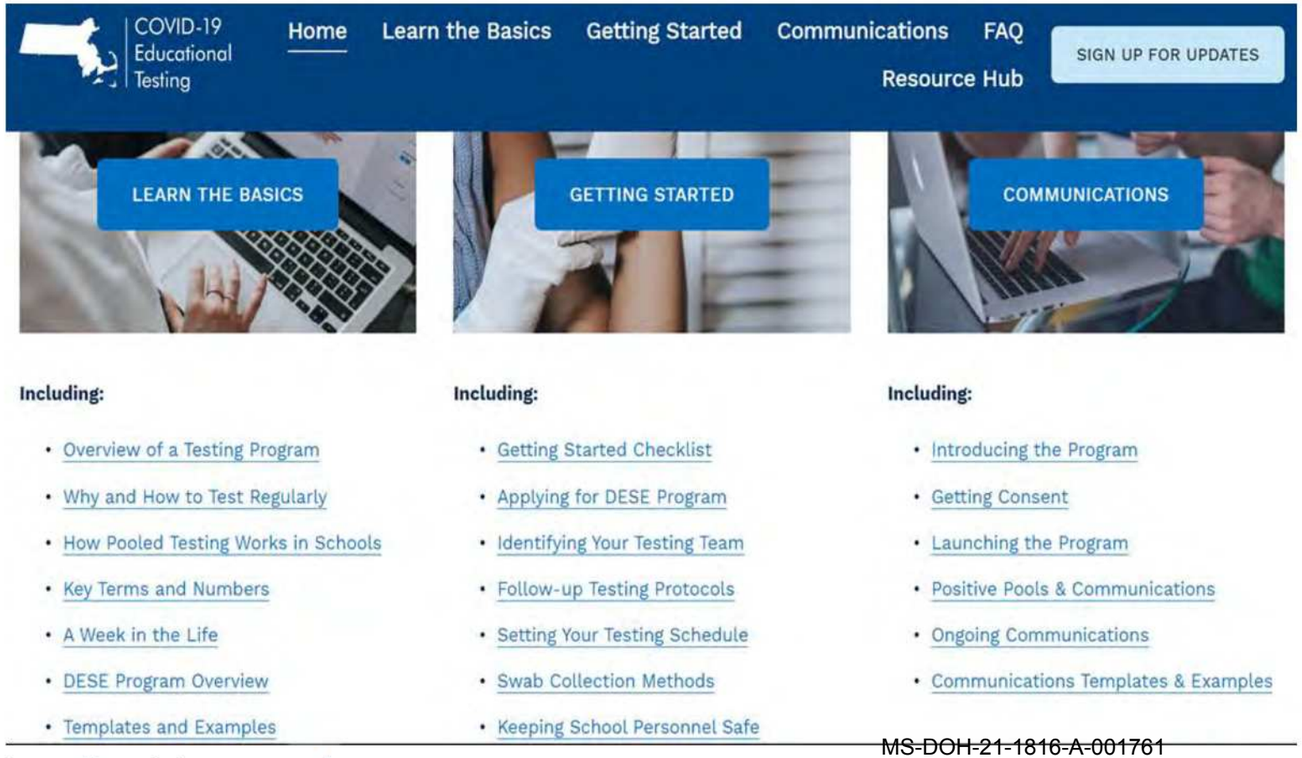
State Engagement

- State Education Agencies (SEAs)/ Local Education Agencies (LEAs)
- State and Territory Alliance for Testing (STAT) Rockefeller Calls



District Engagement

- Toolkits: communication, templates, staffing, consent, interface with the lab/vendor



https://covidedtesting.com/

Program Design

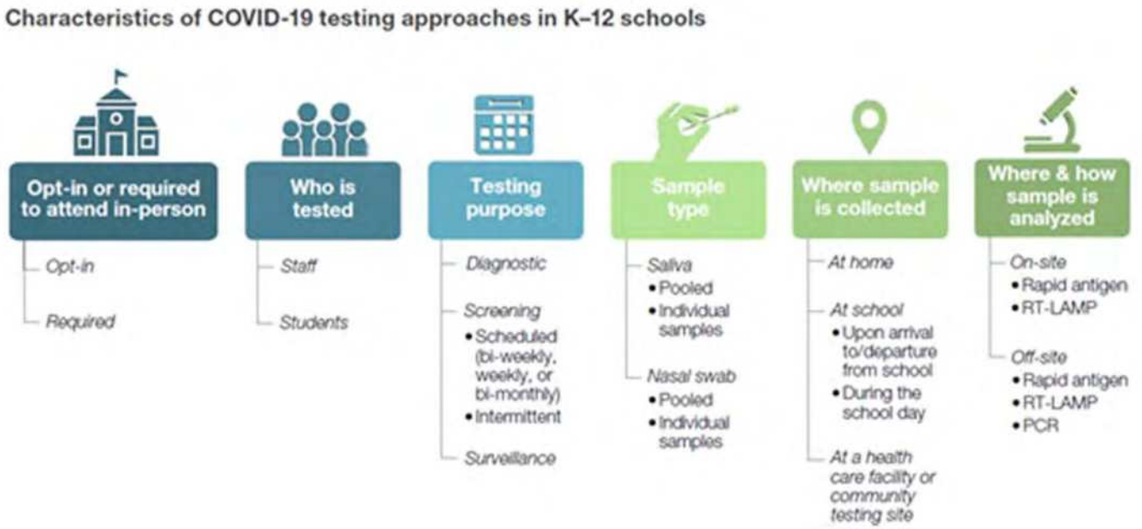


Figure Credit: COVID-19 Testing in K-12 Schools: Insights from Early Adopters, RAND Corporation, 2021:

Program Design

- **Purpose** (screening, diagnostic, surveillance)
- **Policy Approach** (opt-in, opt-out, mandatory)
- **Consent** (streamline, program)
- **Population** (students and staff; risk)
- **Participation** (demand creation, athletic programs, extracurricular activities)
- **Modality** (individual-pooled, pooled, point of care)
- **Test Type** (PCR, antigen, etc.)
- **Vendors** (service model, tiered)
- **Labs** (capacity, funding)

Photo Credit (right): COVID-19 Testing in K-12 Schools: Insights from Early Adopters, RAND Corporation, 2021:
Photo Credit (left): The COVID-19 Educational Testing Toolkit, Shah Family Foundation:

Considerations in Implementing Screening Testing in K-12 Schools

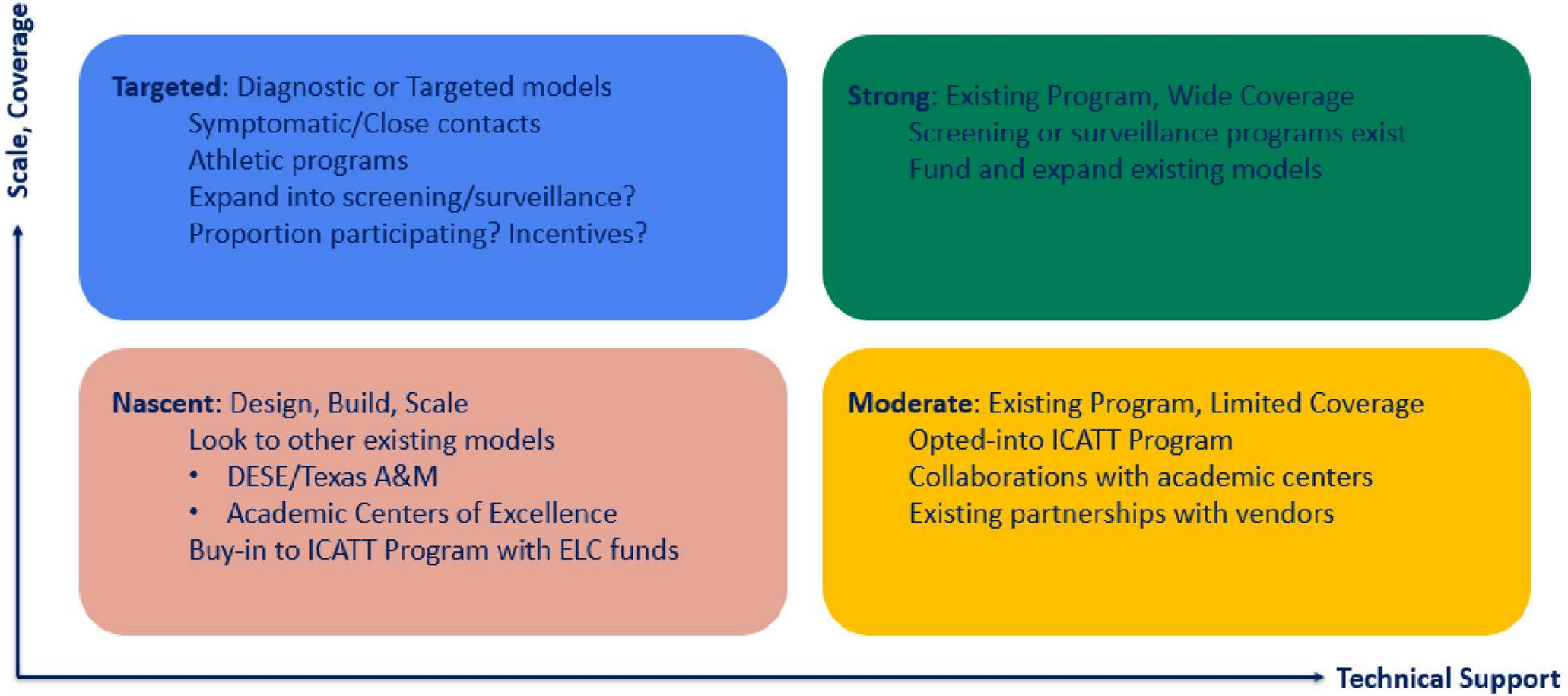
- Priorities for testing:
  - Teachers and staff
  - High school students, then middle school students
  - Elementary school students

- Prioritize access to testing in **schools that serve populations experiencing a disproportionate burden of COVID-19 cases or severe disease**.
  - Communities with moderate or large proportions of groups that experienced disproportionately high rates of COVID-19
  - Geographic areas with limited access to testing

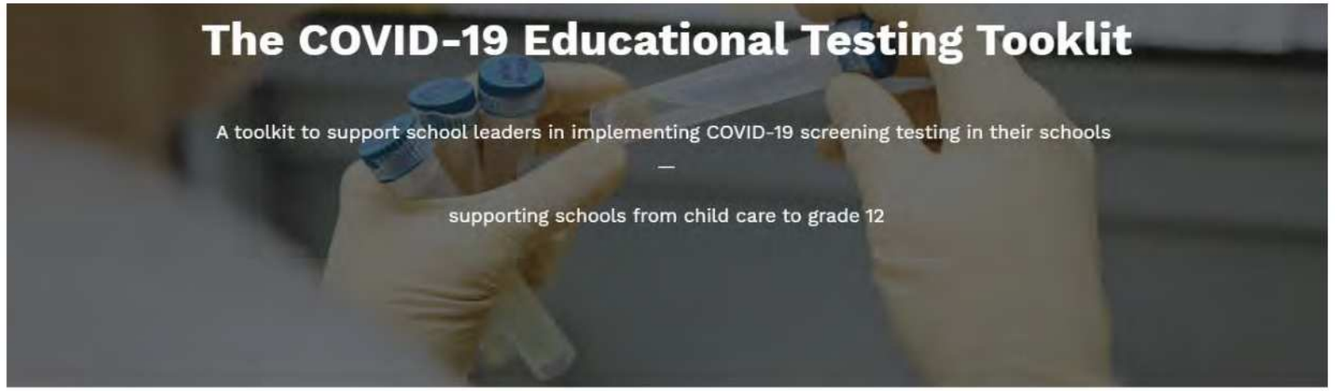
Elements Needed for Screening Testing in K-12 Schools

- Dedicated infrastructure, staffing, and resources to support school-based testing
- CLIA certificate of waiver
- Mechanism to report all testing results
- Timely reporting of results (<24 hours) is key
- Ways to obtain parental consent for minors and informed consent for adults
- Physical space to conduct testing safely and privately, protocols to maintain confidentiality of results
- Plans to confirm result of antigen testing need to be established

Level of Readiness: Starting, Scaling or Sustaining K-12 Testing



Tools and Resources



https://covidedtesting.com/

Early Adopters: Feasibility, Acceptability, Effectiveness

Academic Centers

- Massachusetts General Hospital (MGH)
- Children's Healthcare of Philadelphia (CHOP)
- ABC Collaborative
- Texas A&M

Community of Practice

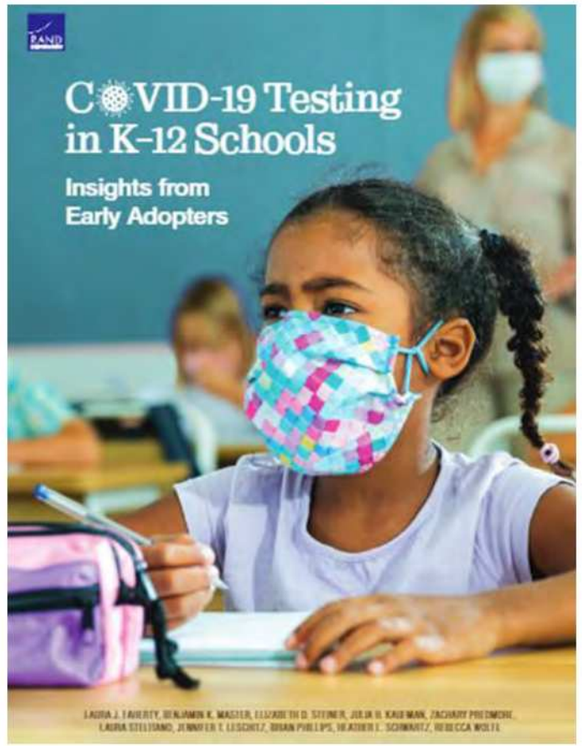
- 64 Jurisdictions
- School Fieldwork Section

Foundations

- Rockefeller Foundation
  - K-12 Testing Playbook
  - Resource Repository
- Shah Family Foundation
  - Educational Testing Toolkit
- RAND Corporation
  - Insights from Early Adopters

Innovation

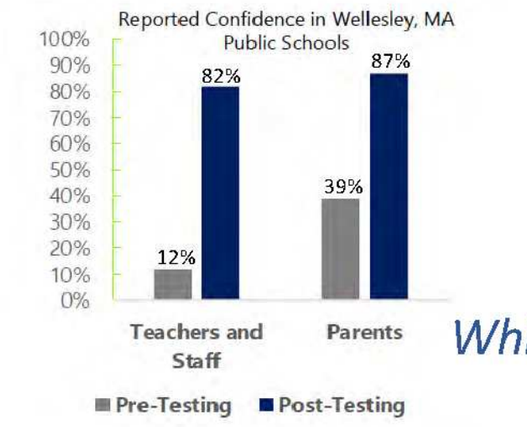
- NIH RADx-UP



Program Benefits: K-12 School Testing

Intangible

- Reassurance, confidence, trust
- Feel safer
- Increased comfort with in-person learning



Tangible

- Identify and isolate individuals with COVID-19
- Prevent ongoing transmission
- Identify and improve prevention measures
- School COVID-19 prevalence; transparency

Photo Credit: COVID-19 Testing in K-12 Schools: Insights from Early Adopters, RAND Corporation, 2021: https://www.rand.org/pubs/research_reports/RRA1103-1.html

*While half of families reported no perceived detriments, it is important address community concerns.**

*Doron et al. (2021) Weekly SARS-CoV-2 screening of asymptomatic students and staff to guide and evaluate strategies for safer in-person learning. BMJ Yale, medRxiv preprint: https://www.medrxiv.org/content/10.1101/2021.03.26.21.pdf

Building Stakeholder Confidence

Wide-spread adoption and participation relies on building confidence for participants by understanding their priorities and concerns. State and local leadership must proactively reassure and address the concerns of stakeholders.

	Superintendents	Teachers and Staff	Parents	Students
Priorities and Concerns	• All willing individuals are getting tested • Results are obtained quickly • Payments and funding vehicles are in place	• Keeping themselves and students safe • Preparing for when someone gets sick in school • Missing work when they test positive • Data privacy • Test collection safety	• Safety of children • Testing without parent/guardian present • Perceived Cost / Time of confirmatory test if applicable • Data privacy • Test collection safety	• Fear of getting the swab • Test collection safety • Stigma / lost school time linked to positive results
Actions to Build Confidence	• Set frequency and sensitivity standards • Provide easy to use consent forms • Provide central POC to ask questions	• Provide guidance on isolation and other mitigation strategies • Bring in trained people to administer tests • Be transparent about data privacy and use	• Provide information on getting confirmatory tests • Make consent easy to understand • Provide results quickly • Be transparent about data privacy and use	• Make the testing process as easy as possible to reduce stress and anxiety • Provide guidance on what do you if you're feeling sick

***Note: The Rockefeller K-12 Playbook provides a tactical communications plan to engage stakeholders including who is responsible for the communication.**

Figure Credit: K-12 National Testing Action Program (NTAP), Rockefeller Foundation:
https://www.rockefellerfoundation.org/wp-content/uploads/2021/02/The-Rockefeller-Foundation-Covid-19-K-12-Testing-Playbook-for-Educators-and-Leaders.pdf

School Subject Matter Experts

Jessica Gross

Lisa Barrios

Lessons Learned from K-12 Screening Testing Programs

Three Testing Models:

1. New York City Public Schools
2. Children's Hospital of Philadelphia - Regional Testing Program
3. Utah's Statewide Test to Play/Test to Stay

New York City Public Schools

- Continuously monitor school safety by testing 20% of asymptomatic students and staff physically present in school each day.
- Establish a joint coordination center of agencies working in school health to manage the complex process of continuously receiving, investigating, and acting upon COVID-19 cases.
- Voluntary testing creates challenges – need to actively encourage testing at school rather than in the community to reduce turnaround time, cost, and variability in quality of results.

Children's Hospital of Philadelphia

- Use point of care testing through a health order permitting schools to test under existing laboratory licenses
  - Simplified testing and analysis processes
  - Allowed for standardized training of staff conducting testing
- To meet resources needed for a large-scale testing program:
  - Worked with HHS and CDC to get rapid POC tests (BinaxNow; Que)
  - Used an app (STRAC) and data dashboard that allowed for timely, high volume reporting

Utah - Test to Play/Test to Stay

- Testing preserves in-person school days and extracurricular activities
  - **Test to Play:** rapid antigen testing every 14 days; required for participation in extracurricular activities
  - **Test to Stay:** school-wide testing when outbreak threshold is crossed; required for in-person learning
- Use consistent communication to gain family/community support
- Allow for time and resources needed to train staff and obtain large numbers of rapid antigen test kits
- Work with local health departments and school health partners to increase capacity to conduct testing and respond to positive test results

Summary of Lessons Learned

- School-based COVID-19 screening testing helps to:
  - Preserve in-person instruction and extracurricular activities
  - Reduce in-school transmission
- Recommendations:
  - Combine testing with prevention measures
  - Decide whether testing will be mandatory or voluntary
  - Assess inventory and training needs
  - Determine how test results will be reported and processed
  - Promote collaboration between agencies working on school health

Insight from the Field

Elizabeth Larsen Director of Strategy, MA COVID-19 Command Center

Natasha Bagdasarian Senior Public Health Physician, Michigan

Andrew Sweet & Mara Aspinall Rockefeller Foundation

Insight from the Field

Elizabeth Larsen Director of Strategy, COVID-19 Response Command Center, Massachusetts

Natasha Bagdasarian Senior Public Health Physician, Michigan

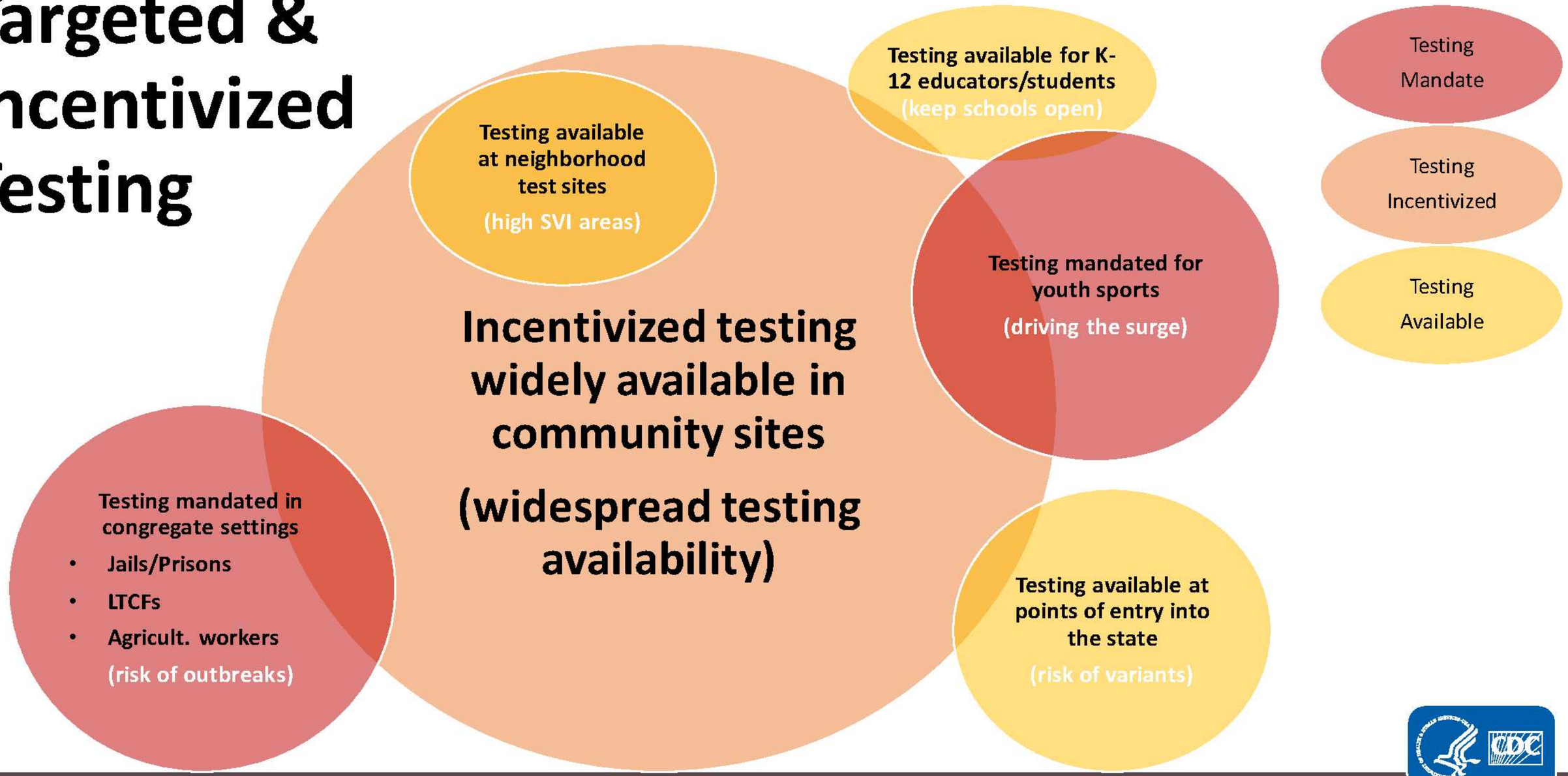
Andrew Sweet & Mara Aspinall Rockefeller Foundation

MI K-12 Testing Strategy

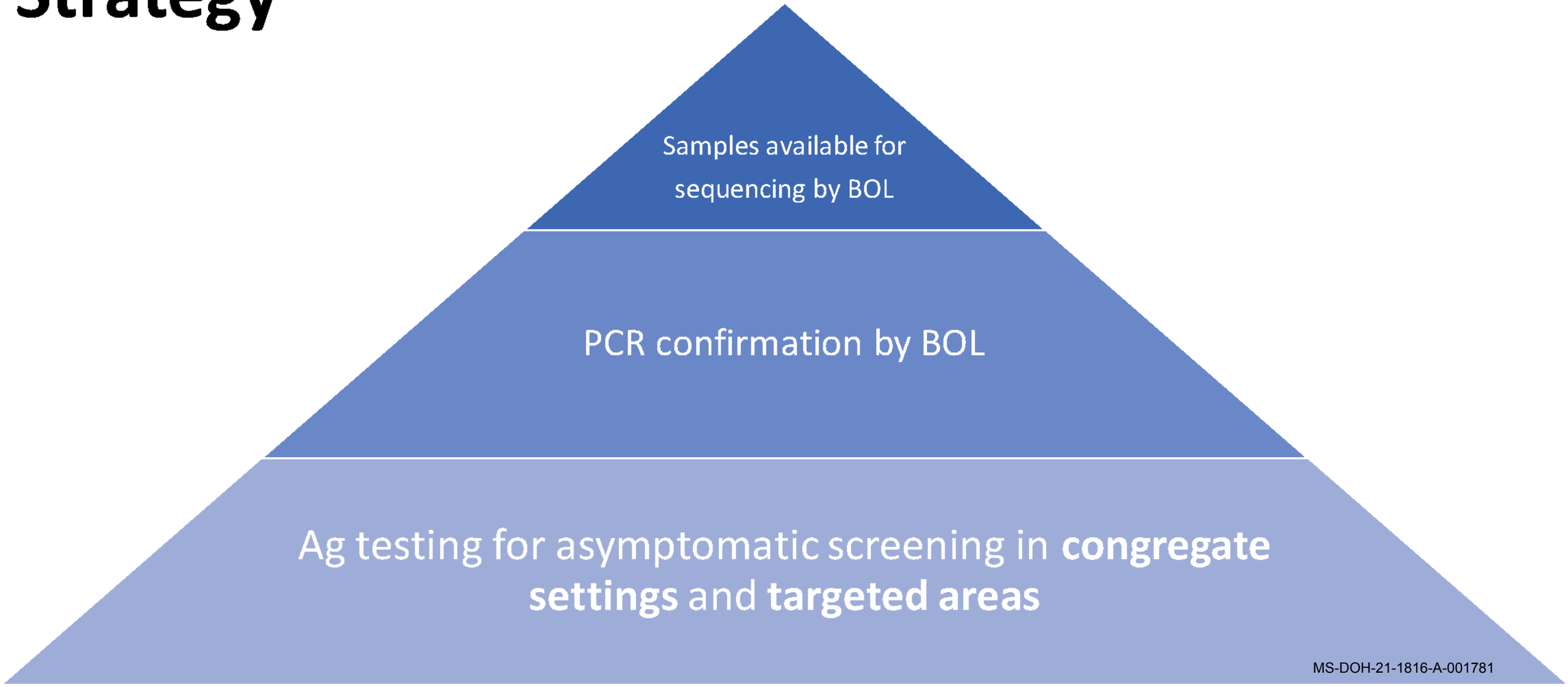
Natasha Bagdasarian MD, MPH

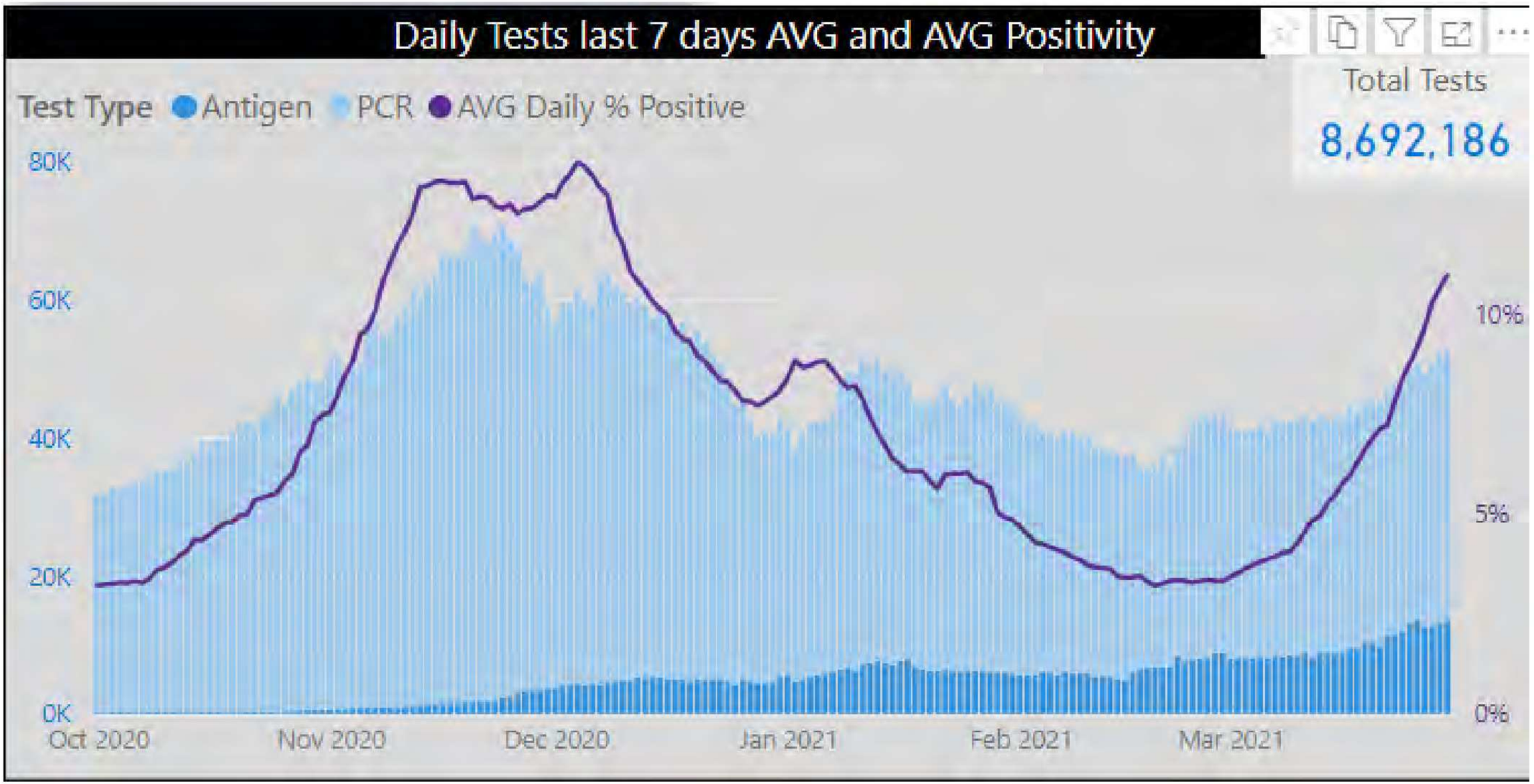
Senior Public Health Physician MDHHS

Targeted & Incentivized Testing



MI Overarching State Supported Testing Strategy

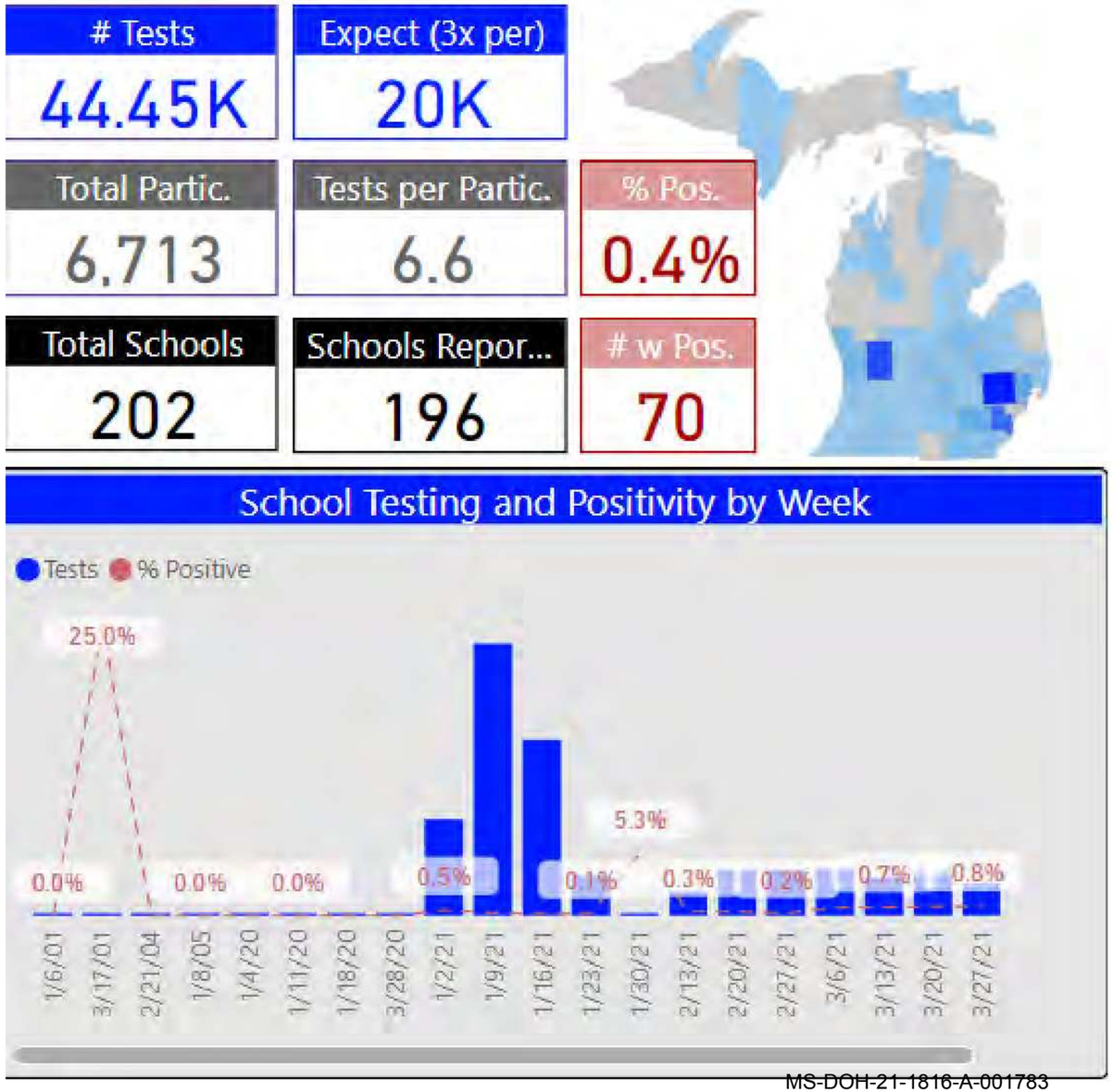



Daily Tests last 7 days AVG and AVG Positivity
Test Type
Antigen
PCR
AVG Daily % Positive
Total Tests
8,692,186
80K
60K
40K
20K
0K
10%
5%
0%
Oct 2020
Nov 2020
Dec 2020
Jan 2021
Feb 2021
Mar 2021

Fall Sports Testing Pilot –
Assessed feasibility of antigen testing in K-12

Barriers we worked through

- Supply chain
- CLIA Waivers
- Order for tests
- Biohazard
- Teaching non-medical staff to perform tests
- Reporting of tests

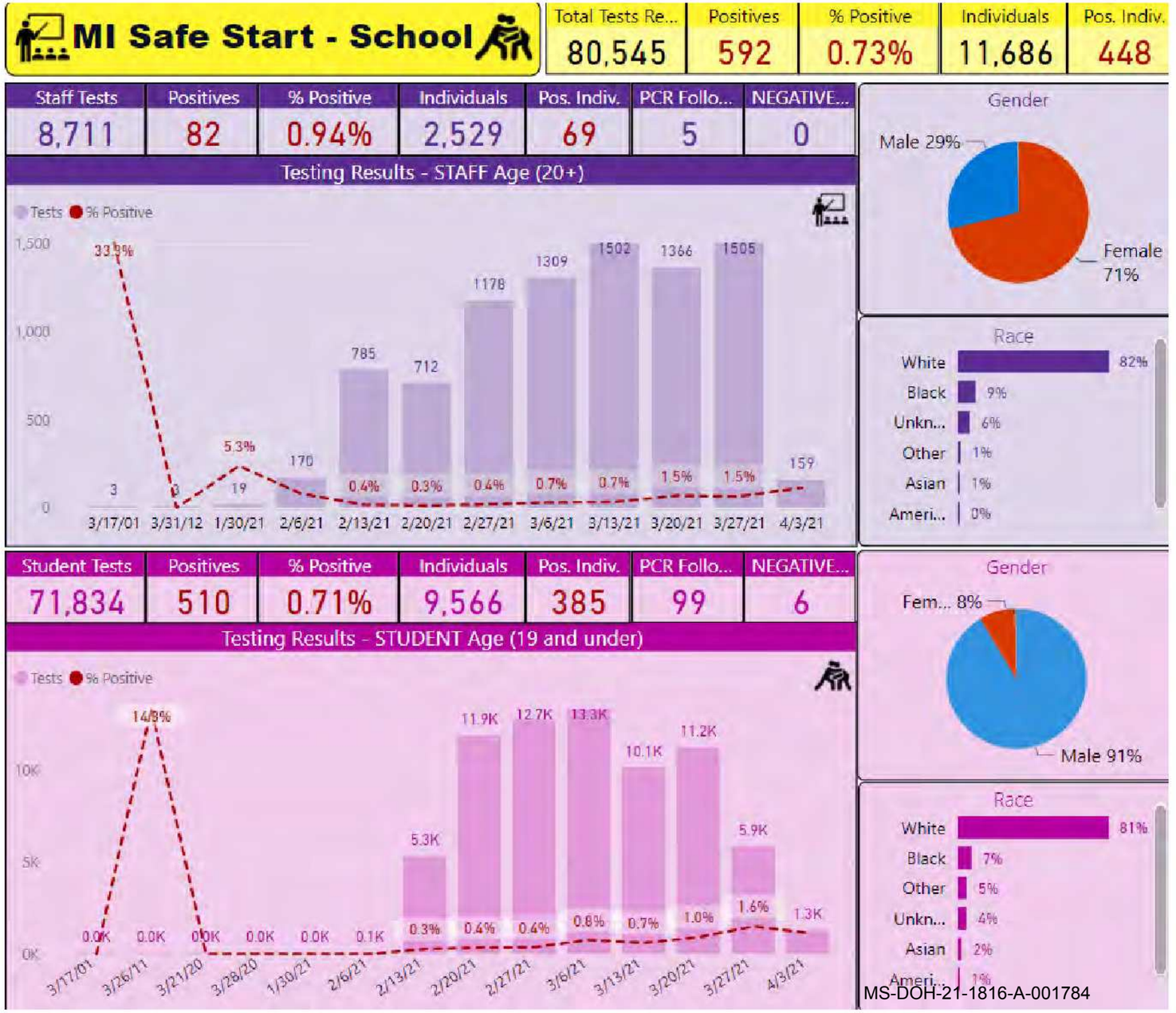


Winter Schools Testing Program

- Mandated for “mask-less” sports
- Available for other students/athletes/educators

Barriers

- Lack of participation where not mandatory
- Lack of cooperation with case investigation, quarantine etc.



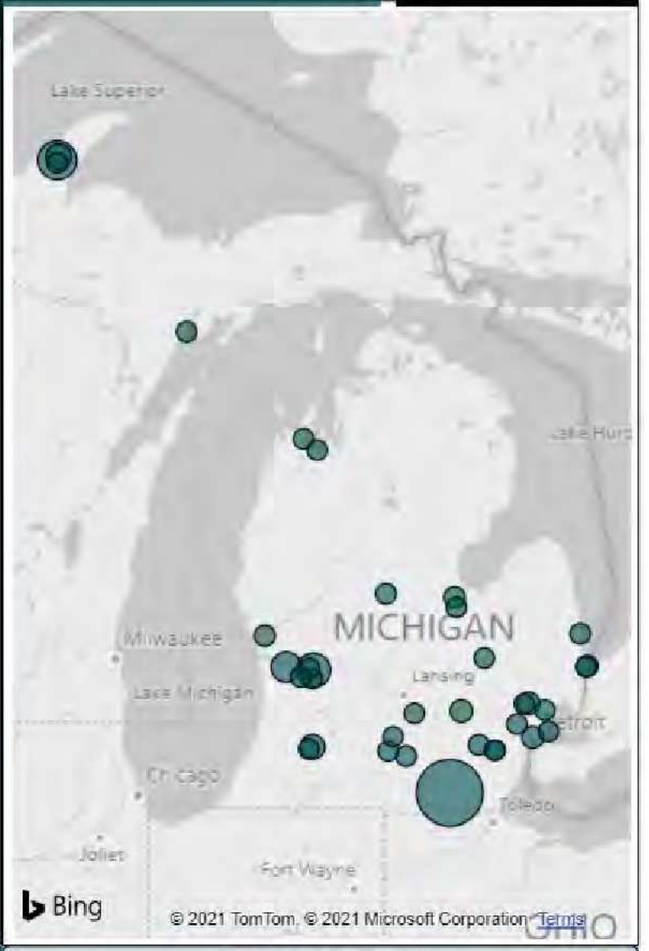
College/University Antigen Testing

Total Tests Re...	Positives	Positives	Colleges/Uni...
31,211	204	0.65%	22

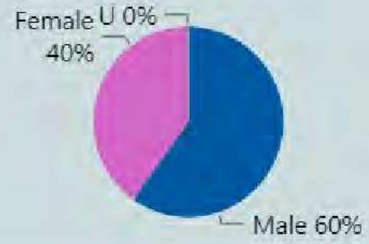
College/University: All

Week End Sat: All

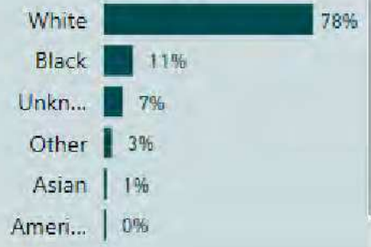
Testing Results



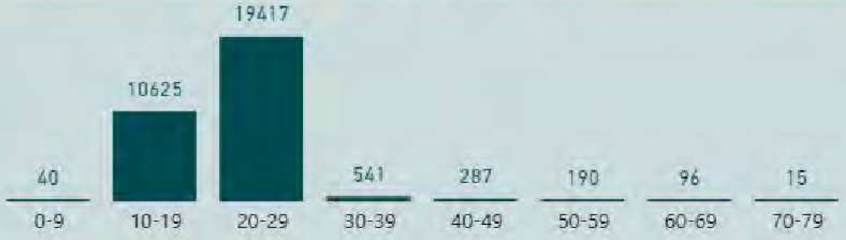
Gender



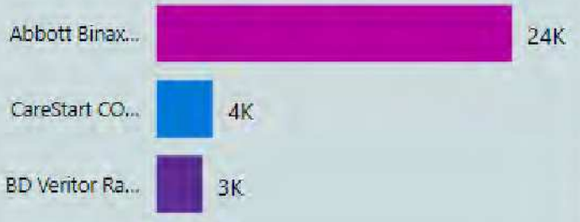
Race



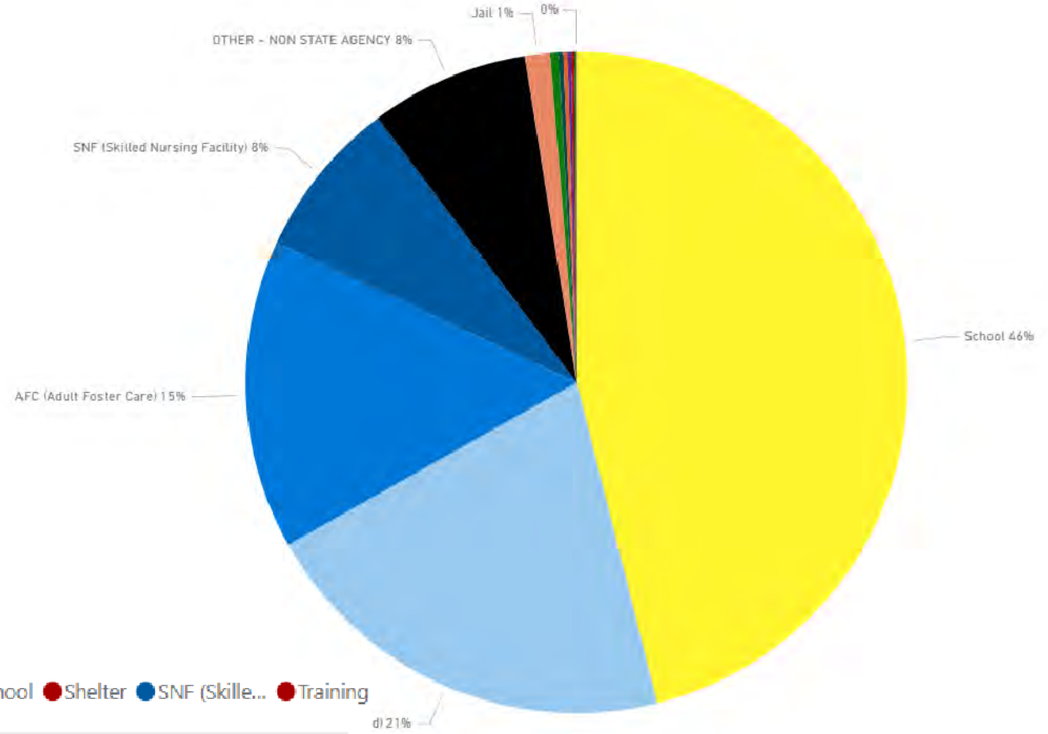
Results by Age Buckets

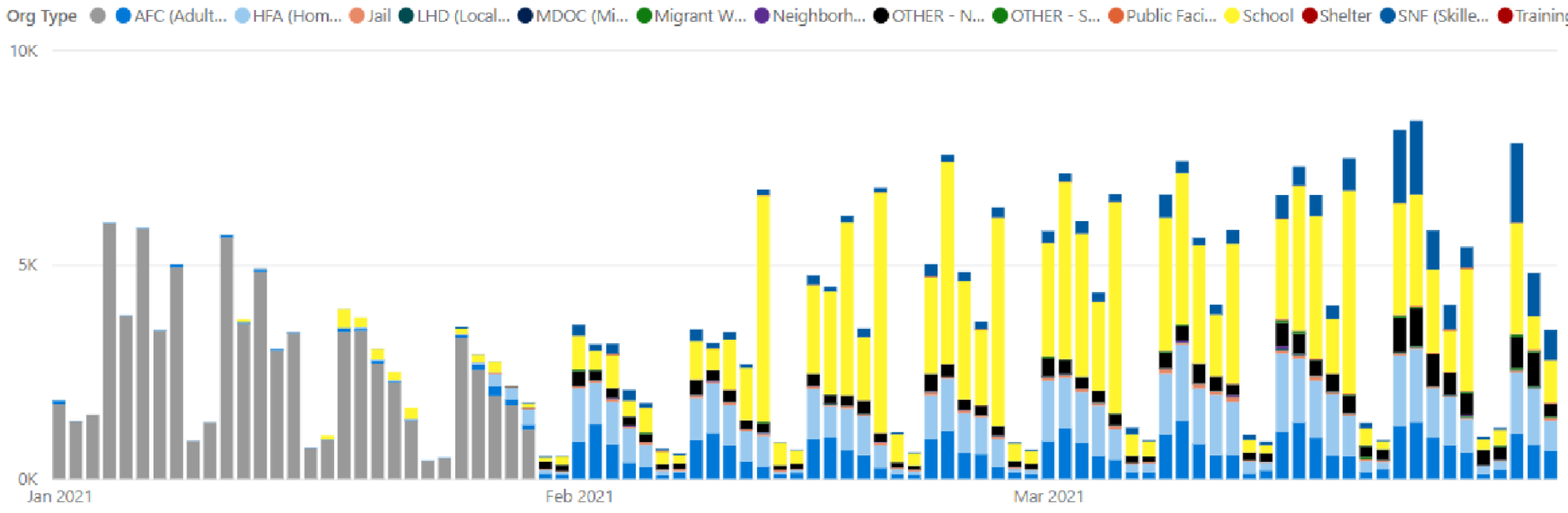


Antigen Test Types



Ramp Up of Antigen Testing Across MI





Insight from the Field

Elizabeth Larsen Director of Strategy, COVID-19 Response Command Center, Massachusetts

Natasha Bagdasarian Senior Public Health Physician, Michigan

Andrew Sweet & Mara Aspinall Rockefeller Foundation

K-12 NATIONAL TESTING ACTION PROGRAM (NTAP)

Connecting schools with the nation's leading testing companies to safely reopen

The ROCKEFELLER FOUNDATION

HEALTH CATALYSTS GROUP

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Context

- The K-12 National Testing Action Program (NTAP) is a plan to provide free Covid-19 testing for K-12 public schools to enable safe in-person learning

Situation

- Due to Covid-19, a majority of US K-12 public schools are operating remotely or in hybrid learning
- Online learning is not an adequate replacement for in-person school and is creating large education and socialization gaps

Complication

- Teachers, students and communities may fear the spread of Covid-19 in schools
- Schools are not fully equipped to provide necessary mitigation measures including testing
- While testing capacity exists, labs do not have a clear signal on how to make capacity readily available to schools
- The value of testing is getting lost amid the focus on vaccination

Question

- How do we safely and sustainably re-open the nation's K-12 public schools as quickly as possible?
- How do we make testing free, easy and widely available for schools?

Answer

1. ***Implementation of full safety and mitigation activities***
2. ***Prioritized vaccination for teachers and staff***
3. ***Weekly testing for students, teachers and staff***

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K-12 National Testing Action Program (NTAP) Summary (1 of 2)

The school changes stemming from the Covid-19 pandemic have significant impacts:

- Student learning, as well as mental and physical health, particularly for underserved populations
- Parent economic security, particularly for women
- Teacher well-being, including where they focus their money, time, and mental health
- The national economy, including billions of dollars of projected losses

K-12 testing programs can help reopen schools:

- Testing programs work to quickly identify positive cases for isolation, keeping school infection rates well below their local community. Schools are the safest place for kids and adults and are safer than the grocery store
- Logistics are feasible for public schools, both large and small. Testing protocols become second nature within weeks
- Testing dramatically increases confidence in re-opening for teachers and parents. We have seen confidence grow from about 20% to over 80%
- Federal actions provide funding & demonstrate the importance of testing as the "missing link" to re-open schools and get all students back for in-person learning

Re-opening schools safely this spring requires:

1. Safety and mitigation measures (masking, distancing, cohorting, etc.)
2. Teacher and staff vaccination
3. Regular and reliable testing of students and adults

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K-12 National Testing Action Program (NTAP) Summary (2 of 2)

Testing protocols are critical to program success:

- Step 1 - PCR 'pooling' or antigen tests with either anterior nasal swabs or saliva
  - Screening testing frequency is often once per week for students and up to twice per week for teachers and staff
- Step 2 - Follow-up diagnostic PCR or rapid antigen testing for individuals in positive pools
- Optional but recommended Step 0 - Test all participants as program begins

NTAP implementation and logistics requires diligent planning and partnership:

- Labs provide lab testing and logistics (including information systems) to schools and parents
  - Capacity for schools must be guaranteed and must not be reduced
  - School testing capacity must not reduce testing capacity or increase Turn Around Time for the general public
- All results must be returned to schools and test takers in 24 hours or fewer
- Costs for tests and additional test-related costs at each school are reimbursed by the state from their allocation of the $10 billion federal allocation of the American Rescue Plan Act for school testing

K-12 NTAP compilation team includes:

- Representatives from the nation's largest labs and test manufacturers with deep experience in Covid-19 testing for schools
- Representatives from the world's largest lab supply manufacturers with deep experience in manufacturing and distribution
- Representatives from information service providers
- In addition, the team met with school superintendents, principals, teachers and parents to inform the plan

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Acknowledgements

SONIC HEALTHCARE USA
A Division of Sonic Healthcare
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EXACT SCIENCES
Veritas The Genomic Company
CIC Health
GENETWORX
COVID-19 Response Advisors
Roche
labcorp
Helix
BD
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GINKGO BIOWORKS™ THE ORGANISM COMPANY
Sonora Quest Laboratories™
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Introduction and current K-12 landscape

Impact of school changes on students

- Impact on learning:
  - **25% decrease** in **post-educational learning potential** among ninth graders in poorest communities
  - Returning students expected to have only **63-68% and 37-50% annual learning gains** in reading and math respectively

Food insecurity and mental health:

- **169.6M** school meals missed weekly impacting **student nutrition** & **food security**
- **24%** increase in **emergency department visits related to mental health** for **children aged 5-11** and **31%** increase among **adolescents aged 12-17**

Minority Populations

In Washington D.C., the number of **Black and Latino children who met literacy benchmarks dropped by 12-14%** compared to white students, whose numbers dropped by 6%

Black and Latino students could experience **learning losses equivalent to 9-10 months** as a result of the pandemic

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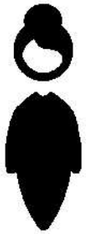
Sources: Washington Post , New York Times ,Yale, AERA, AJPH, CDC, The Atlantic, USDA, CDC, NYT

Impact of school changes on parents

70% of working parents
do not have access to regular caregivers, and their return to work is dependent on in-person schooling for their children

4 in 10 parents
say they have less job security due to the pandemic and fear being penalized because they have childcare responsibilities



4x more women
compared to men left the workforce as the new school year began due to students at home

Sources: Brookings, Catalyst, NPR

MS-DOH-21-1816-A-001796

Impact of school changes on teachers

3 in 4 teachers

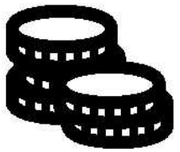
are working more hours during Covid-19 than before; of these, nearly **one in 5** were working more than 15 hours more per week during Covid-19

3 in 4 teachers

report their school or district does not provide adequate access to counselors and mental health support for both students and teachers

9 in 10 teachers

felt their expertise was not appropriately tapped by decision-makers in the transition to distance and hybrid learning; nearly half of these expert teachers said their expertise was not tapped at all



1 in 3 teachers

report spending more out-of-pocket money teaching under Covid-19 than before; one-quarter are spending more than $500 more than before

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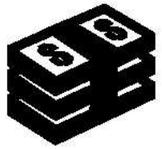
Source: National Board for Professional Teaching Standards

Impact of school changes on economy

$2.5 trillion

estimated cost to the U.S. in future earnings of four months of lost education – equivalent to 12.7% annual GDP



$350 billion

of lost revenue and growth could be reversed with the opening of schools, according to some estimates

13.8 million

Years of Life Lost (YLL) may be associated with the school closures during the Covid-19 pandemic

$64.5 billion per year

in lost wages and economic activity from women leaving the labor force and/or reducing working hours to assume caretaking responsibilities

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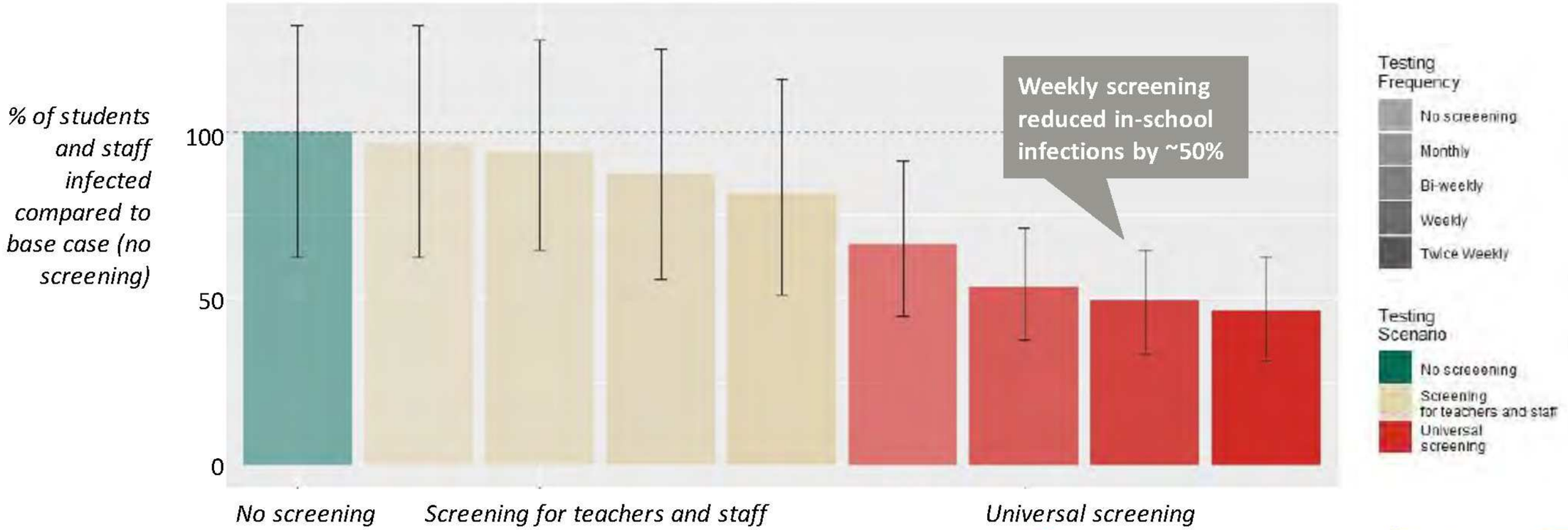
Sources: Brookings, USA Today, JAMA, Center for American Progress

Successful programs: testing works to keep schools safer

Regular testing in schools can reduce infection

Evidence from Mathematica and RAND Corporation, supported by The Rockefeller Foundation, found that **weekly testing** of all students, teachers and staff can **reduce in-school infections by an estimated 50%**

Cumulative COVID-19 infections among students and staff in high schools



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Source: Mathematica

School prevalence rates are 10x lower than community rates

Aggregate data across multiple schools and their contiguous communities shows **average school positivity is 0.25% to 0.5%** while surrounding **community positivity is ~ 7.23%***

NYC

0.53% positivity rate in K-12 schools

5.60% positivity rate in community

COLORADO

0.5% positivity rate among teachers

4% positivity rate across the state

CDC and others support a return to in-person schooling, citing low prevalence rate in schools as a key part of the justification

Disclaimer: It is important to note that community testing is an opt-in process, and the actual community positivity may be different

*Calculated by aggregating data collected by Ginkgo, CiC Health and JCM Analytics

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Sources: New York State Dashboard, NYC Dept. of Education Testing Report, USA Today, CDC

Testing brings student, parent and teacher confidence

"I feel **more safe now knowing solid facts** about who has it and that the people who have it are not at school. So, it's keeping everything safer." - *Parent*

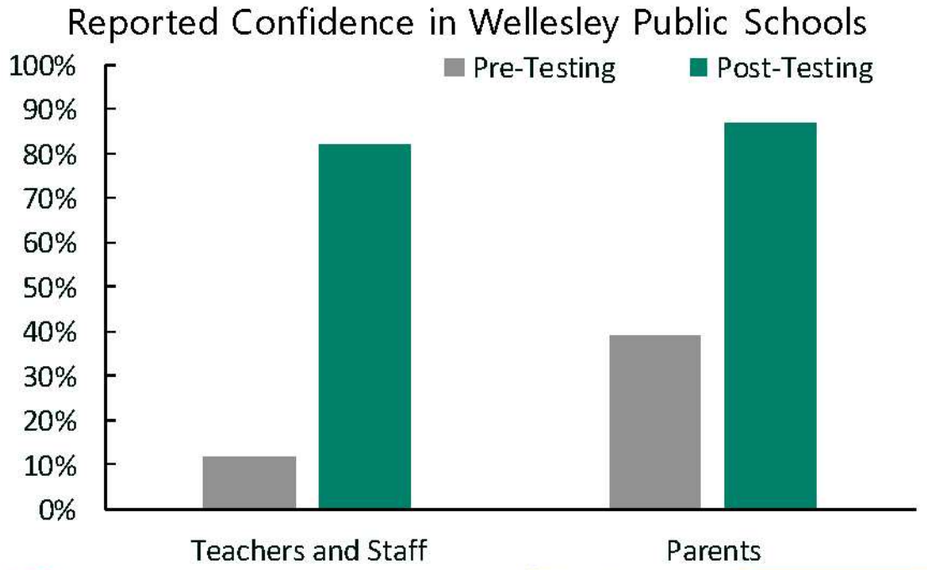
Participants strongly supported the use of testing to confidently return to in-person learning

WIS WASHINGTON INTERNATIONAL SCHOOL

UNITEDHEALTH GROUP

SURVEY RESULTS (% agree/strongly agree)	Parents	Students	Staff
Testing students, staff and teachers on a regular basis is important to ensure that school can remain open and the WIS community can be as safe as possible	91.8	95.1	92.6
Post-launch: I am open to being part of a pooled testing protocol once or twice a week, with an individual confirmatory test required if the pool is positive	90.3	93.4	98.8
I feel that students or teachers who refuse to be tested individually or as part of a pool on a frequent basis should not be allowed to attend in person classes	80.4	83.13	74.1

Baseline testing increased confidence of safety of in-person learning



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Sources: WBUR,WPS Viral Testing Information, Covid-19 Testing in K-12 Brochure, UnitedHealth Group

Successful K-12 testing: Massachusetts Schools (1 of 2)

Program overview:

- **Weekly testing** for every classroom across the state **(900K+ students)**
- Students and staff **self-swab** with a lower nasal swab
- **10+ swabs pooled together** and run using an accurate molecular test
- Samples processes at **local and regional labs**
- **Follow-up testing** for individuals in positive pools using Abbot BinaxNOW

Initial data:

154
school districts have rolled out testing

940 or 50%
of public schools participating

~13,000 tests
in first week of testing

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Sources: Boston Globe, Boston Herald, WPS Viral Testing Information, Mass. DoE

Successful K-12 testing: Massachusetts Schools (2 of 2)

Pooled testing in Massachusetts, a collaborative effort between the Massachusetts Department of Public Health and the Department of Elementary and Secondary Education with implementation support from the Shah Family Foundation, is the **first statewide pooled testing effort to offer weekly testing to *all* students, teachers and staff in public schools**. The program launched in January and schools are already testing students

Pooled testing offering:

- The tests are front-end or on-site pooling of swabs where roughly 10 swabs are put into one tube and sent to the lab for **less than $5/swab**
- **Rapid antigen tests are provided free to schools** to do follow-up tests of positive pools
- Vendors also provide individual PCR tests for **follow-up testing for $26.50-$85**
- The **state is paying for the first phase of the program through March 28** for any interested district. To continue programs, districts may use other federal funds

Operationalizing school testing:

- Most schools are **administering the program themselves** using nurses and other school staff to administer program and observe tests
- Some **larger school districts are contracting** with ambulance companies or bringing in nursing students to help with program administration

Key partners:

Massachusetts Department of Elementary and Secondary Education — Program design and outreach

Shah Family Foundation — Implementation support

Commonwealth of Massachusetts Department of Public Health — Public health guidance

Key learnings

- More districts, including more urban districts, are **returning to in-person learning with testing**
- Early data indicate that **positivity rates in schools are lower than community rates**
- Pooled testing is more **doable & manageable** than some might realize – it is very possible to implement the initiative within all kinds of districts
- It's essential for the state to establish critical components of this initiative – including **funding, a state contract list, and regulatory** enablement – but **districts need to have the ability to adapt** the model to reflect the strengths & challenges of local contexts
- It's very important to **aggregate resources**, examples and tools to streamline the process for everyone (e.g., common consent form in multiple languages, Covid Ed Testing website)
- High quality **parent engagement** is crucial
- It is vital to have **good vendor and inter-governmental partners**

The Rockefeller Foundation | Health Catalysts Group | CDC

Sources: Boston Globe, Mass. DoE, Mass DoE memo, Covid Ed Testing

Successful K-12 testing: NYC public schools

In September, BioReference embarked on a journey in collaboration with **New York City Health and Hospitals** to **bring school back** and help keep teachers and students safe **throughout the school year**

64 BioReference teams in the field
200 Schools per day
1200 Total schools

TAT **<38 hours**
209,790 students and staff tested to date
.47% positivity

1 Order → 2 Collect → 3 Transport → 4 Accession → 5 Test → 6 Report

-Turn-key operation that includes a pre-accessioning process, onboarding, training, scheduling, consent, collection and timely TAT
-PCR lab-based testing
-Multiple daily communications with city and school command center
-Minimal disruptions in schools including normalizing testing for younger students
-Daily analytics of results

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Sources: BioReference

Successful K-12 testing: District of Columbia schools

Current status:

All students and staff tested weekly

Over 605 samples from students and staff tested each event

7.3 people in the average pool

2 positive pools (1 faculty, 1 kindergarten) to date

WASHINGTON INTERNATIONAL SCHOOL

UNITEDHEALTH GROUP

Key learnings

- **Pooling in a pod is the most cost-effective** and sustainable method for testing
- Staff and older students can **self-swab**
- **Transparent communication** to parents, staff and students about importance of testing (in multiple languages) is critical
- Pooling-specific, cloud-based **information management** system should be used to effectively **track data**
- Clear **standard operating procedures** and setting up a governance structure is critical for success
- A **list of FAQs** should be created and updated as necessary to address staff and family concerns

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Source: UnitedHealth Group

Successful K-12 testing: Baltimore city schools

Baltimore city schools have been utilizing weekly testing with different systems for elementary, middle and high schools

CBS Baltimore

Baltimore City Schools To Offer Weekly COVID-19 Testing For Students, Staff

FOX 5 NEWS

Baltimore City Schools re-open with voluntary in-person learning

by Rachel Aragon | Monday, March 1st 2021

Current status:

- **~10K** students and staff tested
- **750+** pools
- **78** schools (soon to be 110)

Common characteristics:

- Weekly testing
- Parent consent is required for in-person learning, which includes Covid-19 screening/testing

Elementary and middle schools:

- Students and staff self-collect with lower nasal swabs
- 5-25 individuals pooled together
- Samples processed at local/regional lab
- Results ~24 hours from when samples arrive at the lab
- If a positive result, classrooms will quarantine for 2 weeks and follow up with individual PCR tests

High schools:

- Students and staff self-collect individual saliva samples
- Samples processed at a mobile lab in DC
- Results ~8 hrs from when samples arrive at the lab
- Individuals and close contacts will quarantine for 2 weeks if a positive result

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Sources: Concentric by Ginkgo, CBS Baltimore, Fox 5 News

Successful K-12 testing: Delaware public schools

- School testing in Delaware, a collaborative effort between the Delaware Health and Social Services and Department of Education, has successfully demonstrated a scalable, in-person, low-resource program utilizing BD antigen tests. This program started in a handful of public charter schools and has quickly expanded across the state with buy-in from parents, staff and administrators

Current status:

75+ public schools participating

33% of schools in Delaware

5,000+ students and staff tested

Easy to implement:

- Flexible program implemented by school staff. Estimated need for 2-3 FTE / 1,000 people
- Automated results reporting expected to simplify workflow further

Return to school:

- Positive cases have been identified without impacting school opening
- Schools see parents switching back from virtual to in-person education

Key learnings

- Prioritizing **communication** to all stakeholders throughout the process is key
- Students can be introduced to swabbing in a **drive-through environment** with parents nearby
- Focusing on **logistics** is crucial. **Walk-up service** may work well for older students, while **classroom service** may fit for cohorted and youngest students
- **Self-swabbing** under observation with oldest students improves throughput and logistics
- Clear guidance on obtaining **consent** and addressing **legal requirements** early is critical
- Continuous **feedback** from all stakeholders can make the program sustainable
- Objective **assessment of test results** minimizes staff confusion and improve logistics
- **Reporting and documentation** is a significant resource challenge. **Automating reporting** may save 2 FTE time

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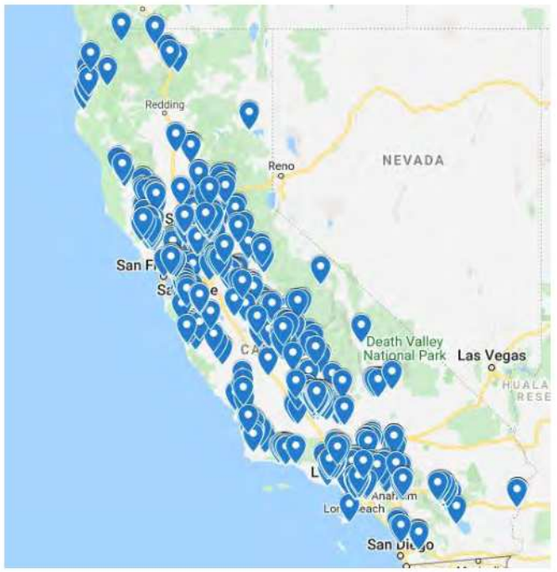
Sources: NCES, Delaware Health and Social Services

Successful K-12 testing: California schools

- A collaboration between Color and Perkin Elmer to provide access to high-quality, fast PCR testing for public and private schools throughout California started with a focus on testing staff and has expanded to include students and student athletes. The program led by the California Department of Public Health has supported statewide onboarding for all school districts and standardized a scalable model across diverse populations



Map of CA K-12 schools testing

10,000+

Schools eligible for program

1,600+

School staff trained

50,000+

K12 tests in less than 6 weeks

Key learnings

- Standardized, state-level onboarding of over **1,000 districts** helps provide **clean, school-level data to the state** for public health planning and interventions
- Creating plug-and-play processes such as **pre-assembled testing kits significantly reduces errors** during sample collection and increases scalability
- **One-time consent and HIPAA authorization** early is critical to streamline testing processes
- **In-house staff can be trained at scale** to support sample collection and program administration when coupled with easy-to-use software and centralized support infrastructure
- **Clear funding models help improve access** for underserved populations
- In addition to capacity requirements, key pieces of successful implementation also include **coordinated onboarding, shipping and information management** between testing partners
- **Simplified logistics** and consistent, easy-to-understand processes has supported **effective use of time and resources** and increased time spent in the classroom in K-12 California schools

Source: Color, California Dept. of Education

Successful K-12 testing: nationwide pilot with PCR pooling

Current status of Concentric by Gingko's pilot of **pooled testing** in over 130 schools across 11 states:

- **<15 minutes** to run a full-classroom collection
- **1000+** classrooms tested
- **10,000+** students and educators tested
- **32** positive individuals identified and isolated to reduce transmission

Kids feel empowered to self-swab, help their community, and teach others

> Swabs go "**Boogers down**".
>
> YORK ACADEMY

> You only have to go up to **the squishy part of your nose**.
>
> PARK STREET SCHOOL

> We have a jingle - "**1, 2, 3, 4 - switch it over, do 4 more**"
>
> SHARON PUBLIC SCHOOLS

> It's a **free chance to pick your nose**, and no one is going to yell at you.
>
> SHARON PUBLIC SCHOOLS

Key learnings

- Clear communication increases confidence among students, parents, teachers and administrators
- Streamlined and human-readable consent forms are vital for ensuring parent buy-in
- Build infrastructure (including registration portals) that can scale
- Streamlining school onboarding virtually (via a website and videos) enables rapid scale
- Minimized disruption to classroom is needed for adoption (<15 minutes and self-collection)
- Pod-pooling approach can work in a wide range of schools (multiple states, low-income areas, minority communities, etc.)

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Source: Concentric by Gingko

Successful K-12 testing: Cross-City Learning Group pilot sites

The Cross-City Learning Group was formed through The Rockefeller Foundation's partnerships with HHS, Duke-Margolis Center for Health Policy, Johns Hopkins University, Mathematica and **six cities/states willing to pilot testing programs**

Washington D.C.

8
learning hubs

Rhode Island

78
schools and learning education agencies

New Orleans

45
schools

Tulsa

70
schools

Louisville

12
regional testing sites

Los Angeles

60
Parks and Recreation centers

Key learnings

- Engaging early with district administrators and local partners can help gain their buy-in and support for identifying resources
- Clear communications, delivered by trusted leaders in the community, are needed to build community members' understanding of the program and encourage participation
- The testing approach should be designed using both evidence-based guidance and on-the-ground knowledge of what will be acceptable to students, parents, teachers and staff

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Sources: The Rockefeller Foundation, Mathematica

K-12 National Testing Action Program: Overview

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CDC

MS-DOH-21-1816-A-001812

What is the vision: K-12 National Testing Action Program

Testing is the missing link to K-12 schools reopening safely in-person this spring

Thus, the K-12 National Testing Action Program focuses on:

A. **Free and easy testing** for schools, kids and parents

B. Reliable and predictable testing availability for schools

C. **No reduction** of testing availability elsewhere in the country

D. Public and private **resources mobilized** and coordinated for sustainable capacity

E. A maximum **24-hour turnaround time** – from swab to results

F. **Simple procurement, funding and implementation** processes, including results reporting

G. Ability to **adapt and improve**, keeping pace with scientific advances

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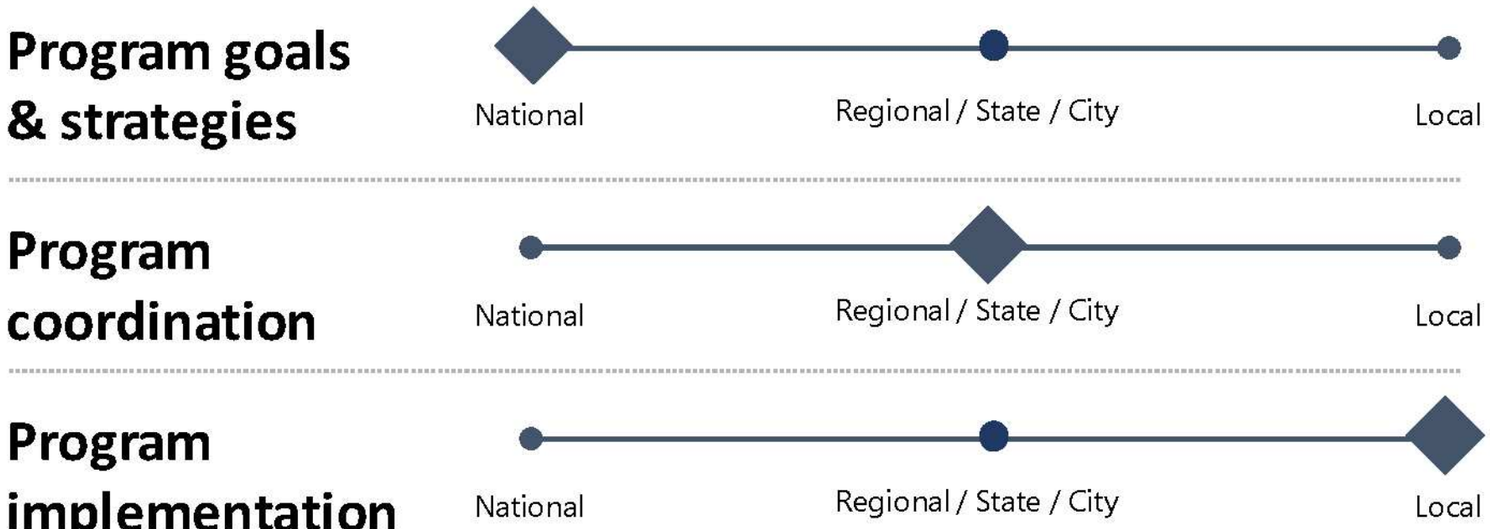
How does it work: national, regional and local collaboration

The K-12 National Testing Action Program is designed to be **federally guided, state/regionally coordinated, and locally implemented**, all with the aim to **support the safe reopening of 100% of K-12 schools**



K-12 NTAP will provide enough support to test:

- 100% of willing students weekly (per appropriate consent/assent)
- 100% of willing teachers and all staff up to twice weekly

"Everything should be made as simple as possible but no simpler" – Albert Einstein

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Key requirements for successful K-12 testing programs

Easy

Testing an entire classroom should take minimal time (e.g., ~12 minutes). Testing must be easy for students as young as kindergarten to do. Logistics should be streamlined and should not burden school staff

Effective

Testing should be accurate and give school communities data that provides them with confidence to maintain in-person learning

Accessible

Testing should be easy to access for every school and should be easily scalable to cover entire school districts

Affordable

The cost of testing should allow for every student to be tested every week. Federal funding may be leveraged to cover costs

How to choose a test: steps in the testing protocol

A strong testing protocol consists of three steps:

Step 0

Initiation testing *(if possible)*

When program begins – especially for schools in high prevalence areas – all students, teachers and staff should be tested individually or in small pods before regular weekly testing begins*

Step 1

Asymptomatic screening

High-quality 'pooled' PCR tests or antigen tests administered weekly to students and twice-weekly to teachers and staff

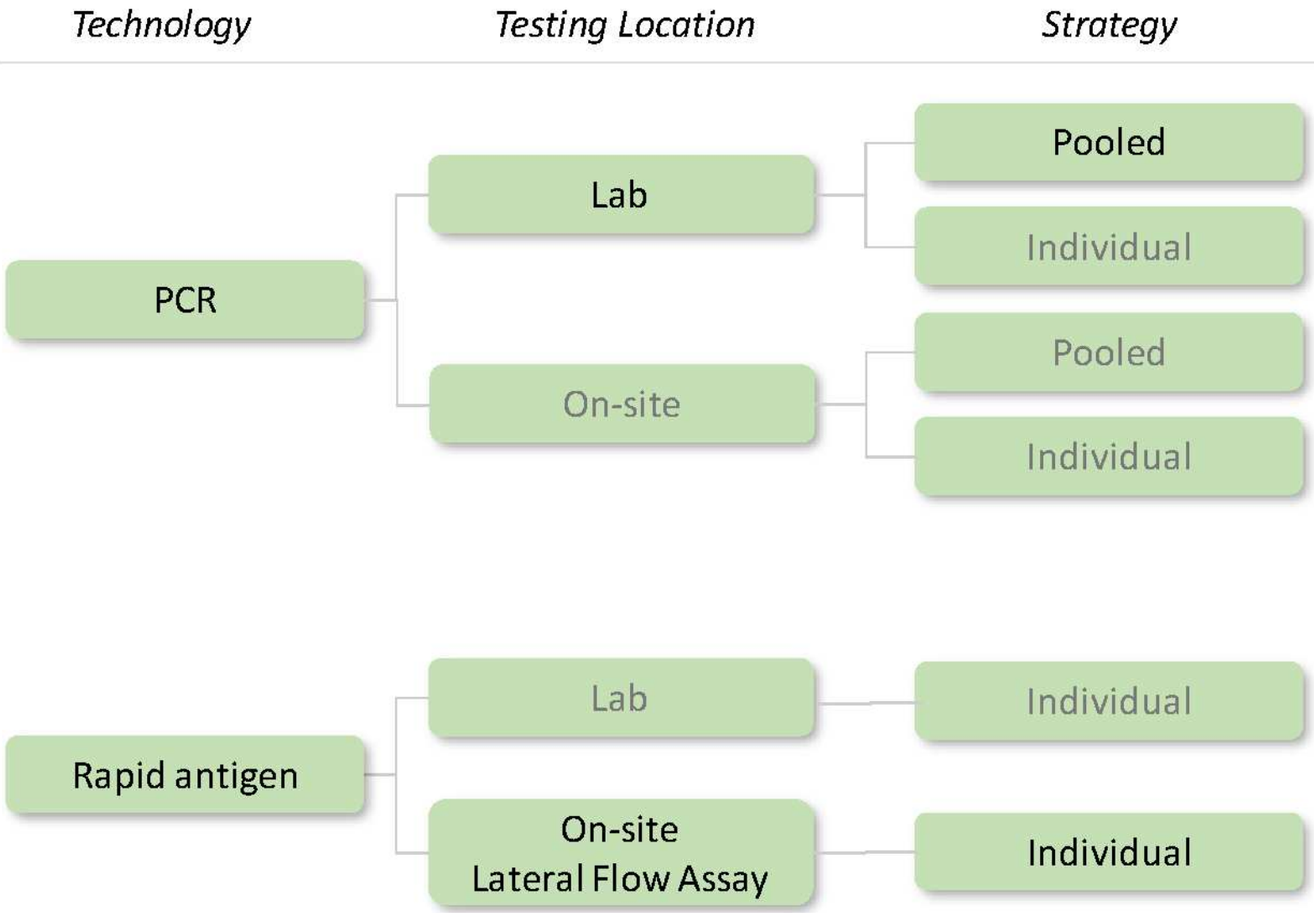
Step 2

Positive pool follow-up testing as required

For individuals in positive pools, provide individual PCR or antigen diagnostic tests: via at-home, on-site, clinic, lab or pharmacy testing

*While Step 0 is not discussed in further detail here, it is possible to leverage similar testing strategies to those described for steps 1 and 2. The purpose of Step 0 is to identify infected individuals before regular testing begins, which will make it easier to identify new cases moving forward.

How to choose a test: asymptomatic screening options (step 1)



Multiple testing technologies and systems will be needed to collectively meet school demand and diversify the supply chain. Common types of testing include:

Pooled PCR testing is recommended as the preferred option for routine screening testing. Samples are collected at the school and sent to a lab for processing. Data management handled by test provider.

Rapid antigen testing is recommended for routine asymptomatic testing of parts of a population or for diagnostic testing. Samples are collected at the school and tested on-site for fastest results. Data management is handled by provider, in-state or vendor-provided portals. Individual testing for screening can be advantageous if the number of cases is high in a school.

How to choose a test: follow-up testing options (step 2)

Step 2 testing options:

Follow-up test:

- Same Sample Reflex: Test provider can deconvolute a positive PCR pool directly with the initial saliva or nasal swab, most common with lab-pooling where part of each sample may be available for retest.
- New Sample Reflex: A new sample from those in the positive pool is collected and then retested.
- Rapid antigen test

Pre-paid coupon: Can be redeemed at a local retail pharmacy, clinic, testing lab or hospital to obtain proof of negative result to return to school

At-home kit: Can be used to self-collect a nasal swab or saliva sample and ship it back to a lab for testing. A pre-paid shipping label will be provided

Other sources: Collaboration with local Public Health Lab or university or other community labs may be used to get a confirmatory test using a pre-paid coupon

Benefits of the K-12 NTAP program

- ✓ Provides schools and families the **flexibility** to choose the right test option and location for them
- ✓ Improves **equity and access to confirmatory testing**
- ✓ Quickly allows students to get the confirmatory results required to return to school
- ✓ Optimizes use of **local testing resources** based on availability and preference
- ✓ **No cost to families or schools**

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PCR pooling: the evolution of PCR testing

The path from individual to pooled testing: what we've learned

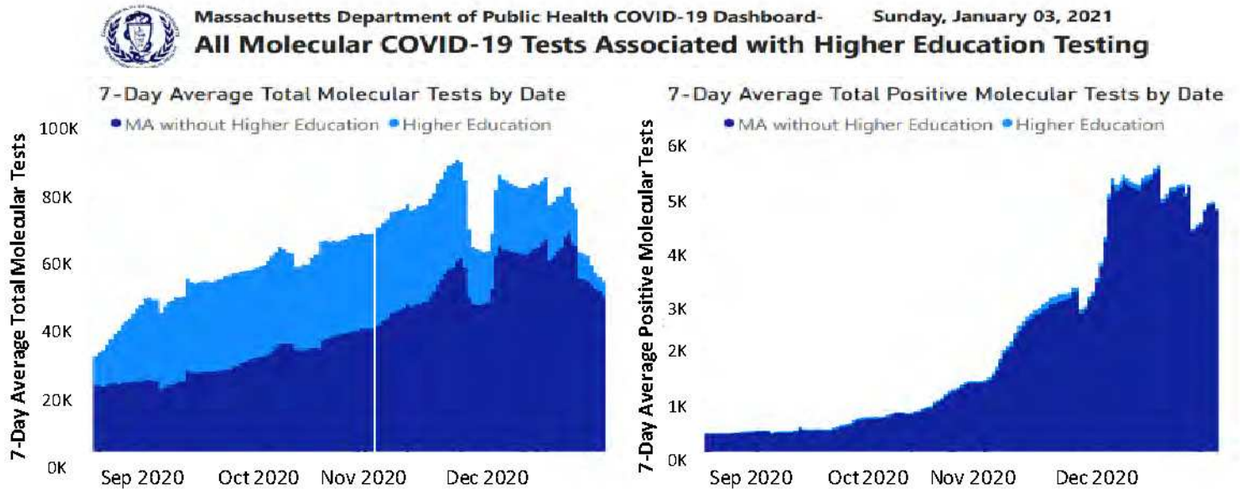
Colleges and universities demonstrate effectiveness of testing, infection control, and isolation measures by creating sub-communities with lower Covid-19 prevalence and test positivity rates than the surrounding communities

Tufts University implemented a **regimented individual PCR testing strategy** in partnership with the Broad Institute to obtain community prevalence data across campus sites

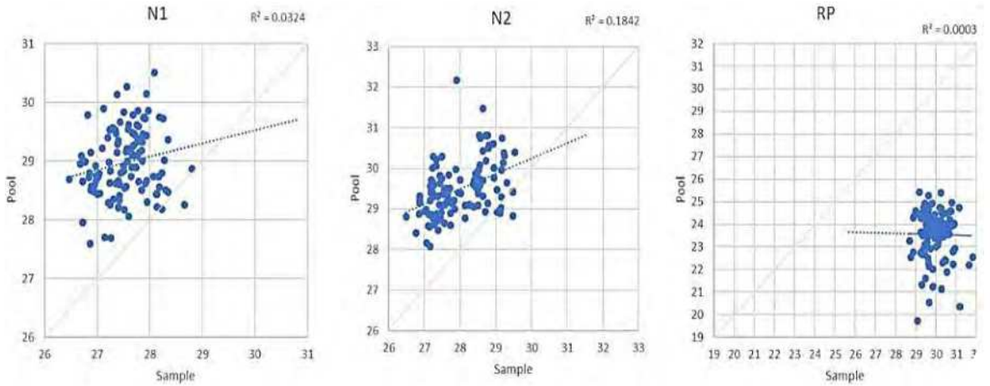
High costs limit the accessibility of repeated individual PCR testing for K-12 communities

Tufts University designed a **study of pooled testing to evaluate the specificity and sensitivity** of a pooled assay, which provides great confidence in identifying all positive individuals using pooling. Pooling becomes more popular in K-12 schools

While sample dilution was an upfront concern for pooling, as it could result in false negatives, pilot results from 1576 individuals (students, staff, faculty, etc.) **showed 100% congruence between pooled and individual results, no false negative results, and slightly elevated CT-values**



Data Sources: COVID-19 Data provided by the Bureau of Infectious Disease and Laboratory Sciences; Tables & Figures created by the Office of Population Health. Note: All data are current as of 11:59 PM on 1/2/21. Due to lag in reporting by labs, counts for most recent dates are likely to be incomplete. This includes individuals who have had more than one molecular test



Ct results comparing pool Cts (y-axis) with the Ct value of the corresponding single positive sample (x-axis). Each graph represents a different probe; N1 and N2 detect regions of SARS-CoV-2 virus RNA while RP represents host genetic material abundance. Blue line: trendline of data; grey line: y=x bisector.

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Source: Massachusetts Dept. of Public Health Covid-19 Dashboard of Public Health Indicators; Pooling for SARS-CoV2 Surveillance: Validation & Strategy for Implementation in K-12 Schools

PCR pod pooling: how it works

Classroom pooling

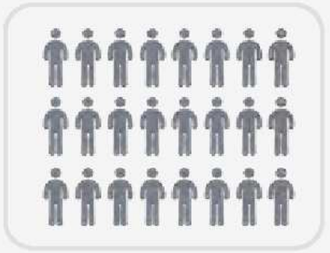
All students and teachers in a pod **swab their noses** with short swabs (think: cotton swabs). Swabs are placed in one tube (this is the "pooling" step). This pool is then run as a single test at a local lab.

Key benefit: **groups of 25 people can be tested using one test**. For a school of 500, only 20 tubes must be collected and managed, instead of 500 when testing individually.

Only positive pools result in further action. Next steps are decided by the school.

STEP 1 - **Pods self-swab**

Individuals in a pod (e.g., classroom) self-swab and place swabs into a single tube. Takes minutes to complete for an entire pod



STEP 2 - **Test the pools**

Each tube is then run using one test at a local lab, and the classroom is provided with one result

STEP 3 - **Get results**

Results can be used by schools to make more informed decisions, detect the virus earlier, and mitigate spread

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PCR pod pooling: testing options following a positive pool

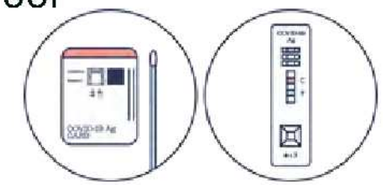
What happens if there's a positive pool?

The solution will look a little different for each school based on unique circumstances. **However, K-12 NTAP recommends all follow-up testing be fully government funded to ensure equitable access and fast results, with no additional administrative or billing burden.**

Approaches for follow-up testing:

School-based testing (preferred option)
Rapid antigen tests or on-site collection for lab-based nasal or saliva tests administered at school

At-home testing
Self-collected nasal or saliva sample sent to labs for testing using pre-paid shipping



Pre-paid coupon
Coupon redeemable at local pharmacies, clinics, testing labs or hospitals to obtain proof of negative result to return to school

Community-based testing
Tests administered at pharmacies, clinics, doctor's offices, community centers or other publicly accessible sites

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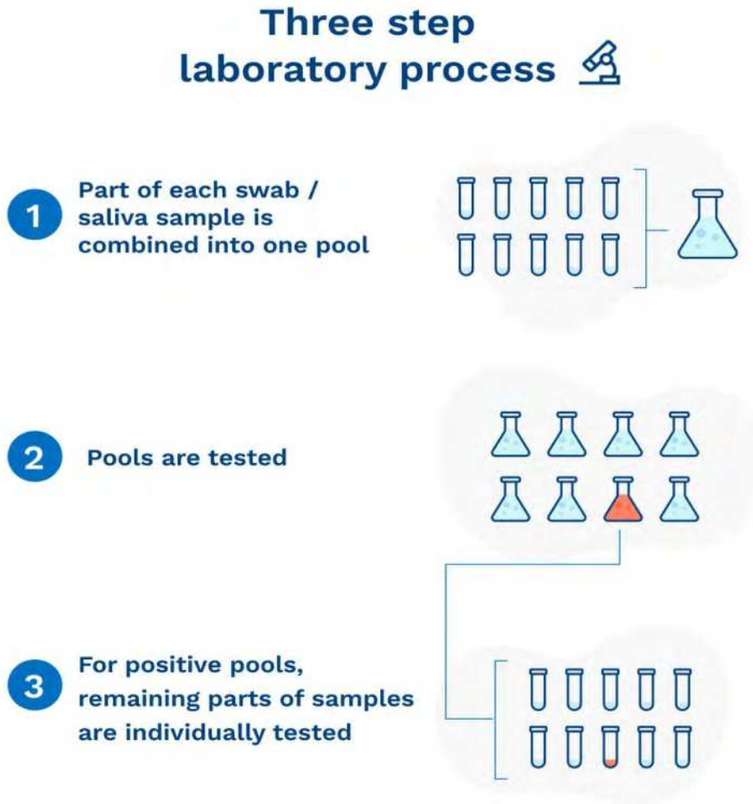
PCR in-lab pooling: how it works

In-Lab Pooling

All students and teachers **swab their noses** with short swabs (think: cotton swabs) or **produce saliva samples** samples in individual tubes. Tubes are sent to the lab where part of each sample is combined with other samples to form a pool. This pool is then run as a single test at a local lab.

Key benefits: school can benefit from the efficiency of pooled testing **without the need for separate follow-up sample collection**. It also allows for the use of tests with **at-home sample collection options**, which can minimize the operational burden on schools



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PCR pooling: sensitivity

Studies comparing the sensitivity of pooled versus individual tests confirm that **PCR pooling is more than sufficient** for asymptomatic screening tests and has **similar sensitivity to individual**

BROAD INSTITUTE

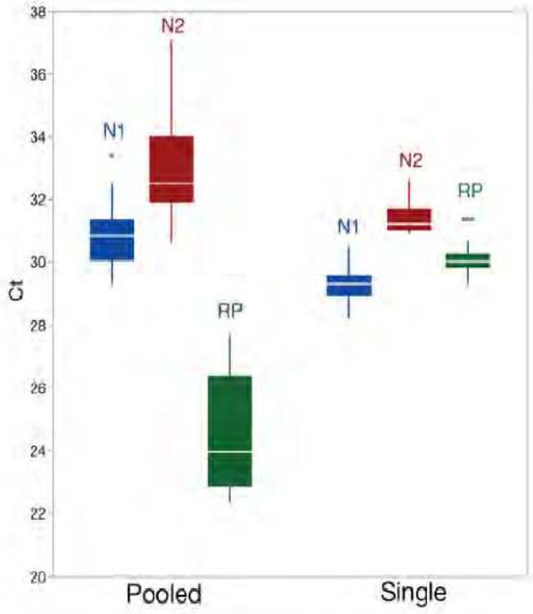
A study conducted by *The Broad Institute* found comparable levels of detection when samples are pooled or individually tested

Results show that the sensitivity was comparable for pooled and individual/single samples

Notes on the graph:

- *10 samples* were pooled together to compare sensitivity ***N1 and N2*** samples look for Covid-19 virus genome and ***RP*** samples look for human genome (control)
- A lower Ct value means a higher amount of virus genome is present
- The RP Ct is significantly lower in the pool as expected since human genomic material is present on both positive and negative swabs

Pooled vs individual testing sensitivity



UNITEDHEALTH GROUP

A study by the *UnitedHealth Group* showed pooled testing had comparable performance to individual PCR testing

Results show that up to 15 samples could be pooled together to reduce costs and supplies while maintaining accuracy of results

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Sources: Pooling for SARS-CoV2 Surveillance: Validation and Strategy for Implementation in K-12 Schools, Bethany L Hyde, Ethan Berke, Prat Verma

Rapid antigen: how it works

Rapid antigen testing

Students and teachers have their noses swabbed with short swabs. Each swab is applied to a test card or cassette and allowed to run for the appropriate amount of time.

Each person tested has their own test. For a school of 500, a total of 500 tests are needed to test everyone.

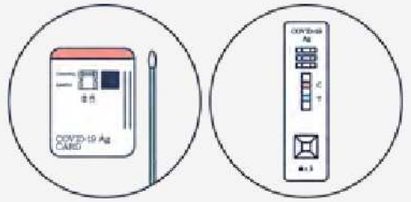
Once the necessary time has elapsed, **trained staff interpret and record each result**. Positive results are communicated to the individuals and families.

STEP 1 - **Individuals swabbed**

Individuals are swabbed either by a trained staff member or a healthcare professional

STEP 2 - **Test each swab**

Each swab is applied to a test card or cassette by a trained staff member or healthcare professional



STEP 3 - **Get results**

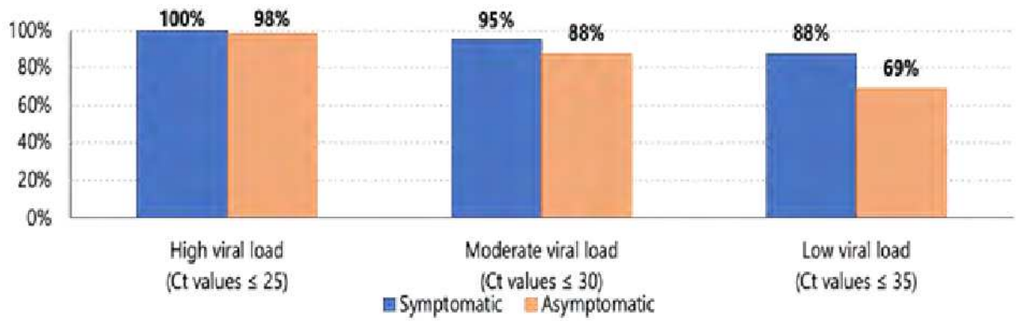
Results are interpreted and recorded by a trained staff member or healthcare professional. They can be used to make more informed decisions, detect the virus, and mitigate spread

Test Result:
Negative

Rapid antigen: use for pool deconvolution

Given the speed, accuracy, price and widespread availability, some schools are using **rapid antigen testing as a way for recommended follow-up testing** to support the pooled test program

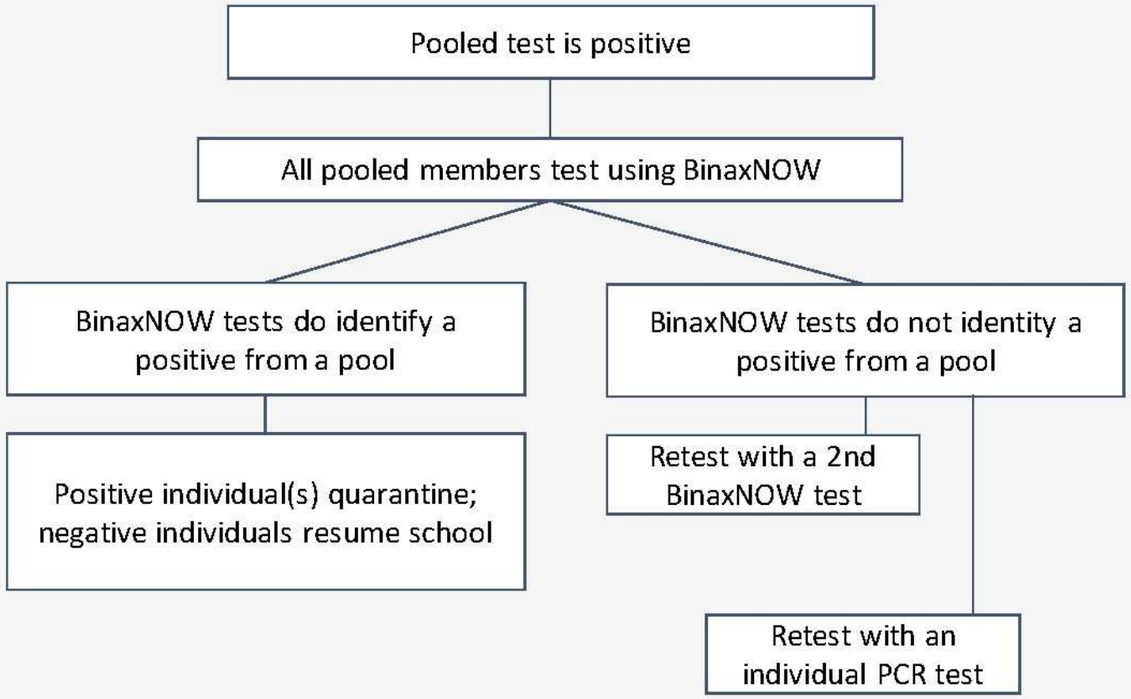
Percentage of positive PCR tests accompanied by a positive BinaxNOW test, by viral load
All other results were false negatives (PCR positive & BinaxNOW negative)



When compared to PCR tests, BinaxNOW is **accurate in detecting COVID-19 in children with moderate to high viral loads,** even if they are asymptomatic.

These children are the most likely to be highly contagious and transmit the disease.

One potential follow-up testing approach
Example: BinaxNow in Massachusetts



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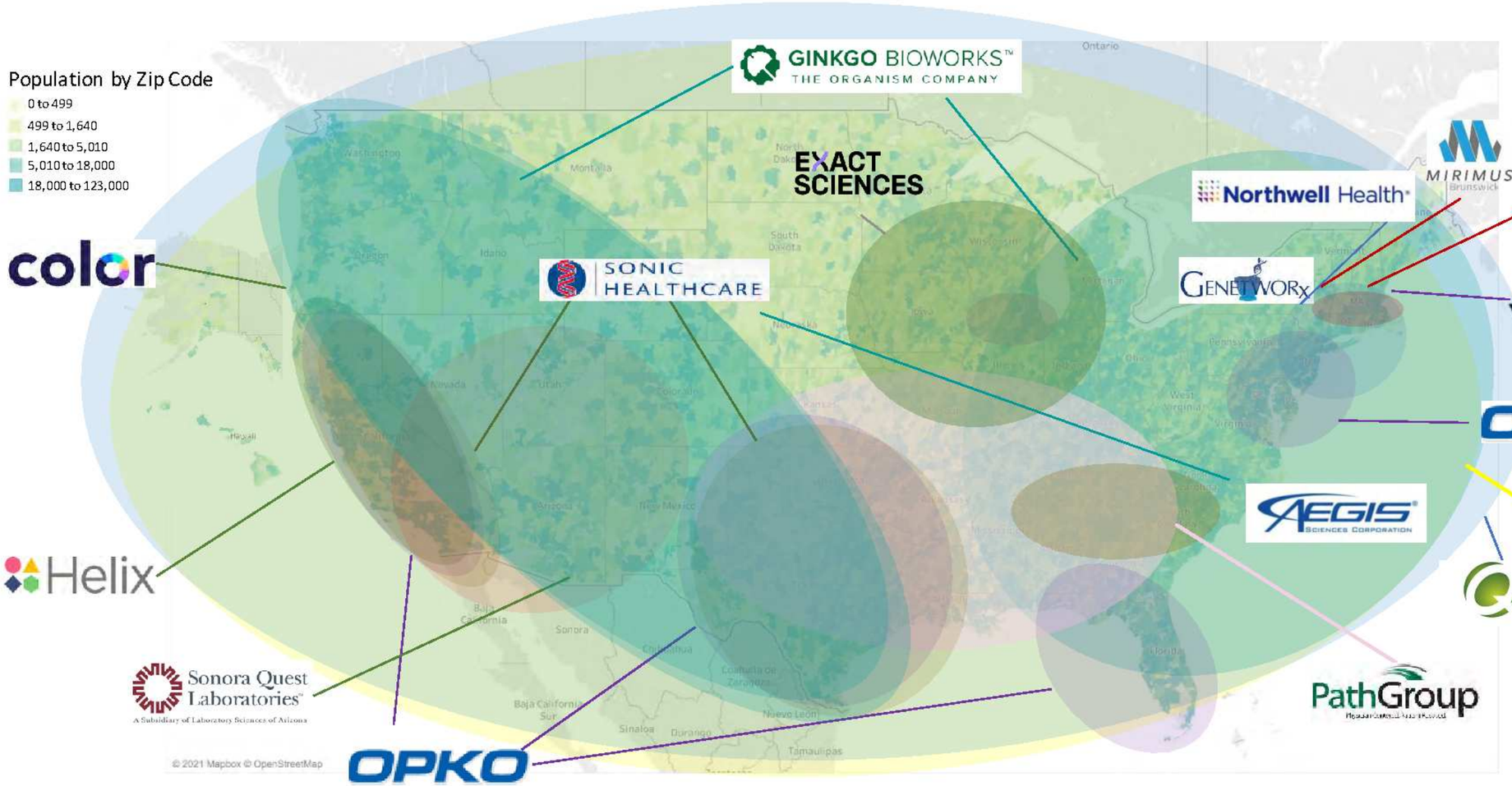
Sources: Massachusetts Department of Elementary and Secondary Education, BinaxNow Study, Covid Response Advisors

Who provides testing: testing footprint for scaling K-12 testing



Antigen Test Suppliers

- QUIDEL
- BD
- Abbott

Note: Lab coverage areas are approximate within national map. Additional coverage possible through public health and university labs

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What will it cost: all-in cost estimates and assumptions

ALL-IN COST PARAMETERS

$30 per person for Step 1: asymptomatic testing

$10-15 per person: pooled PCR or antigen tests
$15-20 per person: school administrative costs

$60 per person for Step 2: positive pool follow up

$40-50 per person: individual PCR or antigen
$5-10 per person: school administrative costs

ASSUMPTIONS

Per person testing costs, including school administrative costs, are estimated from current operations in school testing programs

Assumption that ~1% of pools are positive and require deconvolution / Step 2 testing

Note: These numbers are included as an illustration of current market conditions. As more testing vendors enter this market, we expect the resulting competition will drive prices down.

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Source: Testing for America; estimates include PPE, logistics, software, labor, and overhead

K-12 National Testing Action Program: Implementation Logistics

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CDC

MS-DOH-21-1816-A-001828

Minimum standards for program success

STANDARDS FOR SUCCESS

A. School and community alignment and engagement

B. 'Right test, right place, right time'

C. Necessary supply of tests, supplies and other resources

D. Resources to administer and process tests efficiently and effectively

E. Clear public health guidance and resources for every stage of the process

F. Reporting and data systems

G. Regulatory support

H. Ensuring equity and broad access

Minimum standards help ensure quality testing programs are available to all students, teachers and all staff, while still allowing the schools flexibility to design and customize their programs based on their unique context and needs

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Program minimum standards (1 of 2)

A. School and community alignment, engagement and education

- School committees, superintendents, teachers, unions and families should understand the goals of the testing program and how it helps to safely and sustainably reopen

B. ''Right test, right place, right time" (pooling or individual testing strategy)

- A standardized menu of testing protocols and workflows should be designed for schools that offer 24-hour results to test takers
- Testing programs should screen students and staff at a frequency that prevents outbreaks and enables the quarantining of individuals who test positive

C. Necessary supply of tests, supplies and other resources

- A stable and reliable supply of tests with a consistent process and result reporting should be available
- Fulfilling school demand nationally requires multiple types and sources of tests

D. Resources to administer testing programs efficiently and effectively

- Testing service providers should manage procurement, contracting and onboarding with individual districts and schools
- Testing playbooks and toolkits can explain how to roll out and manage a testing program at the district or school level
- Testing lead or coordinator should be appointed for each school; potentially a school nurse, school administrator, district administrator, or USPHS Commissioned Corps

E. Clear public health guidance and educational resources for every stage of the process

- Easy-to-understand rationale for and explanation of testing protocol is critical
- There should be an explanation of how schools and families should react to a positive case in school or in household
- Situations that necessitate confirmatory tests require some guidance
- Protocol for quarantine and return-to-school should be published

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Program minimum standards (2 of 2)

F. Reporting and data systems

- Aggregate pool results should be reported to school, parents and students; tracking should be facilitated by online secure software products
- Any positive individual diagnostic results – whether antigen or molecular -- should be reported to local public health authorities per existing public health laws and facilitated by HIPPA-compliant software products
- Test results are intended to keep school open and are not aimed at individual diagnostics

G. Regulatory support

- Standard consent for adults and students is necessary, including release of personal health data as appropriate
- A quick and easy option is to have schools designated as CLIA sites for POC testing when relevant
- It can be useful to have a standing physician order to authorize individual diagnostic tests under school testing protocol

H. Ensuring equity and broad access

- All public schools and districts are encouraged to participate in program
- Testing programs should be offered at no cost to schools or participants or families
- State and local customization can provide varying levels of support for school districts with differing needs
- Test demand forecast can be created on objective factors (# students, ages, geographic densities et. al.)

What do schools do: rubber hits the road – operation overview

There are 4 key steps to executing K-12 NTAP, but each component within the key steps must be designed and executed based on individual needs of the school

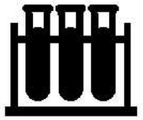
Key steps

1) Coordination & administration	2) Testing modality selection	3) Facility set-up	4) Results reporting
• Establish key positions & roles • Hire, train and build partnerships • Receive authorization and registration for testing	• Choose testing partner(s) • Finalize protocols for Step 1 Asymptomatic Screening and Step 2 Follow-up Testing for positive pools • Decide on Initiation Testing	• Set-up on-site, centralized, decentralized or other physical models	• Decide reporting strategy • Establish procedures for reporting positive results and confirmatory testing

Considerations for tailoring design and execution

Local epidemiology

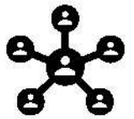
Student population needs (age, special needs, etc.)



Access to approved contracts and vendors

Proximity to labs

Human and financial resources



Number of students, teachers and staff

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For additional resources to support school operations and planning, see: Testing for America

What do schools do: coordination and administration

Successful implementation, coordination and administration requires that schools fill staff positions prior to launching K-12 NTAP; schools can choose to hire additional employees, partner with external stakeholders, and/or train existing staff for these roles

Positions necessary to implement K-12 NTAP

Coordinator(s)
Oversee the daily operations and verify authorization/consent and registration

- **Ushers** — *Direct students, teachers and staff to testing locations*
- **Test Administrators** — *Collect or oversee sample collection*
- **Logistics Leads** — *Ship collected samples to labs and maintain shipping records*
- **Quality Controllers** — *Manage safe testing environment and disposal of biohazards*
- **Results Manager** — *Ensure all results are promptly shared with key stakeholders*

Depending on the position being filled and experience of the individual, specific trainings and certifications may be needed

A combination of hiring, training and partnerships can be used for these positions. Options include:

- **Hire temporary employees**
- **Partner with external stakeholders** (e.g., Commissioned Corps or health professionals)
- **Train existing staff**

Example: Watertown Public Schools, Broad Institute and CIC Health collaborated to administer individual testing for high need students

✓

✓

»» Cost savings from leveraging in-house resources

Source: Watertown Public Schools

What do schools do: setting up collection facilities

To maintain quality and consistency, on-site collection (e.g., at schools, local pop-up labs, etc.) is preferred to at-home collection. School's can tailor their on-site collection set up based on size, resource availability and testing modality

Set-up options

Centralized (walk-up)

Examples: Gym, cafeteria

When it works well:

- ✓ High-volume testing
- ✓ Limited testers available
- ✓ Test technologies that require more equipment or storage

Challenges:

- ✓ Space may already be in use for other school activities and social distancing needs

Decentralized

Examples: Individual classrooms

When it works well:

- ✓ Homeroom or pod model
- ✓ Minimizes day-to-day disruptions for younger students (more familiar to them)

Challenges

- ✓ Staff capacity
- ✓ Transporting PPE and supplies to each location (e.g., hazard waste removal)

Centralized (drive-thru)

Examples: Parking lot, drop-off zones

When it works well:

- ✓ Areas with high community prevalence (limits potentially infected individuals from entering common areas)
- ✓ For testing one-time visitors, substitute teachers, etc.

Challenges:

- ✓ Sufficient physical space may not be available

Photo Credit: Natasha Bhalla

Example: Washington International School and UnitedHealth Group collaborated to perform weekly pooled rapid testing

- 👍 Centralizing sample collection to make it easy was the key to success
- 👍 Using a phased approach allowed continuous improvement in sample collection methods

Alternative collection approaches

At-home collection may be used for several reasons including when individuals are showing Covid-19 symptoms or when a school lacks the staff needed to test the volume of students necessary

Off-premise testing at pharmacy or other third-party location may be used when individuals prefer their primary care provider to testing in school

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Source: UnitedHealth Group

What do schools do: results reporting

Regular and prompt reporting of results to testing participants and their families, schools and school districts and the state and federal government is critical to maintaining safe school environment and overall public health

What to report on

Results to students, teachers and staff

PCR pool test results / antigen test results
Clearly and promptly provide test results as soon as they are available

Quarantine and isolation guidance
Reshare quarantining and isolation guidelines when positive pools/individual tests are identified

School positivity rates and trends
Regularly share updates to the school community on the total number of cases and positivity trends to maintain trust

Results to local, state and federal government

Positive cases
Provide regular updates on the total number cases and positivity trends at school or school district level (according to state and federal guidelines)

Tools and technologies to facilitate reporting

- **Centralized information platform** to store data with the ability to remove PII and aggregate at school district level as needed per FERPA and HIPAA guidelines
- **Website and/or text messaging** options to share results as soon as they are available
- **Inquiry form** to get status updates if the test results are not available in the expected timeframe

Example: Washington International School and UnitedHealth Group collaborated to perform weekly pooled rapid testing

- Use cloud-based information management system to track results and communication
- Report results to parents, staff and students within 40 minutes
- Created list of easily accessible FAQs about testing, operations, data security and safety

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Source: UnitedHealth Group

School operations in action: school nurse perspective

Nurse Jamie is the head nurse at a high school in a city supporting the school principal and the district superintendent as they adopt the K-12 NTAP. She firmly believes that both students and teachers should be tested regularly if the school is to reopen for in-person learning

Coordination and test modality

Over the last few weeks, the Nurse Jamie (testing coordinator), the district superintendent, principal and school nurses have coordinated to obtain consent to test and completed registration to begin testing. They have determined that groups of 10 students will be pooled and teachers tested individually, all via PCR testing. Pre-paid vouchers for confirmatory testing will be provided to parents in positive pools

Set-up

Nurse Jamie, in close collaboration with the school nurses, helped by hiring additional temporary staff to help with ushering, testing and shipping tasks. She also helped coordinate the set-up of testing booths in the gym for students and a separate area to test teachers. The testing team conducted a dry run of all operation on Sunday before school reopened

Sample collection

It's Monday and students and teachers begin to arrive to school. Nurse Jamie is in the command center of the school making sure that all individuals are getting tested. Once all the test samples are collected, Nurse Jamie checks in with the logistics staff to ensure all samples get shipped promptly to the nearby labs

Results reporting

Nurse Jamie gets to school early on Tuesday and sees she has an email from the lab saying that 2 pools in grade 8 tested positive. She immediately sends an email voucher to the parents of the students in the pool to get an individual test

When she comes back on Wednesday, she sees emails from all the parents who needed to get individual tests and 3 out of the 30 students were positive while the others negative for Covid-19. She authorized the remaining 27 to come back to school the following Monday and shared the update with school Principal and Superintendent

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School operations in action: student perspective

Molly's school has worked hard to implement the K-12 NTAP program, which is a national testing strategy that allows teachers and students to safely come back to school in-person. She can hardly contain her excitement to start school this coming week because she will finally be able to see her friends and teachers in-person

Engagement | **Testing** | **Results**

Over the last few weeks, Molly's parents have been talking with the school about the new testing program to understand all the steps they are taking to safely test Molly and keep her safe when she is in school. They have filled out required consent forms and registered for regular testing

It's Monday and when Molly arrives at school with her new rainbow mask, one of the school staff checks her in and directs her to head to the gym with the rest of her homeroom classmates. There are arrows on the ground directing her to one of the several tables that are set up in the gym. She only waits in line for 5 minutes (standing 6 feet apart from her classmates of course)

When it is her turn, the school nurse watches Molly swab her nose. That took only a minute and wasn't as scary as she thought it would be! Then Molly follows the arrows out of the gym and back to her class for the rest of the day

Molly comes back to school on Tuesday. While her whole class is there, the class next to them is empty because someone in that pod had a positive test. The teacher explains that the students in that pod will be tested again to confirm the positive individual

Molly's parents are made aware the positive pod pool but reminded of schools' general low overall prevalence rate. They are also reminded of the voucher program which will enable those students to get confirmatory antigen tests to confirm the positive individual, who will then remain at home for the necessary time

Molly's parents receive another email from the school on Wednesday confirming the Covid-19 positive individuals were successfully identified and asked to continue in-home learning for at least 2 weeks and provide a Covid-19 negative result. For contact tracing purposes, they were also told that Molly was not in contact with the Covid-19 positive individuals and should attend school normally

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Who is needed: building confidence for participants

Wide-spread adoption and participation relies on building confidence for participants by understanding their priorities and concerns. State and local leadership must proactively reassure and address the concerns of stakeholders

	Superintendents	Teachers and staff	Parents	Students
Priorities and Concerns	• All willing individuals are getting tested • Results are obtained quickly • Payments and funding vehicles are in place	• Keeping themselves and students safe • Preparing for when someone gets sick in school • Missing work when they test positive • Data privacy • Test collection safety	• Safety of children • Testing without parent/guardian present • Perceived cost and time of confirmatory test if applicable • Data privacy • Test collection safety	• Fear of getting the swab • Test collection safety • Stigma or lost school time linked to positive results
Actions to Build Confidence	• Set frequency and sensitivity standards • Provide easy-to-use consent forms • Provide central POC to ask questions	• Provide guidance on isolation and other mitigation strategies • Bring in trained people to administer tests • Be transparent about data privacy and use	• Provide information on getting confirmatory tests • Make consent forms easy to understand • Provide results quickly • Be transparent about data privacy and use	• Make the testing process as easy as possible to reduce stress and anxiety • Provide guidance on what do you if you're feeling sick

*Note: The Testing for America K-12 Playbook provides a tactical communications plan to engage stakeholders including who is responsible for the communication

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For additional resources to support school operations and planning, see: Testing for America

Contact Information (1 of 3)

General Information					Testing Technology				Experience and Readiness		
Company	HQ	Contact name	E-mail	Geographic Reach	PCR - pooled	PCR - individual	Antigen without instrument	Antigen with instrument	Experience with K-12 Testing	Own lab or partner lab?	Ready to start testing?
					Yes / No	*Yes / No*	*Yes / No*	*Yes / No*	*Yes / No*	*Own / Partner*	*Yes / No*
Abbott	Chicago, IL	Brian StCyr, Adam Bishop	brian.stcyr@abbott.com; adam.bishop@abbott.com	National	Yes	Yes	Yes	No	Yes	Partner	Yes
Aegis Sciences	Nashville, TN	Regina Sweeney	regina.sweeney@aegislabs.com	National	Yes	Yes	No	No	Yes	Own	Yes
BD (BD Veritor)	Franklin Lakes, NJ	Jeff Eisinger	jeff.eisinger@bd.com	National	No	Yes	No	Yes	Yes	Partner	Yes
BioReference Laboratories	Elmwood Park, NJ	Ellen Beausang	ebeausang@bioreference.com	National	Yes	Yes	Yes	Yes	Yes	Own	Yes
CIC Health	Cambridge, MA	Lindsay Clark	clark@cic.com	National	Yes	Yes	Yes	Yes	Yes	Broad Institute	Yes
Color	Burlingame, CA	Caroline Savello	caroline@color.com	National	Yes	Yes	Yes	No	Yes	Both	Yes
Exact Sciences	Madison, WI	Melanie Hayward	mhayward@exactsciences.com	Midwest	Yes	Yes	No	No	Yes	Own	Yes
GENETWORx	Glen Allen, VA	Maryrose Roberts	mroberts@recoverycoa.com	National	Yes	Yes	Yes	No	Yes	Own	Yes
Ginkgo BioWorks	Boston, MA	Matt McKnight	mmcknight@ginkgobioworks.com	National	Yes	Yes	Yes	No	Yes	Partner	Yes
Helix	San Mateo, CA	Ed MacBean	edgar.macbean@helix.com	National	Yes	Yes	No	No	Yes	Own	Yes

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General Information					Testing Technology				Experience and Readiness		
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					Yes / No	*Yes / No*	*Yes / No*	*Yes / No*	*Yes / No*	*Own / Partner*	*Yes / No*
LabCorp	Burlington, NC	Kevin DeAngelo	deangek@labcorp.com	National	Yes	Yes	Yes	Yes	Yes	Own	Yes
Mirimus	Brooklyn, NY	Prem Premsrirut	prem@mirimus.com	National	Yes	Yes	No	No	Yes	Own	Yes
Northwell Health Laboratories	Lake Success, NY	Bridgette Mastaglio	bmastaglio@northwell.edu	NY	Yes	Yes	Yes	Yes	Yes	Own	Yes
PathGroup	Brentwood, TN	Richard Halstead; Brent Sower	rhalstead@pathgroup.com; bsower@pathgroup.com	National	Yes	Yes	No	No	Yes	Own	Yes
Quest Diagnostics	Secaucus, NJ	Stacia Rivello	stacia.x.rivello@questdiagnostics.com	National	Yes	Yes	Yes	Yes	Yes	Own	Yes
Quidel Corporation	San Diego, CA	Patrick Sweeney; Rick Graham	patrick.sweeney@quidel.com; rick.graham@quidel.com	National	Yes	Yes	Yes	Yes	Yes	Partner	Yes
Sonic Healthcare USA - Clinical Pathology Laboratories	Austin, TX	Tony Jones	tjones@cpllabs.com	TX, LA, OK, NV, NM	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonic Healthcare USA - Clinical Labs of Hawaii	Honolulu, HI	Michele Cox	michele.cox@hawaiilabs.com	HI	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonic Healthcare USA - American Esoteric Laboratories	Memphis, TN	David Smalley, PhD	dlsmalley@ael.com	TN, MO, AR, MS	Yes	Yes	Yes	Yes	Yes	Own	Yes

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General Information					Testing Technology				Experience and Readiness		
Company	HQ	Contact name	E-mail	Geographic Reach	PCR - pooled	PCR - individual	Antigen without instrument	Antigen with instrument	Experience with K-12 Testing	Own lab or partner lab?	Ready to start testing?
					Yes / No	*Yes / No*	*Yes / No*	*Yes / No*	*Yes / No*	*Own / Partner*	*Yes / No*
Sonic Healthcare USA - Sunrise Medical Laboratories	Hicksville, NY	Alan Greenberg	agreenberg@sunriselab.com	NY, CT, DC, MD, VA	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonic Healthcare USA - West Pac Laboratories	Santa Fe Springs, CA	Joel Bentz, MD	jbentz@westpaclab.com	CA	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonic Healthcare USA - Eastside Clinical Laboratories	Providence, RI	Gary Sammarco	gary@esclab.com	RI, MA	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonic Healthcare USA - Bernhardt Laboratory	Jacksonville, FL	Bruce Walton	bwalton@auroradx.com	FL	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonic Healthcare USA - Laboratory Medicine Consultants	Las Vegas, NV	Bruce Walton	bwalton@auroradx.com	NV	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonic Healthcare USA - Seacoast Pathology	Exeter, NH	Bruce Walton	bwalton@auroradx.com	VT, NH	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonic Healthcare USA - Greensboro Pathology Associates	Greensboro, NC	Bruce Walton	bwalton@auroradx.com	NC	Yes	Yes	Yes	Yes	Yes	Own	Yes
Sonora Quest Laboratories / Laboratory Sciences of Arizona	Phoenix, AZ	Sonya Engle; Tom Leggett	sonya.engle@sonoraquest.com; tom.leggett@sonoraquest.com	Arizona	Yes	Yes	No	No	No	Own	Yes
Veritas Genetics	Danvers, MA	Mirza Cifric	mcifric@veritasgenetics.com	National	Yes	Yes	No	No	Yes	Both	Yes

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Questions and follow up

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Appendix & Resources

CDC RECOMMENDS SCREENING TESTING TO REDUCE TRANSMISSION

"Viral testing strategies in partnership with schools should be part of a comprehensive prevention approach. Screening testing is intended to identify infected people without symptoms…to prevent further transmission." – CDC Guidelines

	CDC Recommendations for Screening Testing		
Community transmission	**Students**	**Teachers**	**Athletics**
Low (~30% of states) *In last 7 days, 0-9 new cases per 100K, <5% positive tests*	• **No screening** testing	• At least **once per week**	• At least **once per week**
Moderate (~70% of states) *In last 7 days, 10-49 new cases per 100K, 5-7.9% positive tests*	• At least **once per week**	• At least **once per week**	• At least **once per week**
Substantial or High (~0% of states) *In last 7 days, 50+ new cases per 100K, 8%+ positive tests*	• At least **once per week**	• At least **once per week**	• **Twice per week** for high-risk sports, at least once per week for all others

Given the **CDC recommends screening testing in schools in most instances**, it is critical to establish a program that is **easy to administer** and **requires minimal additional resources** from schools

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Sources: CDC recommendations; State transmission rates (New York Times)

BUSINESS AND HEALTH LEADERS SUPPORT SCHOOL REOPENING

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GUIDING PRINCIPLES FOR K-12 NTAP DEVELOPMENT

The K-12 NTAP team operates by a set of core principles which have guided the design and implementation of the program:

Think Big but Design Small – Standardize guidance to be widely applicable and scalable yet also tailorable for state-level coordination and school or district-level implementation

Provide Clear, Simple and Realistic Guidelines – Encourage use and adoption by making the guidelines easy to follow and proactively identifying ways to reduce barriers

Be Reasonably Comprehensive – Provide a common platform to understand the minimum requirements for K-12 testing at a broad level to enable the return of in-person learning

Be Focused – Prioritize testing solutions and strategies. Other mitigation strategies are assumed but secondary to this program (e.g., vaccine distribution, masking, physical distancing)

Enable Agility – Develop a plan that is practical and sustainable, while acknowledging the dynamic environment and likely necessity of real-time adaptation

Build Capacity – Identify ways meet demand for K-12 testing without diminishing existing testing capacity

Minimize Burden – Minimize burden on schools and families throughout the process to increase adoption

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Resources

- CDC guidance for schools https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html)
- Rockefeller Foundation's reopening playbook https://www.rockefellerfoundation.org/report/covid-19-testing-in-k-12-settings-a-playbook-for-educators-and-leaders/
- Shah Foundation
  - MA COVID testing site https://covidedtesting.com/
  - MA peer-to-peer site https://covidedtesting.com/peer-to-peer
- COVID-19 Community of Practice for Hot Spots Contributors Webinar https://cdc.zoomgov.com/rec/share/z9B4EuDd9kVJEoGOtmCBSvR6GZjJeaa8hHBP86UEnUmXaNADar9A55XG094EwYSX

Questions?

For any questions, please contact your ELC Project Officer or ELC@cdc.gov

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Monday, April 05, 2021 7:41 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 4/5

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 5, 2021:

Highlights from Friday and Monday's White House COVID-19 Response Team briefing:

Jeff Zients

- **Vaccine Supply:** Last week, a total of more than 33 million doses went out to states, Tribes, and territories, and through the federal channels, including pharmacies and community health centers. This is a record level of weekly vaccine supply.
- **Mask Mandates:** We are working to put this pandemic behind us as fast as we can, but we're not there yet. We need everyone to do their part. That's why the President called on every governor, mayor, and local leader to maintain or reinstate mask mandates.

Andy Slavitt

- **Increasing the Number of Vaccination Sites:** Last week, we announced five new sites — in Maryland, Wisconsin, Tennessee, Missouri, and Indiana. And today, we're announcing three additional sites: The first is at the Columbia Place Mall in Columbia, South Carolina. The second is at the Colorado State Fairgrounds in Pueblo, Colorado. And the third is at the Minnesota State Fairgrounds in St. Paul, Minnesota, home of the Minnesota State Fair. Across the country, there's already 25 existing mass vaccination sites that have a combined capability to administer over 95,000 shots per day. Importantly, these new sites will advance our work to equitably distribute vaccines and reach communities that have been hurt the most by the pandemic.
- **Number of People Vaccinated:** We're now averaging 3.1 million shots per day over the most recent seven-day period. Over the weekend, there were more than 4 million recorded vaccinations in a single day for the first time. As of today, nearly one in three Americans and over 40 percent of adults have at least one shot, and nearly one in four adults are fully vaccinated. Seventy-five percent of seniors have now been vaccinated, and more than 55 percent of seniors are fully vaccinated.
- **Johnson & Johnson, AstraZeneca:** It's important to mention that all the Johnson & Johnson vaccine that's available in the U.S. has been authorized by the FDA. None of it came out of this plant in question, and Johnson & Johnson will have the 100 million doses by the end of May as they promised. With assistance from the Health and Human Services Department, Johnson & Johnson has taken complete control of the plant in question, in order to eliminate the potential for any cross-contamination. AstraZeneca is still scheduled to go through the FDA's authorization process as soon as an application is submitted.

Dr. Walensky

- **Case Update:** CDC's most recent data show the seven-day average of new cases is about 64,000 cases per day. This is up approximately 7 percent compared to the prior seven-day period. Hospital admissions have also increased. The most recent seven-day trend average is about 4,970 admissions per day, up about 3 percent from the previous seven-day period. Deaths have decreased to an average of approximately 800 per day. Importantly, we are now entering our fourth week of increased trends and cases.
- **Avoiding a Surge:** As the trends and data have been indicating, cases are increasing nationally, and we are seeing this occur predominantly in younger adults. As more schools are reopening, it's even more important to make sure they do so safely, with strict adherence to CDC guidance, and for all of us to roll up our sleeves for a vaccine as soon as we can. We are learning that many outbreaks in young people are related to youth sports and extracurricular activities. According to CDC guidance, these activities should be limited, but if they are not, the risks of clusters can be prevented with cadence testing strategies, as are being rolled out in so many different places.
- **MMWR:** The Illinois Department of Public Health and staff from a local public health department evaluated a COVID-19 outbreak associated with a bar in a rural area of Illinois. While table spacing and signs encouraged physical distancing and masking, people who attended the event reported that mask use was inconsistent and that six feet of distance was not maintained. The evaluation found 46 COVID-19 cases linked to this event. Of those, 26 were patrons, 3 were bar staff. Seventeen secondary cases occurred among contacts of people who attended the opening and got COVID-19; 12 were household contacts, 3 were long-term care facility contacts, and 2 were school-related contacts. Transmission associated with this opening event also resulted in eight households with infections, a school closure affecting 650 children, and the hospitalization of a long-term care facility resident.
- **Updated CDC Cleaning and Disinfecting Guidance:** CDC has updated its guidance for cleaning and disinfecting facilities and homes to reflect the science on transmission. People can be affected with the virus that causes COVID-19 through contact with contaminated surfaces and objects. However, evidence has demonstrated that the risk by this route of transmission is low. In most situations, regular cleaning of surfaces with soap and detergent, not necessarily disinfecting those surfaces, is enough to reduce the risk of COVID-19 spread.
- **Updated Guidance for Fully Vaccinated People:** We state that fully vaccinated people can resume travel at low risk to themselves. For domestic travel, fully vaccinated people do not need to get a COVID-19 test before or after travel and do not need to self-quarantine after travel. For international travel, fully vaccinated people do not need to get a COVID-19 test before they leave the United States unless it is required by their international destination. However, fully vaccinated people should get tested and have a negative test result before they board an international flight back into the United States and have a negative test three to five days after arrival, but they do not need to quarantine when they arrive here. Our guidance reiterates that all travelers, regardless of vaccination status, should continue to wear masks on planes, buses, trains, and other forms of public transportation while traveling. While we believe that fully vaccinated people can travel at low risk to themselves, CDC is not recommending travel at this time due to the rising number of cases.

Dr. Fauci

- **COVID-19 and Pregnancy:** In November 2020, the CDC did an analysis of about 400,000 women with symptomatic COVID-19. Though the numbers were small, it became clear then that there was very likely an increased risk among pregnant women versus non-pregnant women for adverse outcomes of the pregnancy itself and for them as pregnant women if they contracted the disease, COVID-19.
- **Vaccinations and Pregnancy:** Observational data from vaccinated pregnant individuals are currently being collected both by the CDC and no specific safety signals have been observed thus far among pregnant vaccine recipients. As I mentioned, as of a few days ago, there have been close to 70,000 V-Safe participants that were pregnant at the time they received the vaccination. The CDC is currently

enrolling participants to analyze the data and better understand how vaccination affects pregnant women. In a study recently published in the American Journal of Obstetrics and Gynecology, in 131 reproductive-age vaccine recipients, it became very clear that vaccine-induced, robust immune responses in pregnant women — similar to that in non-pregnant woman — not only was the immunogenicity but the reactogenicity was similar. And importantly, and very favorably, there was immune transfer to the neonates, which occurred both via the placenta in utero as well as through breast milk. In other words, things look very good for the association between vaccination and protecting pregnant women from adverse outcomes from themselves and their fetus.

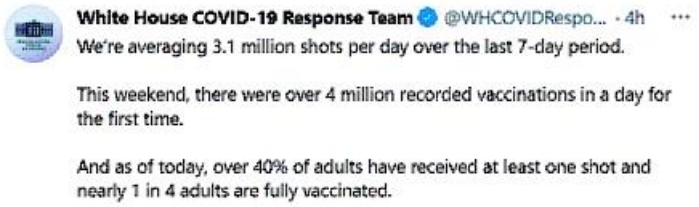
- **Vaccine Rollout Strategy:** We have been concerned, and still are, that when you look at the level of protection after one dose, you can say it's 80 percent, but it is somewhat of a tenuous 80 percent because the level of neutralizing antibodies against the coronavirus. When you just leave it at one dose, the question is: How long does it last? When you're dealing with variants that clearly might be diminished somewhat in their capability through the vaccine-induced antibodies, you're in a tenuous zone if you don't have the full impact. For that reason, although we always continue to keep an open mind, we consider the route that we're on now is the best route.
- **Vaccine Effectiveness:** Vaccines work very well in the real-world setting. They work against variants, although we need further data to confirm that. They are durable for at least six months. And they work in adolescence. These are very good reasons for everyone to get vaccinated as soon as it becomes available to you.

Dr. Murthy, U.S. Surgeon General

- **COVID-19 Public Education Campaign:** Our COVID-19 public education campaign has three goals: One, provide information. We want to give the American people facts to slow the spread of COVID-19 and to protect themselves. Two, build trust. We need to help build confidence in the vaccines by making sure people get accurate, scientific information from trusted sources. And three, connect people to vaccines. We need to mobilize our communities across our country to increase awareness of how you can get the vaccine when it's your turn. This is why we launched the COVID-19 Community Corps, a nationwide grassroots network of health professionals, community organizations, faith leaders, businesses, and Americans from all walks of life who are collectively stepping up to be leaders for their communities in this national vaccination effort. Our plan is to equip them with CDC-approved materials to help them deliver science-based information to their network. We launched with about 275 founding members, and in less than 24 hours, 2,500 more members have signed up.

Vaccine Updates

Vaccination Update: CDC released their COVID data tracker weekly review last Friday, providing an update on the status of vaccinations and the number of reported cases. The United States has administered over 167 million doses **of COVID-19 vaccine**, **with over** 62 **million people having been fully vaccinated.**



Percent of Vaccine Administered: The majority of U.S. states and territories have administered at or above 89% of their first vaccine doses delivered. Because the supply of vaccine is currently limited, CDC made vaccine rollout recommendations. Each state then makes its own plan for who will be vaccinated first and how people can get a vaccine once it is available to them.

Vaccination Demographic Data: CDC updated their vaccination demographic data and information regarding the reported numbers.

Different Vaccines: CDC updated their fact sheet on the different COVID-19 vaccines, which include Pfizer-BioNTech, Moderna, and Johnson & Johnson/ Janssen. The best COVID-19 vaccine is the first one that is available to you. Do not wait for a specific brand. The CDC does not recommend one vaccine over another.

Mobile Vaccination Units: On Friday, the first FEMA mobile vaccination unit is operating in Bridgeport, Connecticut through early next week, bringing vaccinations to hard-to-reach and high-risk populations who cannot access services from larger, fixed centers. Currently, the unit is focusing its efforts on eastern and southwestern areas in the state. A second mobile vaccination unit began administering vaccinations in the Eastern Shore area of Maryland on Saturday.

FDA Approved Moderna's Plan to Increase Doses: On Friday, the FDA announced two revisions regarding the number of doses per vial available for the Moderna COVID-19 Vaccine. The first revision clarifies the number of doses per vial for the vials that are currently available, in that the maximum number of extractable doses is 11, with a range of 10-11 doses. The second revision authorizes the availability of an additional multi-dose vial in which each vial contains a maximum of 15 doses, with a range of 13-15 doses that can potentially be extracted. The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Prescribing Information have been revised to reflect the new information and are intended to help frontline workers administering COVID-19 vaccines understand the number of doses that can potentially be extracted per vial.

FDA Provides PREPP Update: The FDA updated their COVID-19 Pandemic Recovery and Preparedness Plan (PREPP) initiative, identifying five key activities for further development and implementation. These include: reviewing aspects of the EUA processes for medical products and identifying areas for potential improvement in order to ensure transparency and facilitate appropriate integration of these products including diagnostics, therapeutics and vaccines into medical care; reviewing science-based communications to ensure the agency continues to provide timely and accurate communications to the public; evaluating inspectional approaches using next-generation assessment technologies, such as virtual and video-enabled platforms, to further our inspectional reach; evaluating the current supply chain tracking, monitoring and assessment systems to identify gaps and challenges to help stakeholders improve supply chain resilience. View the January 2021 release and summary report here.

BARDA and Johnson & Johnson Expands Trial to Include Adolescents: BARDA and Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), are increasing ongoing efforts to develop an expanded indication for a vaccine to prevent COVID-19 in adolescents ages 12-17. BARDA is supporting additional development of Janssen's COVID-19 investigational vaccine, Ad26.COV2.S, with expansion of a Phase 2a clinical trial for adolescents participating with their parents' consent. The clinical trial is the next step in assessing the safety and efficacy of Ad26.COV2.S in volunteers 12-17 years of age. The trial is currently ongoing in the UK and Spain. Preparations for the clinical trial in the US and other countries are ongoing.

Testing and Treatment

COVID-19 Variants: CDC updated their fact sheet on the variants of the virus, as well as their information on variant cases and variants proportions in the U.S. Multiple variants of the virus that causes COVID-19 are circulating globally and within the United States. There are currently five variants of concern in the United States: B.1.1.7 (U.K.), B.1.351 (South Africa), P.1 (Brazil), B.1.427 (California), and B.1.429 (California). It is important to protect yourself and others against COVID-19 by wearing a mask, staying at least 6 feet apart, avoiding crowds, washing your hands, and getting vaccinated when it's available to you.

FDA COVID-19 Update: On Friday, the FDA released an update on their ongoing response efforts to the COVID-19 pandemic. Following recent FDA actions to support test development, the FDA took swift action this week to get more tests for screening asymptomatic individuals on the market. The FDA also posted a new web page SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests for clinical laboratory staff and health care providers about the impact of viral mutations on COVID-19 molecular, antigen, and serology tests. Furthermore, the FDA posted translations of the Consumer Update: Learn More about COVID-19 Vaccines From the FDA in five additional languages: Chinese, Korean, Spanish, Tagalog, and Vietnamese. As part of the FDA's effort to protect consumers, the agency issued a warning letter jointly with the Federal Trade Commission to Natural Adventure, LLC for selling unapproved products with fraudulent COVID-19 claims. Moreover, the FDA provided COVID-19 testing updates.

Guidance for Cleaning and Disinfecting: CDC updated their information on both cleaning your home and cleaning your facility every day and when someone is sick. The virus that causes COVID-19 can land on surfaces. It's possible for people to become infected if they touch those surfaces and then touch their nose, mouth, or eyes. In most situations, the risk of infection from touching a surface is low. The most reliable way to prevent infection from surfaces is to regularly wash hands or use hand sanitizer.

Reopening Guidance

CDC General Updates on Travel: CDC updated their guidelines on travel, their fact sheet on when not to travel, and information on travel-associated exposures. They also updated their fact sheet on safer travel Ideas, their traveling and COVID page, and their travel FAQs. Furthermore, CDC updated their travel health notices regarding the risk assessment for COVID-19 in other countries.

CDC Guidelines on Domestic Travel: provided updated information for domestic travel during COVID-19, including the following: Fully vaccinated travelers are less likely to get and spread COVID-19. People who are fully vaccinated with an FDA-authorized vaccine can travel safely within the United States; fully vaccinated travelers do not need to get tested before or after travel unless their destination requires it and they do not need to self-quarantine Fully vaccinated travelers should still follow CDC's recommendations for traveling safely including: wear a mask over your nose and mouth, stay 6 feet from others and avoid crowds, and wash your hands often or use hand sanitizer.

CDC Guidelines on International Travel: CDC also updated their guidance surrounding international travel during COVID-19 stating that while fully vaccinated travelers are less likely to get and spread COVID-19, international travel poses additional risks and even fully vaccinated travelers are at increased risk for getting and possibly spreading new COVID-19 variants. CDC recommends delaying international travel until you are fully vaccinated. If you are fully vaccinated with an FDA-authorized vaccine: you should continue to follow CDC's recommendations for traveling safely and get tested 3-5 days after travel; you do not need to get tested before leaving United States unless your destination requires it; and you do not need to self-quarantine after arriving in the United States. Review the updated fact sheet more information on protocols once returning from international travel.

Cruise Ship Guidance: CDC released a new phase of the Framework for Conditional Sailing Order for cruise ships operating or seeking to operate in U.S. waters. CDC published Technical Instructions for cruise ship operators and for local health authorities outlining this phase of the Conditional Sailing Order. CDC recommends that all people avoid travel on cruise ships, including river cruises, worldwide. That's because the chance of getting COVID-19 on cruise ships is high since the virus appears to spread more easily between people in close quarters aboard ships. It is especially important that people with an increased risk of severe illness defer travel on cruise ships, including river cruises. CDC has issued a Level 4 Travel Health Notice for cruise ship travel. CDC also updated their guidance for ship crew members on how to protect themselves and others, as well as criteria for the commercial transport of crew that ships must meet.

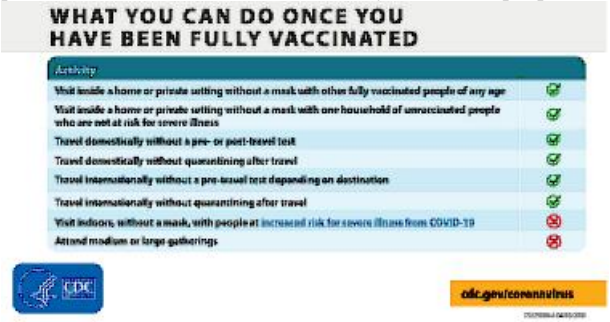
Information for Specific Populations

Schools and Childcare Programs: CDC updated their guidance on COVID-19 safety protocol for schools and childcare. There is specific information for teaching staff, administrators, and the general public. CDC also updated their information for school staff and childcare workers regarding their edibility for their COVID-19 vaccination. U.S. teachers, school staff, and childcare workers in pre-K-12 schools and childcare programs are eligible for COVID-19 vaccination. CDC outlines who can get vaccinated and how to schedule your appointment here.

Staffing Resources: CDC updated their resources and guidance for strengthening the public health workforce. Enhancing frontline public health capacity in state, local, tribal, and territorial health departments to intensify the coordinated response to COVID-19 is critical.

Guidance for Fully Vaccinated People: In a press release, CDC updated their guidance for people who have been fully vaccinated. Based on what we know about COVID-19 vaccines, people who have been fully vaccinated can start to do some things that they had stopped doing because of the pandemic. We're still learning how vaccines will affect the spread of COVID-19. After you've been fully vaccinated against COVID-19, you should keep taking precautions – like wearing a mask, staying 6 feet apart from others, and avoiding crowds and poorly ventilated spaces – in public places until we know more. These recommendations can help you make decisions about daily activities after you are fully vaccinated.

They are *not* intended for healthcare settings. For more information, visit the CDC science brief on the background rationale and evidence for public health recommendations for fully vaccinated people.



Guidance for Older Adults: CDC updated their information for older adults. Risk for severe illness with COVID-19 increases with age, with older adults at highest risk. Certain medical conditions can also increase risk for severe illness. People at increased risk, and those who live or visit with them, need to take precautions to protect themselves from getting COVID-19.

Tribal Communities: CDC updated their information for tribal community members, tribal leaders, and tribal partners on COVID-19 prevention and support.

Temporary Halt in Residential Evictions: CDC updated their information on the temporary halt in residential evictions to prevent the further spread of COVID-19. Director Dr. Rochelle Walensky signed a declaration determining that the evictions of tenants could be detrimental to public health control measures to slow the spread of SARS-Cov-2, the virus that causes COVID-19.

Marketplace Webinar Invitation: Information to Help Tribal Communities: In partnership with the Center for Consumer Information and Insurance Oversight (CCIIO), the CMS Division of Tribal Affairs is co-hosting a webinar providing Marketplace updates on Thursday, April 8, at 1:00 PM ET. This presentation will highlight recent policy changes that may impact American Indian and Alaska Natives (AI/AN), including the special enrollment period (SEP) from February 15 to May 15, 2021, CMS outreach efforts, and the American Rescue Plan Act of 2021 (ARP). Additional information on enrollment of tribal citizens and other Indian Health Service (IHS) eligible individuals in health insurance coverage through a Marketplace, including use of Tribal Sponsorship, will also be presented. You can register here.

CDC's COVID-19 Weekly Partner Calls: CDC released information regarding upcoming partner calls, including with representatives from community-based organizations, local government, the private sector, academia, and the general public to learn more about how they can help slow the spread of COVID-19 in their communities. Each week we feature experts from different parts of CDC's COVID-19 response to deep dive into specific topics, helping you learn more about the latest scientific findings, guidance for operations, information resources, and answering your COVID-19 questions. Sign up to join a call here.

Community Spotlights: CDC updated their community features page to include more information about grassroots efforts in Southwest Kansas to educate refugee communities about COVID-19.

CMS Updates

Acute Hospital Care at Home Program: CMS updated the approved list of hospitals for the Acute Hospital Care at Home Program. The Acute Hospital Care at Home program is an expansion of the CMS Hospital Without Walls initiative launched in March 2020 as a part of a comprehensive effort to increase hospital capacity, maximize resources, and combat COVID-19 to keep Americans safe. This program creates additional flexibility that allows for certain health care services to be provided outside of a traditional hospital setting and within a patient's home. The approved list of hospitals will be moving to the CMS Hospital at Home webpage beginning April 9, 2021.

Research

Community Transmission of SARS-CoV-2: CDC released an *MMWR* on the community transmission of SARS-CoV-2 associated with a local bar opening event in Illinois. Forty-six cases of COVID-19 were linked to an indoor bar opening event that occurred during February 2021 in a rural Illinois county. Event patrons were linked to secondary cases among household, long-term care facility, and school contacts, resulting in one hospitalization and one school closure affecting 650 students. Opening up settings such as bars, where mask wearing and physical distancing are challenging, can affect the community. As community businesses reopen, prevention measures should be emphasized, including limiting building occupancy, improving ventilation, prioritizing outdoor seating, enforcing correct mask wearing and physical distancing, staying home when ill, and encouraging COVID-19 vaccination to reduce transmission on site and within the community.

Surface Transmission: CDC released a new science brief on SARS-CoV-2 and surface (fomite) transmission for indoor community environments. The principal mode by which people are infected with SARS-CoV-2 (the virus that causes COVID-19) is through exposure to respiratory droplets carrying infectious virus. It is possible for people to be infected through contact with contaminated surfaces or objects (fomites), but the risk is generally considered to be low.

Vaccines by Jurisdiction: CDC released a report providing an overview of the multiple channels being used to ensure all Americans have access to COVID-19 vaccine. Jurisdictional delivery and administration portfolios vary across the United States because of population variability.

COVID-19 Outbreak in a State Prison: CDC updated an *MMWR* on the rapid spread of SARS-CoV-2 in a State Prison after introduction by newly transferred incarcerated persons in Wisconsin.

COVID-19 Vaccine Response in Pregnant and Lactating Women: As mentioned above by Dr. Fauci, a study by the American Journal of Obstetrics and Gynecology found that COVID-19 mRNA vaccines generated robust humoral immunity in pregnant and lactating women, with

immunogenicity and reactogenicity similar to that observed in non-pregnant women. Vaccine-induced immune responses were significantly greater than the response to natural infection. Immune transfer to neonates occurred via placenta and breastmilk.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

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Community Transmission of SARS-CoV-2 Associated with a Local Bar Opening Event — Illinois, February 2021

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During February 2021, an opening event was held indoors at a rural Illinois bar that accommodates approximately 100 persons. The Illinois Department of Public Health (IDPH) and local health department staff members investigated a COVID-19 outbreak associated with this opening event. Overall, 46 COVID-19 cases were linked to the event, including cases in 26 patrons and three staff members who attended the opening event and 17 secondary cases. Four persons with cases had COVID-19–like symptoms on the same day they attended the event. Secondary cases included 12 cases in eight households with children, two on a school sports team, and three in a long-term care facility (LTCF). Transmission associated with the opening event resulted in one school closure affecting 650 children (9,100 lost person-days of school) and hospitalization of one LTCF resident with COVID-19. These findings demonstrate that opening up settings such as bars, where mask wearing and physical distancing are challenging, can increase the risk for community transmission of SARS-CoV-2, the virus that causes COVID-19. As community businesses begin to reopen, a multicomponent approach should be emphasized in settings such as bars to prevent transmission* (*1*). This includes enforcing consistent and correct mask use, maintaining ≥6 ft of physical distance between persons, reducing indoor bar occupancy, prioritizing outdoor seating, improving building ventilation, and promoting behaviors such as staying at home when ill, as well as implementing contact tracing in combination with isolation and quarantine when COVID-19 cases are diagnosed.

Investigation and Findings

On February 17, 2021, IDPH was notified through the state's outbreak reporting system of a possible COVID-19 outbreak (i.e., five or more cases linked to a common location) in persons who attended an opening event at a bar in a rural Illinois county. The event had occurred indoors, with no outside air flow, approximately 2 weeks earlier in a 2,800-sq-ft bar during normal operating hours (4:00 p.m. to 1:00 a.m.). Six employees staffed the bar. Although the total number of bar patrons who attended the event is unknown, the bar accommodates approximately 100 persons. Before the event, IDPH reported a 7-day average daily COVID-19 incidence of 41–42 cases per 100,000 persons in the county; 14 days after the event, the 7-day average daily incidence had more than doubled, to 86–87 cases per 100,000 persons (*2*). On February 12, through routine testing and contact tracing, local health department staff members identified a cluster of cases linked to the bar event, including a case in an asymptomatic attendee who received a confirmed COVID-19 diagnosis the day before the event.

A bar attendee case was defined as the onset of COVID-19–like symptoms or receipt of a positive SARS-CoV-2 test result within 14 days of the bar opening event in a bar patron or employee who reported attending the event and who had no previous identified epidemiologic link to a COVID-19 case outside that setting. A confirmed case was defined as receipt of a positive SARS-CoV-2 nucleic acid amplification test (NAAT) or antigen test result by a person who attended the event, and a probable case was defined as COVID-19–like symptoms in a person who attended the event but had no laboratory confirmation of infection.† A secondary case was defined as receipt

* https://www.cdc.gov/coronavirus/2019-ncov/community/large-events/considerations-for-events-gatherings.html; https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html

† https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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of a positive SARS-CoV-2 NAAT or antigen test result by a close contact of a person with event-associated COVID-19.[§]

Local health department staff members, per standard practice, conducted case investigations within 48 hours of receipt of a positive SARS-CoV-2 test result in the county using a standardized questionnaire; demographic data, symptoms, and symptom onset date were entered into an electronic contact tracing platform. Through routine case investigation, local health department investigators identified a cluster of cases linked to the bar opening event through case reports indicating that persons attended the event or were close contacts of a person with an event-associated case during the 14 days before symptom onset or the testing date. All persons with a bar attendee case or secondary case of COVID-19 were interviewed by local health department staff members. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[¶]

Bar patrons and employees. By February 16, 2021, 29 bar attendee cases had been identified among persons who reported attending the opening event (Figure), including 26 (89.7%) in bar patrons and three (10.3%) in employees; all identified cases were confirmed by NAAT or antigen testing, except one probable case in a person who had COVID-19–like symptoms but did not receive testing (Table). Three additional employees worked during the event, all of whom had received a positive test result during the preceding 90 days and had completed 10 days of isolation from symptom onset or test date. Among persons with bar attendee cases, 25 (86.2%) had symptomatic illnesses. Among persons with symptom onset after the start of the event, onset dates ranged from 1 to 7 days after the event. Four (13.8%) persons with bar attendee cases reported having symptoms on the day of the event and were not reported to be contacts of one another before the event. Event attendees reported inconsistent mask use and not maintaining ≥6 ft of physical distance, despite table spacing and signs encouraging physical distancing and mask use. Most persons with bar attendee cases were adults aged 18–44 years (75.9%), male (65.5%), and non-Hispanic White persons (79.3%). One of the 29 persons with a bar attendee case, a bar patron, had received a COVID-19 vaccination before the event (the first dose, 5 days before receipt of the positive SARS-CoV-2 test result). No other persons with bar attendee cases had received a COVID-19 vaccination.

Secondary community cases. After the bar opening event, at least 71 close contacts of persons with bar attendee COVID-19 were reported; among these, 37 (52.1%) received testing, 17 (45.9%) of whom received a positive test result within 14 days of the contact. Two persons with secondary COVID-19 cases were school-related contacts of persons with bar attendee COVID-19, three were LTCF contacts, and 12 were household contacts. Among the 17 persons with secondary cases of confirmed COVID-19, 13 were symptomatic, with symptom onset dates ranging from 3 to 11 days after the event. Median age was 28 years (range = 10–71 years), and nine persons were female.

One bar attendee with COVID-19 reported the onset of a runny nose 2 days after the event and reported 26 close contacts at school during indoor sports practice and in-person school instruction. Two student athletes who were close contacts of this person subsequently received COVID-19 diagnoses 8 and 13 days after the event. Local health department officials were notified by a school official that the school district would close for 2 weeks beginning February 18 because 13 staff members were in isolation, in quarantine, or absent because their own child was quarantined.

One bar attendee who worked at an LTCF as a certified nursing assistant was asymptomatic and received a positive test result during routine COVID-19 testing at the facility 4 days after the event. After receipt of the positive test result, all LTCF residents and staff members in the facility were tested; three secondary cases (one in a staff member and two in residents) in persons who were close contacts of the bar attendee with COVID-19 were identified in the facility 5–9 days after the event. One resident with a secondary case was hospitalized on February 20, within 14 days of the positive test result, and was discharged the same day. None of the four persons in the LTCF with bar attendee or secondary COVID-19 had received a COVID-19 vaccination; all LTCF staff members and residents had been previously offered the vaccine.

By February 26, 12 household contacts in eight different households had received positive SARS-CoV-2 test results, including five school-aged children. Local health department staff members interviewed household contacts to assess exposures. Secondary household cases were linked to nine (31.0%) of 29 bar attendee cases. Eleven persons were symptomatic, and cases were confirmed by NAAT or antigen testing. No household contacts with COVID-19 were hospitalized.

Discussion

An event held to celebrate a bar opening led to an outbreak among bar patrons and employees and was the likely source of subsequent COVID-19 transmission among household members, LTCF residents and staff members, and school athletes, leading to 46 cases, hospitalization of an LTCF resident, and a school closure affecting 650 children. Attendees included one person with an asymptomatic infection who received

[§] Close contact is defined as being within 6 ft of a person with laboratory-confirmed or probable SARS-CoV-2 infection for a cumulative total of ≥15 minutes in a 24-hour period. https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#contact

[¶] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

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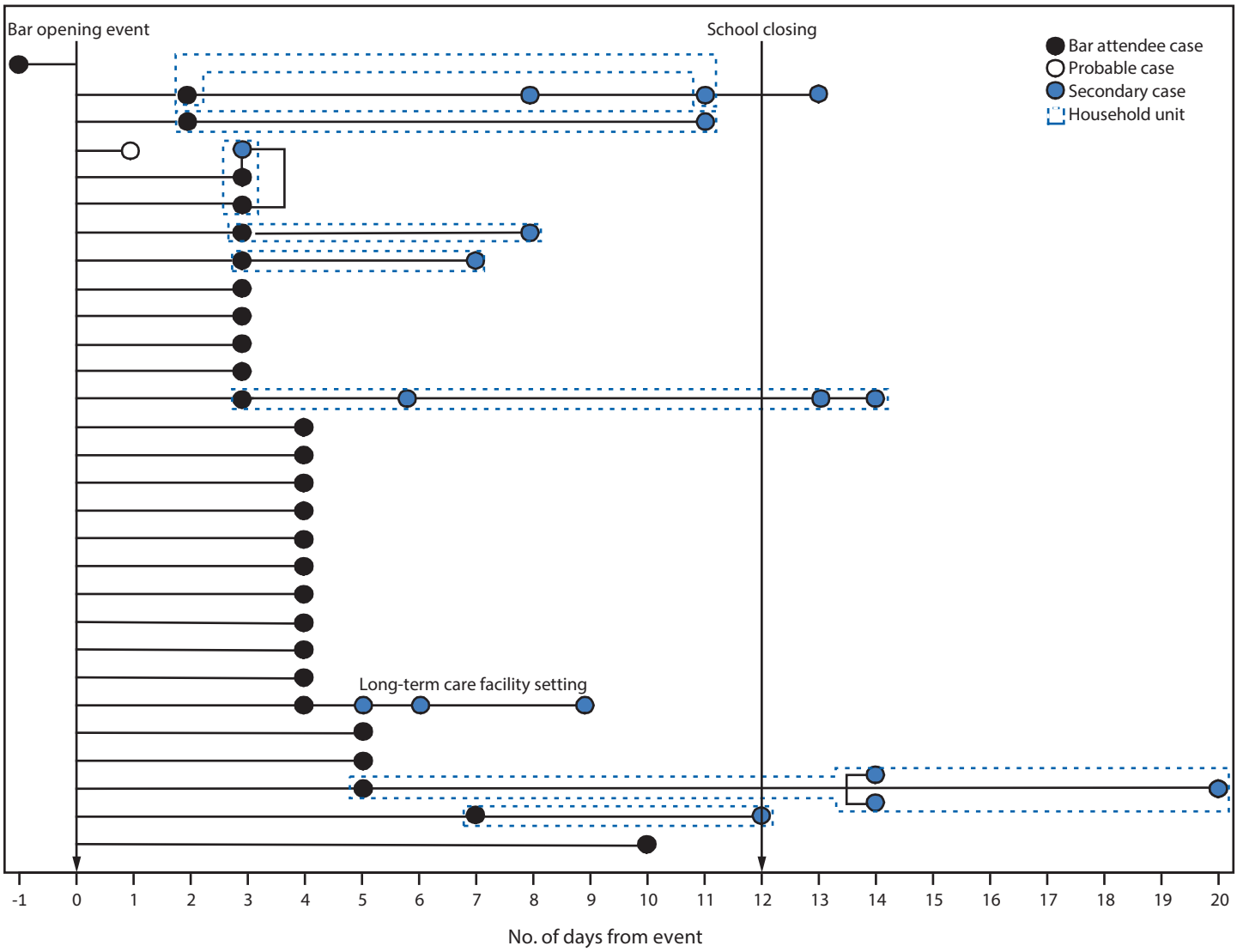
FIGURE. Bar attendee* (N = 29) and secondary† (N = 17) confirmed§ and probable¶ COVID-19 cases associated with a local bar opening event, by timing of specimen collection relative to event — Illinois, February 2021



Abbreviation: NAAT = nucleic acid amplification test.

* Onset of COVID-19–like symptoms or receipt of a positive SARS-CoV-2 test result within 14 days of the bar opening event in a bar patron or employee who reported attending the event and who had no previous identified epidemiologic link to a COVID-19 case outside that setting.

† Positive SARS-CoV-2 NAAT or antigen test result received by a close contact of a person with an event-associated case.

§ Positive SARS-CoV-2 NAAT or antigen test result.

¶ COVID-19–like symptoms in a person with an epidemiologic link to the bar opening event but no laboratory confirmation of infection.

a COVID-19 diagnosis the day before the event and four symptomatic persons who subsequently received a COVID-19 diagnosis after the event. Asymptomatic persons are estimated to account for approximately 40%–45% of infections (*3*); the high percentage (82.6%) of symptomatic persons who were linked to the bar opening event suggests that the total number of cases in this outbreak was higher than reported and highlights the need for increased testing and reporting through contact tracing, in combination with isolation and quarantine, to promptly reduce transmission. As community businesses begin to reopen, these findings underscore the importance of businesses and individuals adhering to public health prevention and mitigation guidelines to reduce additional community transmission, including isolation after receipt of a COVID-19 diagnosis and while experiencing COVID-19–like symptoms, even as vaccination efforts expand.

Similar gatherings that involve eating or drinking, such as on-premises dining at restaurants, weddings, and night clubs, have been associated with increased risk for acquiring COVID-19 and have the potential to become super-spreading

MS-DOH-21-1816-A-001861

TABLE. Number and percentage of COVID-19 cases (N = 46) associated with a local bar opening event, by demographic and clinical characteristics — Illinois, February 2021

Characteristic	No. (%)				
		Secondary cases			
	Bar attendee cases (N = 29)	Total (N = 17)	Household contacts (n = 12)	Long-term care facility contacts (n = 3)	School-related contacts (n = 2)
Classification					
Bar employee	3 (10.3)	NA	NA	NA	NA
Bar patron	26 (89.7)	NA	NA	NA	NA
Adult household contact	NA	7 (41.2)	7 (58.3)	NA	NA
School-aged child (aged 10–16 yrs) contact	NA	7 (41.2)	5 (41.7)	NA	2 (100)
LTCF staff member contact	NA	1 (5.9)	NA	1 (33.3)	NA
LTCF resident contact	NA	2 (11.8)	NA	2 (66.7)	NA
Case status					
Symptomatic confirmed*	24 (82.8)	13 (76.5)	11 (91.7)	1 (33.3)	1 (50.0)
Symptomatic probable†	1 (3.4)	0 (—)	0 (—)	0 (—)	0 (—)
Asymptomatic confirmed§	4 (13.8)	4 (23.5)	1 (8.3)	2 (66.7)	1 (50.0)
Hospitalized¶	0 (—)	1 (5.9)	0 (—)	1 (33.3)	0 (—)
Age group, yrs					
<18	0 (—)	7 (41.2)	5 (41.7)	0 (—)	2 (100)
18–44	22 (75.9)	4 (23.5)	3 (25.0)	1 (33.3)	0 (—)
45–54	5 (17.2)	1 (5.9)	1 (8.3)	0 (—)	0 (—)
55–64	2 (6.9)	3 (17.6)	3 (25.0)	0 (—)	0 (—)
≥65	0 (—)	2 (11.8)	0 (—)	2 (66.7)	0 (—)
Sex					
Male	19 (65.5)	8 (47.1)	5 (41.7)	1 (33.3)	2 (100)
Female	10 (34.5)	9 (52.9)	7 (58.3)	2 (66.7)	0 (—)
Race/Ethnicity**					
Hispanic/Latino	0 (—)	0 (—)	0 (—)	0 (—)	0 (—)
White, non-Hispanic	23 (79.3)	16 (94.1)	12 (100)	2 (66.7)	2 (100)
Black, non-Hispanic	0 (—)	0 (—)	0 (—)	0 (—)	0 (—)
Multiracial/Other race	0 (—)	0 (—)	0 (—)	0 (—)	0 (—)
Unknown	6 (20.7)	1 (5.9)	0 (—)	1 (33.3)	0 (—)

Abbreviations: LTCF = long-term care facility; NA = not applicable; NAAT = nucleic acid amplification test.
* Positive NAAT or antigen test result received by a symptomatic person.
† COVID-19–like symptoms in a person with an epidemiologic link to the bar opening event but no laboratory confirmation of infection.
§ Positive NAAT or antigen test result received by an asymptomatic person.
¶ Hospitalized within 14 days of the positive SARS-CoV-2 test result.
** Persons for whom ethnicity was missing or ethnicity was reported but race was missing were categorized as having unknown race/ethnicity.

events for SARS-CoV-2 infection (*4*–*8*). This investigation further demonstrates that inconsistent mask use and inadequate physical distancing in an indoor environment can increase transmission risk** (*9*,*10*). According to CDC's COVID-19 guidelines for restaurants and bars, reducing patron capacity, ensuring adequate room air ventilation, prioritizing outdoor seating, and promoting behaviors such as staying at home when ill, washing hands often, wearing masks, and maintaining physical distance are important strategies to reduce the spread of SARS-CoV-2 infection (*1*).

The findings in this report are subject to at least four limitations. First, interviews were voluntary, and many community members were reluctant to disclose contacts or additional details about themselves, including their occupation. Therefore, the number of cases described in this report is likely lower than the actual number of bar attendee and secondary cases associated with the event. Second, it is unlikely that all asymptomatic cases were counted, and not all contacts were tested; therefore, some infected contacts might have been missed. Third, information on individual-level behaviors such as wearing masks and physical distancing was not collected from persons with cases. Finally, specimens were not available for whole genome sequencing; thus, the relationship among strains was not documented, and whether the increase in county-level incidence might be attributed to variants that spread more easily than the original SARS-CoV-2 strain cannot be determined.

Bars can play a role in community spread of COVID-19 because of limited mask use while eating or drinking and lack of consistent physical distancing. These findings show that SARS-CoV-2 transmission originating in a business such as a bar not only affects the patrons and employees of the bar but

** https://www.medrxiv.org/content/10.1101/2020.04.04.20053058v1

MS-DOH-21-1816-A-001862

Summary

What is already known about this topic?

Gatherings in settings where mask wearing and physical distancing do not occur are known to increase the spread of COVID-19.

What is added by this report?

Forty-six cases of COVID-19 were linked to an indoor bar opening event that occurred during February 2021 in a rural Illinois county. Event patrons were linked to secondary cases among household, long-term care facility, and school contacts, resulting in one hospitalization and one school closure affecting 650 students.

What are the implications for public health practice?

Opening up settings such as bars, where mask wearing and physical distancing are challenging, can affect the community. As community businesses reopen, prevention measures should be emphasized, including limiting building occupancy, improving ventilation, prioritizing outdoor seating, enforcing correct mask wearing and physical distancing, staying home when ill, and encouraging COVID-19 vaccination to reduce transmission on site and within the community.

can also affect an entire community. As community businesses begin to reopen, considering additional prevention measures is important, such as limiting building occupancy levels and improving ventilation, especially in locations where consistent and correct mask wearing and physical distancing are difficult to enforce. Businesses can work with local health officials to promote behaviors and maintain environments that reduce the risk for SARS-CoV-2 transmission and develop strategies for reopening safely to prevent outbreaks in the community, such as modifying layouts and operating procedures (*1*).

Acknowledgments

COVID-19 case investigators and contact tracers in the local health department.

Corresponding author: Shelby Daniel-Wayman, covid.media@illinois.gov.

[1]CDC COVID-19 Response Team; [2]Illinois Department of Public Health; [3]Douglas County Department of Public Health, Tuscola, Illinois.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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Readers who have difficulty accessing this PDF file may access the HTML file at https://www.cdc.gov/mmwr/volumes/70/wr/mm7014e3.htm?s_cid=mm7014e3_w. Address all inquiries about the *MMWR* Series, including material to be considered for publication, to Editor, *MMWR* Series, Mailstop V25-5, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30329-4027 or to mmwrq@cdc.gov.

MS-DOH-21-1816-A-001863

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Apr. 9 (incl. CDC Info on Vaccine Breakthrough Infections, MH Survey Extension, CDC Webinar on Public Use Data, MMWR Early Release, and more)
Date:	Friday, April 9, 2021 3:03:33 PM
Attachments:	image001.png image002.png COVID-19 Partner Updates April 7th 2021.msg COVID-19 Partner Updates April 9th 2021.msg HHS COVID-19 Update - 46.msg HHS COVID-19 Update - 47.msg HHS COVID-19 Update - 48.msg MMWR ER - April 7, 2021.pdf [redacted] Webinar_ CDC COVID-19 Case Surveillance Public Use Data with Geography - Overview of Privacy Protections.ics

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Resources on COVID-19 Vaccine Breakthrough Infections [Attachment]
  - Please see below for a message from CDC's COVID-19 Vaccine Breakthrough Case Investigations Team. This information is for internal use only, and is **not for distribution**:

    [redacted]

    - [redacted]
    - [redacted]
    - [redacted]

    [redacted]

    - [redacted]

- [redacted]

- Extension: CDC Public Health Worker Mental Health Survey [Link]
    - CDC is conducting a survey intended for people who worked in STLT public health departments in 2020, in an effort to understand and address the mental health impacts and support needs of our crucial public health workforce on the frontlines of the COVID-19 response. All full-time and part-time employees, contractors, fellows and others who work at the health department are eligible to participate, and we encourage you to broadly disseminate the survey to relevant staff.
    - **The survey deadline has been extended to Friday, April 16.** The 10-15 minute anonymous survey is available here.
- Webinar: "COVID-19 Case Surveillance Public Use Data with Geography – Overview of Privacy Protections" [Attachment, Link]
    - CDC will host a webinar **Friday, April 16** at **2:00 pm EDT** to discuss privacy protections for the new COVID-19 Case Surveillance Public Use Data with Geography. Please email questions in advance to eocevent394@cdc.gov with "Question for 4/16 CDC webinar on new public use dataset" in the subject line. Call information is available below:
        - Weblink: https://cdc.zoomgov.com/j/1618567396?pwd=WE9RWitrS09pdk1KSnA5TnhNdEVjQT09
          Meeting ID: 161 856 7396
          Telephone: (669) 254-5252 or (646) 828-7666 or (551) 285-1373 or (669) 216-1590
          Passcode: 44193919
    - An .ICS calendar file is also attached for your convenience.
- MMWR Early Release: "Factors Associated with Participation in Elementary School–Based SARS-CoV-2 Testing — Salt Lake County, Utah, December 2020–January 2021" [Attachment, Link]
    - From the report: *"As schools consider reopening, in-school specimen collection for SARS-CoV-2 testing could help reach potentially underserved populations to reduce community transmission. Explaining testing procedures in a parent's or guardian's preferred language, as was done in this situation, might also be important for promoting participation."*

Standing Updates

- CDC Partner Updates – April 7 & 9 [Attachments]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Updates – April 6, 7, & 8 [Attachments]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the

week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.

- CSTE COVID-19 Response Resource Repository [Link]
  - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
  - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Wednesday, April 07, 2021 3:57 PM EDT
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Mueller, Trisha (CDC/DDNID/NCCDPHP/DRH) <czj5@cdc.gov>
Subject: COVID-19 Partner Updates: April 7th, 2021

Good afternoon partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov. Thank you for your partnership.

Best,

William Carson

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

April 7, 2021

CDC Resources

- **COVID-19 Vaccine Clinician Resources Update:** CDC's Prevaccination Checklist is now available in English and **six** additional languages: Arabic, Spanish, French, Korean, Simplified Chinese, Vietnamese. Translations are available on the *Product Info by Vaccine* webpages under the Administration Resources section (Pfizer-BioNTech, Moderna, and Janssen/J&J).
- **Grassroots Efforts in Southwest Kansas Educate Refugee Communities about COVID-19:**When COVID-19 hit Southwest Kansas in spring of 2020, there was little information on COVID-19 available in languages apart from English. Essential workers from refugee communities turned to their neighbors, who are also healthcare providers, for answers in their own languages. More about Kansas Refugee Communities
- **Baltimore African American Faith Community is Key in Promoting Vaccine Confidence:**The African American faith community in Baltimore has been integral to educating the public about the risks posed by flu and the importance of vaccination. This work now provides immunization partners with lessons learned for the COVID-19 vaccination program. More about Baltimore's Faith Community
- **Connecticut Uses Social Media to Engage Long-term Care Residents:**To connect with residents of long-term care facilities and their families, the Connecticut Long Term Care Ombudsman Program (LTCOP) partnered with colleagues from other state government agencies to hold weekly Facebook Live events. More about Connecticut LTCOP
- **FluView:** The Weekly U.S. Influenza Surveillance Report (FluView), lists key updates for influenza each week. These updates include viruses detected, illnesses reported in clinics, rates of severe disease, reports on U.S. Virologic Surveillance, and Influenza Virus Characterization.
- **Emergency Preparedness Tips for Parents of Children with Special Healthcare Needs** April is National Autism Awareness Month and a month to start preparing for severe weather. This CDC Public Health Matters blogpost provides tips on proper planning for emergencies, peace of mind exercises, and links to additional guides for families who have children with special needs.

Morbidity and Mortality Weekly Report (MMWR)

- **Early Release MMWR, April 7, 2021: Factors Associated with Participation in Elementary School-Based SARS-CoV-2 Testing — Salt Lake County, Utah, December 2020–January 2021.** Link to article here. CDC partnered with the University of Utah and Utah state and local health departments to offer free, in-school testing as part of elementary school COVID-19 transmission investigations in one Utah school district. An analysis found that compared with Non-Hispanic White students, participation in the testing offered was higher among students identifying as Hispanic/Latino white or as members of a racial minority group. As schools consider reopening, in-school testing could help reach potentially underserved populations to reduce COVID-19 spread in the community.

Upcoming Meetings

- **COVID-19 Partner Update April 12, 2021: Contact Tracing for COVID-19: Do we still need it? (You bet we do!):** 3:00-4:00 PM EDT, Monday, April 12, 2021. Join CDC's weekly partner call for updates on the COVID-19 response, including new resources for the private sector and the general public. Register for the event here. For Q&A, please email eocevent337@cdc.gov with "Partner Call 4/12" in the subject line.
- **Community of Practice Call: School-based Screening Testing:** 2:00-3:00 PM EDT, Thursday, April 8, 2021. This week's Community of Practice call will focus on the importance of the partnership between public health and education in establishing COVID-19 K-12 school screening testing programs and provide information on assistance being offered to support these programs.
- **AUCD, ASTHO, and NACCHO Webinar Series: COVID-19 Vaccination and Reaching People with Disabilities:** 1:00-2:00 PM EDT, April 7, April 8, 2021. AUCD, ASTHO, and NACCHO are hosting webinars: COVID-19 Vaccination and Reaching People with Disabilities. Join to hear about promising practices on how states are reaching people with disabilities. Register here.

Additional Resources

- **Federal Emergency Management Agency (FEMA) to Help Pay Funeral Costs for COVID-19-Related Deaths:** In early April, FEMA will begin providing financial assistance financial assistance for funeral expenses incurred after Jan. 20, 2020 for deaths related to coronavirus (COVID-19) to help ease some of the financial stress and burden caused by the pandemic. FEMA is now moving rapidly to implement this funeral assistance program nationwide.
- **VaccineFinder:** VaccineFinder helps individuals find clinics, pharmacies, and other locations that offer COVID-19 vaccines.
- **Characteristics of Multisystem Inflammatory Syndrome in Children During COVID-19:** Authored by Ermias D. Belay, M.D., of the Centers for Disease Control and Prevention, this study examined the clinical and other characteristics of multisystem inflammatory syndrome in children in the United States, a condition that occurs in association with the COVID-19 pandemic.

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Friday, April 09, 2021 3:11 PM EDT
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Mueller, Trisha (CDC/DDNID/NCCDPHP/DRH) <czj5@cdc.gov>
Subject: COVID-19 Partner Updates: April 9th, 2021

Good afternoon partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov. Thank you for your partnership.

Best,

William Carson

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

April 9, 2021

CDC STLT Support Task Force Friday Feature: STLT Task Force/Section Deployment to assist the Shoshone-Bannock Tribes

Tribal leaders invited CDC's Tribal Support Section (TSS) to provideCOVID-19 technical assistance in the areas of vaccine rollout, strategic community outreach, and interdepartmental process development. Two vaccine coordinators and three public health advisors were deployed from March 5 to March 31 and focused on vaccine coordination, contact tracing, and data management support. The five deployers helped develop tribal guidance related to community safe reopening planning, assessment of COVID-19 vaccine hesitancy and barriers, sources for COVID-19 related information, analysis of Indian Health Service (IHS) and Tribal Health vaccination data, operationalization of mass vaccination clinics/events, and the establishment of a mobile vaccine unit. Communication to promote vaccine demand including the development of written communications products, presentations on the tribe's weekly Facebook Live, and discussion sessions to engage key audiences (e.g., casino executives, COVID screening/testing staff, contact tracers, business council, etc.) helped ensure nearly 50% of the estimated 5,500 eligible tribal members received their first vaccine dose. TSS is appreciative of the invitation extended by the Shoshone-Bannock Tribes and for the opportunity to collaborate with our tribal partners, including Tribal Health and Human Services, IHS, and Health Resources and Services Administration (HRSA). The collaborative environment and continued efforts by the tribes and their partners led to the success of this work. To connect with CDC's Tribal Support Section, please email: eocevent362@cdc.gov.

CDC Resources

- **Mental health survey:** CDC's STLT Task Force/Health Department Section is collecting data on the mental health of those who worked in state, tribal, local, and territorial public health departments in 2020 and will look at demographics, job categories and questions to assess symptoms of anxiety, depression, and post-traumatic stress disorder (PTSD). We also hope to hear about your organizational support and the ways you've coped throughout the pandemic. As of April 8, approximately 15,000 individuals have completed the survey! Thank you for your continued support and efforts. Due to requests for more time from multiple health departments, the project team has extended the survey to Friday, April 16, 2021. Please let your members know about this extension. For more information on CDC's mental health study, please contact the survey team at eocevent442@cdc.gov.
- **Tribal Communities: Plan, Prepare, and Respond:** The CDC maintains a comprehensive website that contains resources for both tribal community members as well as tribal partners. The site was recently updated with additional information on the CDC funding agreement, which adds to the information on prevention, strategies, mental health guidance, and considerations for tribal ceremonies, in addition to many other resources.
- **Post-COVID Conditions: Information for Healthcare Providers:** On April 8, the CDC updated the guidance found on here for healthcare providers. Some patients who have been infected with SARS-COV-2 have symptoms and clinical findings that persist beyond four weeks or can recur following initial recovery. Persistent symptoms and clinical findings can occur regardless of the severity of acute COVID-19. Medical and research communities are still learning about these post-acute symptoms and clinical findings.

- **Post-COVID Conditions:** On April 8, the CDC updated the guidance found on here for post-COVID conditions. Although most people with COVID-19 get better within weeks to months of illness, some do not. CDC and experts around the world are working to learn more about short- and long-term health effects associated with COVID-19, who gets them, and why.

Morbidity and Mortality Weekly Report (MMWR)

- **April 9, 2021, COVID-19 Incidence and Mortality Among American Indian/Alaska Native and White Persons — Montana, March 13–November 30, 2021:** Link to article here. COVID-19 incidence and mortality rates among AI/AN persons in Montana were 2.2 and 3.8 times, respectively, those among white persons. The case-fatality rate among AI/AN persons was 1.7 times that among White persons. These findings reinforce importance of using state-level surveillance to develop state and tribal COVID-19 vaccine allocation strategies and to inform local implementation of culturally appropriate public health measures that might help reduce COVID-19 incidence and mortality in AI/AN communities.
- **April 9, 2021, Use of Stay-at-Home Orders and Mask Mandates to Control COVID-19 Transmission — Blackfeet Tribal Reservation, Montana, June–December 2020:** Link to article here. In the Blackfeet Tribal Reservation, enforcement of stay-at-home orders and mandated use of face coverings in public, with potential fines and jail for noncompliance, were associated with a thirty-three-fold reduction in COVID-19 incidence from its peak of 6.40 cases per 1,000 residents per day on October 5 to 0.19 on November 7, 2020. Enforcement of stay-at-home orders and mask use mandates, coupled with robust public health investigations, have been shown to reduce COVID-19 incidence.
- **April 9, 2021, Notes from the Field: COVID-19 Case Investigation and Contact Tracing Program — Spirit Lake Tribe, North Dakota, September–November 2020:** Link to the article here. In the Fall of 2020, in response to increasing incidence of COVID-19 on the Spirit Lake Reservation, CDC assisted the Spirit Lake Tribe in building a tribally managed program for comprehensive COVID-19 case investigations, case notification, contact tracing, contact testing, and contact management to ensure timely implementation of these critical epidemic control measures.
- **April 9, 2021, COVID-19 Stats: College and University* COVID-19 Student Testing Protocols, by Mode of Instruction (N = 1,849) — United States, Spring 2021:** Link to article here. Study that exams the number of public and private, nonprofit 4-year U.S. colleges and universities that provide some type of COVID-19 testing for asymptomatic students. The study also looks at how testing is offered in schools that are conducting classes in-person, online, or in a hybrid setting.

Upcoming Meetings

- **COVID-19 Partner Update April 12, 2021: Contact Tracing for COVID-19: Do we still need it? (You bet we do!):** 3:00-4:00 PM EDT, Monday, April 12, 2021. Join CDC's weekly partner call for updates on the COVID-19 response, including new resources for the private sector and the general public. Register for the event here. For Q&A, please email eocevent337@cdc.gov with "Partner Call 4/12" in the subject line.

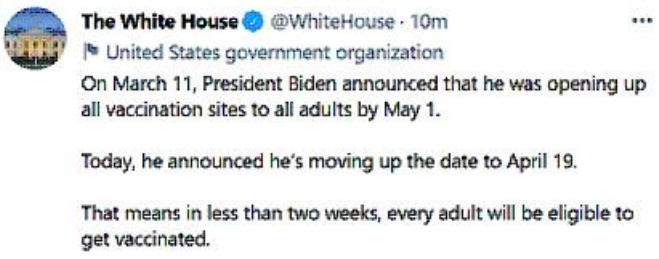
From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Tuesday, April 06, 2021 7:49 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 4/6

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 6, 2021:

President Biden's Remarks on the State of Vaccinations:

- **New Vaccination Goal:** On March the 11th, I announced that I was opening up all vaccination sites to all adults by May 1st. Many governors — Democrats and Republicans — responded and decided to beat that day, which was good. Thanks to their hard work and the hard work of the American people, and the hard work of my team, I'm announcing today that we're moving that date up from May 1st to April 19th, nationwide. That means, by no later than April 19th, in every part of this country, every adult over the age of 18 — 18 or older — will be eligible to be vaccinated. Many states have already opened up to all adults. But beginning April 19th, every adult in every state, every adult in this country is eligible to get in line to get a COVID vaccination.
- **Vaccination Update:** Yesterday, we crossed 150 million shots in 75 days — the first 75 days my administration, on our way to hitting our goal of 200 million shots by the 100th day in office. That, of course, is the new goal I set after passing the original mark of 100 million shots in my first 100 days, doing it in just 58 days. We're now administering an average of 3 million shots per day — over 20 million shots a week. On Saturday alone, we reported more than 4 million shots were administered. We're the first country to administer 150 million shots and the first country to fully vaccinate over 62 million people. The good news is we're on track to beat our goal of 200 million shots in the first 100 days. More than 75 percent of the people over the age of 65 have gotten shots, up from 8 percent when we took office. That's a dramatic turnaround and critical because seniors account for 80 percent of all COVID deaths. To help support my goal of safely reopening a majority of K-through-8 schools by my 100th day in office, I directed states in early March to make educators and childcare workers eligible for vaccines, and to set a goal of getting all who wanted the vaccination to be able to have one and to do it in the month of March. I'm pleased to report, according to CDC estimates, over 80 percent of teachers, school staff, and childcare workers received at least one shot by the end of March. And because our vaccine program is in overdrive, we're making it easier to get a vaccination shot. Last week, I announced that by April 19th of this month, 90 percent of all Americans will be within five miles of a vaccination site.
- **Vaccine Effectiveness:** We're getting more and more data on just how effective the vaccines are. Dr. Fauci recently cited two studies from the New England Journal of Medicine that found fully vaccinated care workers — healthcare workers on the frontlines had an extremely low infections rate, less than two-tenths of one percent, compared to unvaccinated healthcare workers who had considerably higher infection rates.
- **COVID-19 Cases and Variants:** New variants of the virus are spreading and they're moving quickly. Cases are going back up. Hospitalizations are no longer declining. While deaths are still down — way down from January — they're going up in some places. I understand that people may find it confusing that the vaccination program is saving tens of thousands of lives, but the pandemic remains dangerous. Let me explain it in a single word: Time. Time. Even moving at the record speed we're moving at, we're not even halfway through vaccinating over 300 million Americans. This is going to take time. Remember: For a two-dose vaccine, it takes weeks from the time you get your first one until you are able to get your second shot, which makes you fully protected.
- **Importance of Following CDC Guidelines:** We aren't at the finish line. We still have a lot of work to do. We're still in a life-and-death race against this virus. Until we get more people vaccinated, we need everyone to wash their hands, socially distance, and mask up in a recommended mask from the CDC.
- **Getting Vaccinated:** I want to make a direct appeal to our seniors and everyone who cares about them. While we have made incredible progress vaccinating three quarters of our seniors and putting vaccination sites within five miles of 90 percent of the public, it still isn't enough. It's simple: Seniors, it's time for you to get vaccinated now. Get vaccinated now. To make it easier, my administration is sending aid to community groups to drive seniors to vaccination sites. We're incredibly grateful to all the volunteers, houses of worship, and the civic groups that are helping us in this effort. As I ask seniors to sign up for their shots now, I also have a message for people under 65. If you know someone over 65 who has not gotten this life-saving vaccine, call them now. Work with them to get their shots this week or next. Pick them up, drive them. It can be your parents, your grandparents, your aunt, uncle, your neighbors.
- **Access to Vaccines:** We know that there are a number of seniors and people with disabilities and people in many communities of color who may be isolated and lack access to transportation. That's why we're ramping up transportation to vaccination centers and deploying more mobile units and pop-up clinics in the places close to where people live. That's why we're working with faith-based organizations and other community groups to host vaccination clinics, sign people up for appointments, get help — help them get those appointments. That's why we're sending even more vaccines to community health centers, like the one I was in today, that all together serve nearly 30 million Americans, like the ones I visited today. Two thirds of the patients at community health centers live at or below the poverty level. Sixty percent are racial and ethnic minorities. To reach them, we're investing nearly $10 billion to expand testing, treatment, and vaccinations for the hardest hit yet most underserved communities.



Case Update

New Cases (based on 7-day rolling average)

- **30,532,965** US cases
- **3.0% increase** in new cases (7-day average), as of April 4th; (was 13.2% increase last week)

Testing

- **381,757,068** tests completed (4/6)
- **5.7%** positive test rate as of the week of 3/27 – 4/2 (was 5.0% last week)

Hospitalizations

- **1,971,219** total COVID hospital admissions
- The 7-day average (3/28-4/3) number of new confirmed COVID-19 admissions **increased** to **4,843** admissions per day from last week's 7-day average (3/21-3/27) of **4,693** admissions per day

Deaths

- **554,064** total US deaths
- The 7-day average (3/29-4/4) number of reported deaths **decreased by 20.4%** week on week (from 985 to 781 deaths per day)

Vaccines

- **168,592,075** vaccine doses **administered** (4/6)
- **32.6%** (108.3 million people) of the population has received **1 or more doses** and **19%** (63 million people) of the population have been **fully vaccinated**
- **75.9%** of adults 65 and older have received **at least 1 dose** and **56.6%** have been **fully vaccinated**

Vaccine Updates

FEMA Vaccination Sites: This week, federal pilot community vaccination centers are scheduled to open in Gary, Indiana; Greenbelt, Maryland; St. Louis; Memphis, Tennessee and Milwaukee, while FEMA mobile vaccination units have begun operations, bringing vaccinations to hard-to-reach and high-risk populations who cannot access services from fixed sites. Four units are operational: one in Connecticut, two in Maryland and one in Oregon. FEMA has now provided more than $4.5 billion to 42 states, Washington D.C., four tribes and five territories for expenses related to COVID-19 vaccination at 100% federal cost share. These funds cover critical supplies, staffing, training and transportation needs that support increased vaccination efforts.

County-Level Vaccination Data: CDC updated their tracker on county-level vaccination data. This site allows users to explore standardized data across the country, including vaccine data.

V-Safe Pregnancy Registry: CDC updated their information on the V-Safe COVID-19 Vaccine Pregnancy Registry. As of April 5, 2021, more than 77,000 v-safe participants have indicated they were pregnant at the time they received COVID-19 vaccination. CDC is currently enrolling eligible participants and analyzing data to better understand how COVID-19 vaccination affects pregnant people. As CDC learns more about the effects of vaccination during pregnancy, data will be presented at the Advisory Committee on Immunization Practices (ACIP) meetings, which are open to the public, and in published reports.

Reported Adverse Events After COVID-19 Vaccinations: Over 167 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through April 5, 2021. During this time, the Vaccine Adverse Event Reporting System (VAERS) received 2,794 reports of death (0.00167%) among people who received a COVID-19 vaccine. CDC and FDA physicians review each case report of death as soon as notified and CDC requests medical records to further assess reports. A review of available clinical information including death certificates, autopsy, and medical records revealed no evidence that vaccination contributed to patient deaths. CDC and FDA will continue to investigate reports of adverse events, including deaths, reported to VAERS.

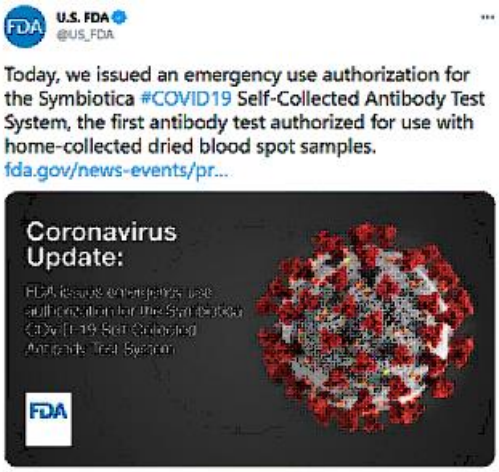
COVID-19 Vaccination Toolkit: CDC updated their COVID-19 vaccination toolkit for health departments and other public health partners. This toolkit provides information for public health partners to help educate communities and promote COVID-19 vaccination. The CDC also updated their information on promoting vaccine confidence.

Resources for Sharing Real-Time Vaccine Information: CDC updated their resources for sharing real-time vaccine information. Virtual communication tools, like virtual town halls, livestreams, and social media, offer public health professionals the ability to engage and disseminate vital information to the public while maintaining social distancing. This page also includes non-CDC resources for virtual meetings.

Customizable COVID-19 Vaccination Content: CDC updated their information on customizable COVID-19 vaccination content for health departments and other public health partners. Health departments and other public health partners can use the content in a variety of formats. It can be customized for newsletters, emails, blogs, matte articles, or other forms of communication. Health departments and public health partners can add their own logos and customize the text to make it appropriate for their community.

Testing and Treatment

FDA Issues EUA for the Symbiotica COVID-19 Self-Collected Antibody Test System: The FDA today announced it has issued an emergency use authorization (EUA) for the Symbiotica COVID-19 Self-Collected Antibody Test System, the first antibody test authorized for use with home collected dried blood spot samples. Samples collected at home are then sent to a Symbiotica, Inc. laboratory for analysis. The COVID-19 Self-Collected Antibody Test System is authorized for prescription use with a fingerstick dried blood sample that is self-collected by an individual age 18 years or older or collected by an adult from an individual 5 years of age and older. The test is intended to aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The COVID-19 Self-Collected Antibody Test System should not be used to diagnose or exclude acute SARS-CoV-2 infection. Currently, it is unknown how long antibodies persist following infection and if the presence of antibodies confers protective immunity.



Drug Applications During the COVID-19 Pandemic: The FDA issued and immediately implemented a new guidance: Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers. The guidance provides general recommendations to prospective generic drug applicants related to generic drug product development and regulatory submissions in the form of questions and answers that have been received and addressed by the FDA during the COVID-19 public health emergency. The FDA is issuing this guidance so that the development of generic drugs and submission of applications can continue during the COVID-19 public health emergency, ultimately helping to ensure that Americans continue to have access to safe, effective generic drugs.

New Initiative for At-Home Testing: NIH Director, Dr. Francis Collins, comments on the launch of the new innovative community health initiative called "Say Yes! COVID Test," led by the CDC, in close collaboration with state and local public health departments and the NIH. The initiative, the first large-scale evaluation of community-wide, self-administered COVID-19 testing, was launched last week in Pitt County, NC, and will start soon in Chattanooga/Hamilton County, TN.

Mask Guidance: CDC updated their guidance for wearing masks, in order to help slow the spread of COVID-19. CDC recommends that people wear masks in public settings, at events and gatherings, and anywhere they will be around other people. Effective February 2, 2021, masks are required on planes, buses, trains, and other forms of public transportation traveling into, within, or out of the United States and in U.S. transportation hubs such as airports and stations. CDC updated their guidance on how to select, wear, and clean your mask. Furthermore, CDC updated their information on how masks can better protect you, and how to improve the fit and filtration of your mask.

Reopening Guidance

Crew Disembarkations through Commercial Travel: CDC updated their information regarding crew disembarkations through commercial travel**.** CDC is committed to helping cruise lines provide for the safety and well-being of their crew members while onboard cruise ships and as they disembark. CDC is allowing crew members to disembark from all cruise ships in U.S. waters with certain precautions. Cruise lines with complete and accurate response plans are able to use commercial travel to disembark crew members from certain ships if the ships meet certain criteria set by CDC. Criteria include no confirmed cases of coronavirus disease 2019 (COVID-19) or COVID-19-like illness onboard the ship within the last 14 days. These ships are also able to lessen certain social distancing restrictions onboard. Cruise lines with complete and accurate COVID-19 response plans but not meeting the above criteria will still be able to disembark their crew members using noncommercial travel. Cruise lines must have measures in place to ensure those involved in transport are not exposed to the virus that causes COVID-19 and follow all CDC requirements to prevent interaction of disembarking crew with the public. Additionally, CDC recommends that all eligible port personnel and travelers (passengers and crew) get a COVID-19 vaccine when one is available to them.

Information for Specific Populations

Staffing Resources: CDC updated their resources and guidance for strengthening the public health workforce. Enhancing frontline public health capacity in state, local, tribal, and territorial health departments to intensify the coordinated response to COVID-19 is critical.

Requirement for Air Passengers Arriving in the U.S: CDC updated their information regarding the requirement for proof of negative COVID-19 test or recovery from COVID-19 for all air passengers arriving in the United States. If you plan to travel internationally, you will need to get tested no more than 3 days before you travel by air into the United States and show your negative result to the airline before you board your flight, or be prepared to show documentation of recovery (proof of a recent positive viral test and a letter from your healthcare provider or a public health official stating that you were cleared to travel).

Essential Services and Critical Infrastructure: CDC updated their fact sheet on how essential services can plan, prepare, and respond to COVID-19 in order to prevent spread of the virus and ensure essential functions continue.

CDC Podcast: CDC Director Dr. Rochelle P. Walensky joins CDC Foundation President and CEO Dr. Judy Moore to discuss the agency's latest work to combat COVID-19 and how public health professionals can help prepare communities for a new normal.

Research

SARS-CoV-2 May Infect Mouth Cells: In an NIH study, researchers find that SARS-CoV-2, the virus that causes COVID-19, can infect cells in the mouth. The findings suggest that the mouth, via infected oral cells, may play a bigger role in SARS-CoV-2 infection than previously thought. Saliva infected by these cells might help infect the lungs when it is breathed in and the gut when it is swallowed. A better understanding of the mouth's role in SARS-CoV-2 infection could help to develop interventions and treat oral symptoms of COVID-19.

COVID-19 Kidney Care Challenge: HHS announced the seven winners in Round 2 of the COVID-19 Kidney Care Challenge. Ranging from digital health to genetic sequencing approaches, their resourceful solutions aim to reduce risk during the pandemic.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Wednesday, April 07, 2021 6:58 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 4/7

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 7, 2021:

Highlights from the White House COVID-19 Response Team Briefing

Andy Slavitt

- **New Vaccination Goal:** The President announced yesterday that all adult Americans will be eligible to be vaccinated by April 19. This is ahead of the original May 1st timeline that he set last month. This means that there is no better time for seniors who haven't been vaccinated to get their shot now. At this point, over 76 percent of seniors have had at least their first shot. If you know a senior who has not yet had the opportunity to get a shot, consider helping them arrange that opportunity and see what help they need. A number of seniors live alone and may need transportation or other help. The good news is there are more and more locations in more places available for them. President Biden also announced that we crossed 150 million shots in just 75 days of his administration.
- **School Reopening**: At the beginning of March, the President directed states and the Federal Retail Pharmacy Program to prioritize the vaccination of teachers, school staff, and childcare workers during the month of March. As the President announced yesterday, as of the end of March, the latest CDC estimates show that almost 80 percent of pre-K through 12th grade teachers, school staff, and childcare workers received at least one shot. The Department of Education released the latest round of data from its own ongoing survey on the impact of COVID-19 on K through 8th grade students and the state of school reopening in the nation. This is encouraging early data — covering the month of February — and shows progress toward the President's goal to have K through 8th grade schools open five days a week.
- **Expanding Vaccination Sites:** We're announcing today that we are expanding our community health center vaccine program so that all of the nearly 1,400 community health centers can sign up to receive and administer doses to their patients. Many community health centers are located in underserved communities and serve patients that are predominantly either uninsured or underinsured.

Dr. Walensky

- **Case Update:** CDC's most recent data show that the seven-day average of new cases is a little more than 63,000 cases per day. This is up approximately 2.3 percent compared to the prior seven-day average. Hospital admissions also continue to increase. The most recent seven-day average — about 5,000 admissions per day — is up about 2.7 percent from the prior seven-day average. And deaths decreased 19.7 percent to a seven-day average of 745 per day.
- **Case Data and Variants:** Across the country, we are hearing reports of clusters of cases associated with daycare centers and youth sports. Hospitals are seeing more and more younger adults — those in their 30s and 40s — admitted with severe disease. Data suggests this is all happening as we are seeing increasing prevalence of SARS-CoV-2 variants, with 52 jurisdictions now reporting cases of variants of concern. Based on our most recent estimates from CDC surveillance, the B.1.1.7 variant is now the most common lineage circulating in the United States.
- **Avoiding a Surge:** We have to recognize the high risk of infection in areas of high community transmission. I encourage communities to consider adjustments to meet their unique needs and circumstances. We have guidance on CDC's website on how to host small events safely, recognizing that our goals are to decrease transmission of COVID-19 and, importantly, to keep schools open and students engaged in in-person learning. We are vaccinating, on average, 3 million Americans every single day — getting shots into arms, providing protection. I urge everyone who has not received a COVID-19 vaccine to roll up their sleeves and join the nearly 108 million people who have already received at least one dose.

Dr. Fauci

- **Duration of Immunity to Natural Infection:** Regarding natural infection, we now have a considerable amount of information related to the duration of what we hope we'll be able to delineate more confidently — namely, what's called the "correlate of immunity." A paper from Science from a couple of months ago looked at the multiple immune memory responses, including both antibodies CD4 and CD8 T cells following natural infection. About 95 percent of the subjects in this study maintained antibodies six months after infection. I want people to realize that that's at least six months. They did not look further than this, so it might be much longer.
- **Duration Following Vaccination:** One representative study, which came out yesterday in the *New England Journal of Medicine* , looked at the persistence of responses through six months following the Moderna vaccine. But there's every reason to believe that similar results will be seen with the Pfizer, as well as the J&J. If you look at this, antibody activity remained high in all age groups out to 209 days in three serological assays. We are still working out the precise correlate of immunity, but antibodies delivered by vaccination persist at least through six months, and likely, from the shape of the curve, well beyond that. In that regard, ongoing studies are monitoring these immune responses beyond six months, as well as determining the effect of a booster dose to extend the duration and breadth of activity against not only wild type, but also emerging viral variants.

Vaccine Updates

Expansion of COVID-19 Vaccine Program: HHS Secretary Xavier Becerra today announced that all HRSA-funded health centers and Health Center Program look-alikes (LALs) will now be invited to participate in the Health Center COVID-19 Vaccine Program. These health centers will have the opportunity to join the program as soon as they are ready, increasing the total number of health centers that have been invited to 1,470 nationwide. This expansion will be made through the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC). Approximately 70 percent of those who have received a vaccine through the Health Center COVID-19 Vaccine Program are racial or ethnic minorities.

Nearly 80 Percent of Educators At Least Partially Vaccinated: CDC issued a media release stating that nearly 80 percent of Pre-K-12 teachers, school staff, and childcare workers received at least their first shot of COVID-19 vaccine by the end of March. More than 2 million teachers, school staff, and childcare workers were vaccinated through the Federal Retail Pharmacy Program during the month of

March. Additionally, 5-6 million were vaccinated through their state programs through the end of March.

Getting Your Vaccine: CDC updated their information for people getting their COVID-19 vaccine. If you receive a Pfizer-BioNTech or Moderna COVID-19 vaccine, you will need 2 shots to get the most protection. COVID-19 vaccines are not interchangeable. If you received a Pfizer-BioNTech or Moderna COVID-19 vaccine, you should get the same product for your second shot. You should get your second shot even if you have side effects after the first shot, unless a vaccination provider or your doctor tells you not to get it.

Vaccine Adverse Event Reporting System: CDC provided information on their Vaccine Adverse Event Reporting System (VAERS), which is an early warning system used to monitor adverse events that happen after vaccination. VAERS is the frontline system of a comprehensive vaccine safety monitoring program in the United States . Millions of people in the United States have received COVID-19 vaccines. Other than rare reports of severe allergic reactions, analysis of VAERS reports has not detected any patterns that would indicate a safety problem with COVID-19 vaccines. More information on vaccine safety and monitoring here.

Testing and Treatment

FDA COVID-19 Update: The FDA released a testing update. As of April 6, 355 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 258 molecular tests and sample collection devices, 75 antibody and other immune response tests, and 22 antigen tests. There are 43 molecular authorizations and 1 antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home test, four over-the-counter (OTC) at-home antigen test, and one OTC molecular test. The FDA has authorized 6 antigen tests and 1 molecular test for serial screening programs.

Funding

CDC Awards $3 Billion to Expand COVID-19 Vaccine Programs: CDC has awarded funding to support local efforts to increase vaccine uptake by expanding COVID-19 vaccine programs and ensuring greater equity and access to vaccine by those disproportionately affected by SARS-CoV-2, the virus that causes COVID-19. The awards are part of $3 billion in funding that CDC has granted to 64 jurisdictions to bolster broad-based vaccine distribution, access, and administration efforts. The funding was made available by the American Rescue Plan and the Coronavirus Response and Relief Supplemental Appropriations Act and will provide critical support through CDC's existing immunization cooperative agreements in communities around the country. To ensure health equity and expanded access to COVID-19 vaccines: 75% of the total funding must focus on specific programs and initiatives intended to increase vaccine access, acceptance, and uptake among racial and ethnic minority communities; and, 60% must go to support local health departments, community-based organizations, and community health centers.

FEMA Vaccination Sites: FEMA has provided more than $4.5 billion to 42 states, Washington D.C., five tribes and five territories for expenses related to COVID-19 vaccination at 100% federal cost share. These funds cover critical supplies, staffing, training and transportation needs that support increased vaccination efforts. Furthermore, FEMA mobile vaccination units have begun operations. These vehicles can bring vaccinations to hard-to-reach and high-risk populations who cannot access services from fixed sites. Six units are operational: one in Connecticut, two in Maryland, two in Nevada and one in Oregon.

Information for Specific Populations

Employer Information for Office Buildings: CDC updated their guidance for office building employers, owners and managers, and operations specialists to create a safe and healthy workplace for workers and clients. CDC states that employers should perform enhanced cleaning and disinfection after anyone suspected or confirmed to have COVID-19 has been in the workplace within the last 24 hours, and to clean high-touch surfaces.

People with Moderate to Severe Asthma: CDC updated their guidance for people with asthma in order to protect themselves from COVID-19. People with moderate to severe asthma should continue to follow CDC guidelines and get a COVID-19 vaccine when it is available to them.

Community Health Workers Support of Home-Based Care: CDC updated their considerations intended for program managers and other public health officials supporting the COVID-19 response in low-resource non-US settings. Protecting community health workers' (CHWs) health and safety is critical, including during the COVID-19 pandemic. With training about prevention and appropriate infection prevention and control measures, CHWs can protect their own health while serving as good examples for how to prevent COVID-19 in the communities they serve. Relying on CHWs can help maximize available resources for managing and caring for people with more severe illness and can help maintain essential health services. CDC offers suggestions for CHWs in order to ensure their safety and the safety of their patients.

CMS Updates

The Value of Affordable Health Care: Secretary Becerra comments on the value of affordable health care , discussing his family's health scare in a time before health care reform. Secretary Becerra applauds both the Affordable Care Act (ACA) passed under the Obama-Biden administration, as well as the American Rescue Plan Act, signed last month by President Biden, as tools towards ensuring health care as a right and not as a privilege.

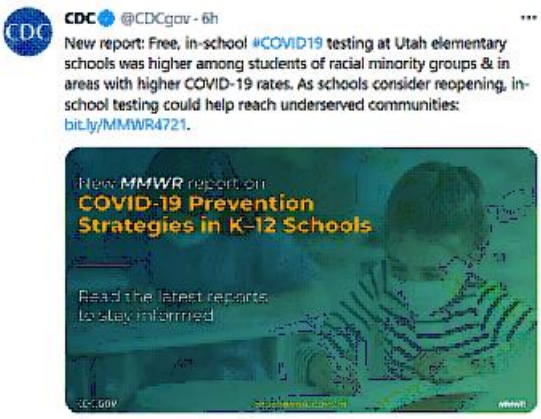
More than 500,000 Americans Have Enrolled in Marketplace Coverage During SEP: Today, HHS Secretary Xavier Becerra announced that more than half a million consumers have already signed up for health insurance through HealthCare.gov as a result of the Biden Administration's Special Enrollment Period (SEP) for the COVID-19 Public Health Emergency. The SEP, along with the additional financial assistance afforded by the American Rescue Plan (ARP), offers the opportunity for individuals and families to take advantage of significantly reduced premiums, increased savings, and quality, affordable health coverage through the Marketplaces using the Federal Platform. Today's report from the CMS, which covers plan selections from February 15 to March 31, also shows gains in enrollment among historically uninsured communities, including Black consumers and Americans near the poverty level. Of applicants who identified a race, 17% identified as Black – compared to about 11% in both 2020 and 2019 during the same time period. Among consumers requesting financial assistance, 41% report being at or slightly above the federal poverty level, compared to 38% in 2020 and 33% in 2019.

FY 2022 Proposed Medicare Payment and Quality Reporting Updates: On April 7, 2021, the CMS issued a proposed rule that would update Medicare payment policies and rates for the Inpatient Psychiatric Facility Prospective Payment System (IPF PPS) for Fiscal Year (FY) 2022 and propose changes to the IPF Quality Reporting (IPFQR) Program. For the FY 2023 payment determination and subsequent years, CMS is proposing to add the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure to the IPFQR Program. The measure addresses the quality priority of "Promote Effective Prevention & Treatment of Chronic Disease" through the Meaningful Measures domain of Preventive Care. The process measure was developed by the Centers for Disease Control and Prevention (CDC) to track COVID-19 vaccination coverage among HCP in the IPF setting. This measure would be reported using the COVID-19 Modules on the CDC's National Healthcare Safety Network web portal.

Research

Study of Allergic Reactions to Moderna and Pfizer-BioNTech COVID-19 Vaccines: NIH begins a clinical trial to determine whether people who are highly allergic or have a mast cell disorder are at increased risk for an immediate, systemic allergic reaction to the Moderna or Pfizer-BioNTech COVID-19 vaccines. A systemic allergic reaction to a vaccine occurs in one or more parts of the body beyond the injection site. If such an allergic reaction occurs in study participants, investigators will assess whether the reactions are more frequent in participants who are highly allergic or have a mast cell disorder than in participants with no allergic history. In addition, investigators will examine the biological mechanism behind the reactions and whether a genetic pattern or other factors can predict who is at most risk. The study team will enroll 3,400 adults ages 18 to 69 years at up to 35 academic allergy-research centers nationwide.

Factors Associated with Participation in Elementary School-Based SARS-CoV-2 Testing: CDC released an *MMWR* on the factors associated with participation in elementary school-based SARS-CoV-2 testing in Salt Lake County, Utah. During December 3, 2020–January 31, 2021, CDC, in collaboration with the University of Utah Health and Economic Recovery Outreach Project, Utah Department of Health (UDOH), Salt Lake County Health Department, and one Salt Lake county school district, offered free, in-school, real-time reverse transcription–polymerase chain reaction (RT-PCR) saliva testing as part of a transmission investigation of SARS-CoV-2, the virus that causes COVID-19, in elementary school settings. Among 856 unique student contacts at 20 elementary schools, 594 who were exposed to 33 index patients at 13 elementary schools were analyzed. The *MMWR* describes the demographic breakdown of the participants in the study, and the potential of in-school specimen collection for SARS-CoV-2 testing to help reach underserved populations to reduce community transmission.



Trends in Geographic and Temporal Distribution of U.S. Children with MIS-C: JAMA Pediatrics published a study on the trends in geographic and temporal distribution of U.S. children with multisystem inflammatory syndrome (MIS-C) during the COVID-19 pandemic. In this cross-sectional study, 1,733 patients with MIS-C were identified with predominantly gastrointestinal, mucocutaneous, and cardiovascular manifestations, and a majority required intensive care. MIS-C peaks closely followed the peaks of COVID-19 and the spread of the pandemic from urban to rural communities. The data are consistent with observations that MIS-C resulted from delayed immunologic responses to infection by SARS-CoV-2.

Case Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 cases will remain stable or have an uncertain trend over the next 4 weeks, with 219,000 to 758,000 new cases likely reported in the week ending May 1, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of new reported cases per week will likely increase in 1 jurisdiction, which is indicated in the forecast plots below. Trends in numbers of future reported cases are uncertain or predicted to remain stable in the other states and territories. View previous case forecasts.

Hospitalization Forecasts: This week's national ensemble predicts that the number of new daily confirmed COVID-19 hospital admissions will

remain stable or have an uncertain trend over the next 4 weeks, with 2,400 to 11,000 new confirmed COVID-19 hospital admissions likely reported on May 3, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of daily confirmed COVID-19 hospital admissions will likely increase in 7 jurisdictions and decrease in 10 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported hospital admissions are uncertain or predicted to remain stable in the other states and territories. View previous hospitalization forecasts.

Death Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 deaths will remain stable or have an uncertain trend over the next 4 weeks, with 2,300 to 10,100 new deaths likely reported in the week ending May 1, 2021. The national ensemble predicts that a total of 568,000 to 588,000 COVID-19 deaths will be reported by this date. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of newly reported deaths per week will likely decrease in 3 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported deaths are uncertain or predicted to remain stable in the other states and territories. View previous death forecasts.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Thursday, April 08, 2021 7:26 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 4/8

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for April 8, 2021:

Vaccine Updates

Vaccination Toolkits: CDC updated their vaccination toolkits, which provide audience-specific information and language for healthcare teams and community administrators.

Getting Your COVID-19 Vaccine: CDC updated their information regarding getting your COVID-19 vaccine. CDC reiterated that COVID-19 vaccines are not interchangeable. If you received a Pfizer-BioNTech or Moderna COVID-19 vaccine, you should get the same product (or brand) for your second shot.

FEMA Vaccination Sites: Yesterday, federal pilot community vaccination centers opened in Gary, Indiana; Greenbelt, Maryland; St. Louis; Memphis, Tennessee and Milwaukee, with additional federal pilot community vaccination centers scheduled to open next week in Pueblo, Colorado; St. Paul, Minnesota; and Columbia, South Carolina. FEMA mobile vaccination units are now operating in Nevada, Oregon, Connecticut and Maryland, bringing vaccinations to hard-to-reach and high-risk populations who cannot access services from fixed sites. FEMA has now provided more than $4.5 billion for expenses related to COVID-19 vaccination at 100% federal cost share.

DOD Prioritizing COVID-19 Vaccinations to Those Deployed: The Defense Department is rapidly administering COVID-19 vaccines in a tiered priority process to service members, DOD contractors and civilians and their families who are stationed overseas and who wish to have them. Based on current projections of vaccine supplies and health care providers who administer them, the department projects that by the middle of May, all deployed personnel who want them will have had at least the initial vaccination dosage.

Testing and Treatment

Contact Tracing Resources for Health Departments: CDC updated their contact tracing resources for health departments in order to stop the spread of COVID-19. CDC added a resource on how to talk to your close contacts . It encourages people who have COVID-19 to notify their close contacts so that they can quarantine at home and get tested.

Reopening Guidance

Requirement for All Air Passengers Arriving in the U.S: CDC updated their fact sheet and Q&A regarding the requirement for proof of a negative COVID-19 test or recovery from COVID-19 for all air passengers arriving in the United States**.** If you plan to travel internationally, you will need to get tested no more than 3 days before you travel by air into the United States and show your negative result to the airline before you board your flight, or be prepared to show documentation of recovery (proof of a recent positive viral test and a letter from your healthcare provider or a public health official stating that you were cleared to travel).

Information for Specific Populations

Emergency Transportation for Tribal Communities: CDC updated their guidance for tribal communities in order to minimize risk of spreading COVID-19 when sharing personal vehicles.

Fraud Alert – COVID-19 Scams: The HHS Office of Inspector General is alerting the public about fraud schemes related to the novel coronavirus (COVID-19). Scammers are using telemarketing calls, text messages, social media platforms, and door-to-door visits to perpetrate COVID-19-related scams. Fraudsters are offering COVID-19 tests, HHS grants, and Medicare prescription cards in exchange for personal details, including Medicare information. However, these services are unapproved and illegitimate. If you suspect COVID-19 health care fraud, report it immediately online or call 800-HHS-TIPS (800-447-8477).

CMS Updates

FY 2022 Skilled Nursing Facility Prospective Payment System Proposed Rule: On April 8, 2021, CMS issued a proposed rule that would update Medicare payment policies and rates for skilled nursing facilities under the Skilled Nursing Facility (SNF) prospective payment system (PPS) for fiscal year (FY) 2022. In addition, the proposed rule includes proposals for the SNF Quality Reporting Program (QRP), and the SNF Value-Based Program (VBP) for FY 2022. CMS is proposing the adoption of the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) Measure beginning with the FY 2023 SNF QRP. This measure would require SNFs to report on COVID-19 HCP vaccination in order to assess whether SNFs are taking steps to limit the spread of COVID-19 among their HCP, reduce the risk of transmission within their facilities and help sustain the ability of SNFs to continue serving their communities throughout the COVID-19 PHE and beyond. Under this proposal, SNFs would report the vaccination data through the Centers for Disease Control and Prevention National Healthcare Safety Network beginning October 1, 2021.

FY 2022 Hospice Payment Rate Update Proposed Rule: On April 8, 2021, CMS issued a proposed rule (CMS-1754-P) that would provide routine updates to hospice base payments and the aggregate cap amount for FY 2022 in accordance with existing statutory and regulatory requirements. This proposed rule also includes a comment solicitation regarding hospice utilization. In addition, this rule proposes to rebase the hospice labor shares and clarify certain aspects of the hospice election statement addendum requirements. This rule proposes changes to the Hospice Conditions of Participation (CoPs) and Hospice Quality Reporting Program (HQRP). The proposed rule also includes a Home Health Quality Reporting Program (HH QRP) proposal to display publicly three quarters of certain outcome and assessment information set (OASIS) data

due to the COVID-19 public health emergency (PHE) exemptions of the 2020 first and second quarter data.

FY 2022 Inpatient Rehabilitation Facility Prospective Payment System Proposed Rule: On April 7, 2021, CMS issued a proposed rule that would update Medicare payment policies and rates for facilities under the Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS) and the IRF Quality Reporting Program (QRP) for fiscal year (FY) 2022. In the ongoing efforts to address the COVID-19 public health emergency, CMS is proposing the adoption of the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) Measure to require IRFs to report COVID-19 HCP vaccinations in their facilities. This proposed measure is designed to assess whether IRFs are taking steps to limit the spread of COVID-19 among their HCP, reduce the risk of transmission within their facilities, and help sustain the ability of IRFs to continue serving their communities through the public health emergency and beyond.

PPE

Optimizing N95 Respirator Supplies: CDC updated information offering a series of strategies or options to optimize supplies of disposable N95 filtering facepiece respirators (commonly called "N95 respirators") in healthcare settings when there is limited supply. CDC adds clarifications on use of facemasks as a crisis capacity strategy and outlines the assumptions to implement contingency and crisis strategies.

Research

Post-COVID-19 Conditions: CDC released information on post-COVID-19 conditions, which include a wide range of health consequences that are present more than four weeks after infections with SARS-CoV-2. CDC outlines the types of post-COVID conditions including long COVID, multiorgan effects of COVID-19, and effects of COVID-19 treatment or hospitalization. There are ways to help manage post-COVID conditions, and many patients with these symptoms are getting better with time. CDC recommends that people get vaccinated regardless of whether they already had COVID-19. CDC continues active investigation into the full spectrum of COVID-19 illness, from the acute phase to longer term effects and conditions.

Accelerated Research to Address Concurrent HIV and COVID-19 Pandemics: In a review article published in the *Journal of Infectious Diseases*, Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases, part of the NIH, and colleagues call for accelerated research to address concurrent HIV and COVID-19 pandemics. The COVID-19 pandemic is affecting people with or at risk for HIV both indirectly, by interfering with HIV treatment and prevention services, and directly, by threatening individual health. An effective response to these dual pandemics requires unprecedented collaboration to accelerate basic and clinical research, as well as implementation science to expeditiously introduce evidence-based strategies into real-world settings.

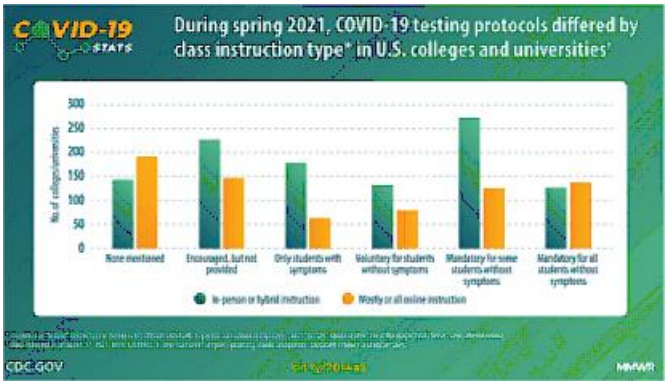
Substance Abuse Disorders During the COVID-19 Pandemic: NIH Director, Dr. Francis Collins, discusses his conversation with Dr. Nora Volkow, Director of NIH's National Institute on Drug Abuse, regarding the impact of the COVID-19 pandemic on people struggling with substance use disorders and those who are trying to help them . While the demands of the pandemic have been challenging for everyone, biomedical researchers have remained hard at work to address the opioid crisis. Among the many ways that NIH is supporting these efforts is through its Helping to End Addiction Long-Term (HEAL) Initiative, which is directing more than $1.5 billion to researchers and communities across the country.

COVID-19 Incidence and Mortality Among AI/AN and White Persons: CDC released an *MMWR* on COVID-19 incidence and mortality among American Indian or Alaska Native (AI/AN) and White persons in Montana from March 2020 – November 2020. Aggregate analyses of data from selected U.S. states indicate that COVID-19 incidence and mortality are higher among AI/AN persons than they are among White persons. COVID-19 incidence and mortality rates among AI/AN persons in Montana were 2.2 and 3.8 times, respectively, those among White persons. The case-fatality rate among AI/AN persons was 1.7 times that among White persons. These findings reinforce importance of using state-level surveillance to develop state and tribal COVID-19 vaccine allocation strategies and to inform local implementation of culturally appropriate public health measures that might help reduce COVID-19 incidence and mortality in AI/AN communities.

COVID-19 Transmission in the Blackfeet Tribal Reservation: CDC released an *MMWR* on the use of stay-at-home orders and mask mandates to control COVID-19 transmission in the Blackfeet Tribal Reservation in Montana from June 2020 – December 2020. Community mitigation measures (e.g., stay-at-home orders and mask use), coupled with case investigation and contact tracing with immediate isolation or quarantine, are primary approaches to preventing and controlling community SARS-CoV-2 transmission. In the Blackfeet Tribal Reservation, enforcement of stay-at-home orders and mandated use of face coverings in public, with potential fines and jail for noncompliance, were associated with a thirty-three-fold reduction in COVID-19 incidence from its peak of 6.40 cases per 1,000 residents per day on October 5 to 0.19 on November 7, 2020. Enforcement of stay-at-home orders and mask use mandates, coupled with robust public health investigations, have been shown to reduce COVID-19 incidence.

Spirit Lake Tribe COVID-19 Case Investigation and Contact Tracing Program: CDC released an *MMWR* with notes from the field on a COVID-19 case investigation and contact tracing program within the Spirit Lake Tribe in North Dakota from September 2020 – November 2020. Through the Spirit Lake Tribe case investigation and contact tracing program, the tribe's COVID-19 Incident Command System staff members conducted case investigations and contact tracing, provided COVID-19 education, followed up with patients regularly by telephone, and monitored daily symptoms of close contacts. Members of the Spirit Lake community served as contact tracers. Symptom monitoring was facilitated through CDC's Text Illness Monitoring system (version TIM²), using a free, two-way text-messaging platform to query enrolled contacts about daily COVID-19 symptoms. The system also alerted Spirit Lake Tribal Health authorities when participants reported symptoms or did not to respond. This tribally managed COVID-19 case investigation and contact tracing program effectively reached Spirit Lake tribal members to provide isolation, quarantine, symptom monitoring, and support services and contributed to timely case and contact management. This program might help guide similar programs in other tribes and the public health community.

College and University COVID-19 Stats: CDC released an *MMWR* on COVID-19 student testing protocols by mode of instruction at colleges and universities during the spring of 2021. As of March 17, 2021, a total of 899 (49%) of 1,849 public and private, nonprofit 4-year U.S. colleges and universities provided some type of COVID-19 testing for asymptomatic students, including 548 (30%) institutions conducting classes in-person or in a hybrid format. Among institutions providing testing for asymptomatic students, 389 (43%) had protocols that required periodic testing for various subgroups (e.g., athletes, fraternity and sorority activity participants, and a random sample of students); 287 (32%) mandated that all students receive testing (ranging from every other day to once every other week), which did not vary by public or private, nonprofit status or by mode of instruction. Among institutions, 18% (338 of 1,849) did not mention a COVID-19 testing protocol on their websites, including146 with in-person or hybrid instruction. Although asymptomatic transmission is estimated to account for approximately one half of SARS-CoV-2 transmission, a majority (950; 51%) of institutions did not publish a testing protocol for screening asymptomatic students in spring 2021.



Provisional Mortality Data: CDC updated an *MMWR* on provisional mortality data. This report was posted online as an *MMWR* Early Release on March 31. The COVID-19 pandemic caused approximately 375,000 deaths in the United States during 2020. The age-adjusted death rate increased by 15.9% in 2020. Overall death rates were highest among non-Hispanic Black persons and non-Hispanic American Indian or Alaska Native persons. COVID-19 was the third leading cause of death, and the COVID-19 death rate was highest among Hispanics. Provisional death estimates provide an early indication of shifts in mortality trends. Timely and actionable data can guide public health policies and interventions for populations experiencing higher numbers of deaths that are directly or indirectly associated with the COVID-19 pandemic.

COVID-19 Mortality Surveillance: CDC updated an *MMWR* on death certificate-based ICD-10 diagnosis codes for COVID-19 mortality surveillance. This report was posted online as an *MMWR* Early Release on March 31. Among 378,048 death certificates from 2020 listing COVID-19, 5.5% listed COVID-19 without codes for any other conditions. Among 357,133 death certificates with at least one other condition, 97% had a co-occurring diagnosis of a plausible chain-of-event condition (e.g., pneumonia or respiratory failure), or a significant contributing condition (e.g., hypertension or diabetes), or both. These findings support the accuracy of COVID-19 mortality surveillance in the United States using official death certificates. High-quality documentation of death certificate diagnoses is essential for an authoritative public record.

Community Transmission of SARS-CoV-2: CDC updated an *MMWR* on the community transmission of SARS-CoV-2 associated with a local bar opening event in Illinois. This report was posted online as an *MMWR* Early Release on April 5. Forty-six cases of COVID-19 were linked to an indoor bar opening event that occurred during February 2021 in a rural Illinois county. Event patrons were linked to secondary cases among household, long-term care facility, and school contacts, resulting in one hospitalization and one school closure affecting 650 students. Opening up settings such as bars, where mask wearing and physical distancing are challenging, can affect the community. As community businesses reopen, prevention measures should be emphasized, including limiting building occupancy, improving ventilation, prioritizing outdoor seating, enforcing correct mask wearing and physical distancing, staying home when ill, and encouraging COVID-19 vaccination to reduce transmission on site and within the community.

COVID-19 Science Update: CDC released a COVID-19 Science Update, presenting the latest COVID-19 research on a range of topics including but not limited to vaccine effectiveness, strategies for testing asymptomatic airline passengers, and the B.1.1.1.7 variant.

Healthcare Operations During the COVID-19 Pandemic: The HHS Assistant Secretary for Preparedness and Response (ASPR) program TRACIE – Technical Resources, Assistance Center, and Information Exchange – presents ways to address tough healthcare problems like supply chain issues, delays in emergency care, and the deferred elective procedures during the COVID-19 pandemic.

Non-COVID-19 Updates

Health Equity: CDC published a webpage to examine how racism is a serious threat to the public's health . The data show that racial and ethnic minority groups, throughout the United States, experience higher rates of illness and death across a wide range of health conditions, including diabetes, hypertension, obesity, asthma, and heart disease, when compared to their White counterparts. Additionally, the life expectancy of non-Hispanic/Black Americans is four years lower than that of White Americans. The COVID-19 pandemic, and its disproportionate impact among racial and ethnic minority populations is another stark example of these enduring health disparities.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Aug 6. (Early MMWRs, CDC Media Statement on Post-Vaccination COVID-19 Infection Rates, Updated Guidance for COVID-19 Prevention in K-12 Schools and more)
Date:	Friday, August 6, 2021 3:26:47 PM
Attachments:	image001.png image002.png mm7032e1-H.pdf mm7032e2-H.pdf mm7032e3-H.pdf Webinar_DOJ-ConfinementFacilities_Final.pdf Webinar_DOJ-ConfinementFacilities_QA-Summary.pdf Webinar_DOJ-ConfinementFacilities_Transcript.pdf ELC Enhancing Detection PM Guidance_8_5_2021_FINAL.pdf COVID-19 Partner Updates August 04 2021.msg HHS COVID-19 Update - 85.msg COVID-19 Partner Updates August 06 2021.msg

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- Early MMWRs - Vol. 70, No. 31 [Attachments, Links]
  - The **August 6** edition of CDC's Morbidity and Mortality Weekly Report (MMWR) includes the following COVID-related articles:
    - Rapid Increase in Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — Mesa County, Colorado, April–June 2021COVID-19 Vaccine Administration, by Race and Ethnicity — North Carolina, December 14, 2020–April 6, 2021
    - Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021
    - Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥65 Years — 13 states, COVID-NET, February–April 2021
- New CDC Study: Vaccination Offers Higher Protection than Previous COVID-19 Infection [Link]
  - In response to today's MMWR on post-vaccination COVID-19 infection rates (linked here), CDC issued a media statement, announcing in part: "*In today's MMWR, a study of COVID-19 infections in Kentucky among people who were previously infected with SAR-CoV-2 shows that unvaccinated individuals are more than twice as likely to be reinfected with COVID-19 than those who were fully vaccinated after initially*

contracting the virus. These data further indicate that COVID-19 vaccines offer better protection than natural immunity alone and that vaccines, even after prior infection, help prevent reinfections."

- Read the CDC's full media statement here.

- Updated CDC Guidance for COVID-19 Prevention in K-12 Schools [Links]
  - On **August 5**, CDC updated its Guidance for COVID-19 Prevention in K-12 Schools to align with CDC's existing guidance for fully vaccinated people and assist K-12 schools in opening for in-person instruction and remaining open. Additionally, the Considerations for Case Investigation and Contact Tracing in K-12 Schools and Institutions of Higher Education (IHEs) has been updated to align with new CDC guidance.
  - The full updated Guidance is linked here.
- CDC COCA Call: Therapeutic Options to Prevent Severe COVID-19 in Immunocompromised People [Links]
  - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **Thursday, August 12** at **2:00 pm EDT** to discuss the FDA's role in issuing EUAs for certain monoclonal antibodies, options for compassionate use, the process for ordering and distributing monoclonal antibodies, and current data on using monoclonal antibodies for both non-hospitalized and immunocompromised patients. Presenters will also cover preventing, diagnosing, and treating COVID-19 in immunocompromised patients, including the role of monoclonal antibodies, serologic testing, and potential third dose of COVID-19 vaccinations.
    - Weblink: https://www.zoomgov.com/j/1612254638?pwd=SmNaNlJEUWt3YWdBMGtNRjhxRlZ1UT09
      Telephone: (646) 828-7666 or (669) 216-1590 or (551) 285-1373
      Webinar ID: 161 225 4638
      Passcode: 980771
      Access materials post-call:
      https://emergency.cdc.gov/coca/calls/2021/callinfo_081221.asp
- ELC & DOJ Webinar: Detection & Mitigation of COVID-19 in Confinement Facilities [Attachments, Link]
  - On **August 5**, CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) and the Department of Justice (DOJ) hosted a webinar, "Detection & Mitigation of COVID-19 in Confinement Facilities."
  - In case you missed it, you may watch/download the full webinar here. Also attached are a transcript and summary of the Q&A portion of the webinar.
- Updated ELC Enhancing Detection Performance Measures Guidance [Attachment]
  - Today, **August 6**, CDC released an updated ELC Enhancing Detection Performance Measures Guidance document (attached) for this new budget year that started August 1, 2021.
  - This guidance provides details for all ELC Enhancing Detection performance measures including all data elements, reporting frequency, and reporting timelines.
- Updated CDC Public Health Science Priority Questions [Link]
  - The CDC's *Public Health Science Agenda* for COVID-19 articulates key areas of scientific inquiry and opportunities to guide the development of actionable, evidence-based public health guidance to limit the spread and impact of SARS-CoV-2 and ultimately end

the COVID-19 pandemic. As the evidence base and public health response to the COVID-19 pandemic continues to evolve, this Public Health Science Agenda has helped promote efforts to fill critical, time-sensitive scientific gaps and to inform evidence-based decision making.

- On **August 4**, a second update to the Priority Public Health Science Questions was released (linked here) to help achieve the objectives outlined in the Public Health Science Agenda for COVID-19. The newest update includes 15 Priority Public Health Science Questions that were systematically developed to be relevant, actionable near-term, and reflective of the evolving needs of the ongoing public health response.

Standing Updates

- CDC Partner Updates – August 4 & August 6 [Attachments]
  - Please see attached for the latest update from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – August 5 [Attachment]
  - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
  - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
  - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
  - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Wednesday, August 04, 2021 4:17 PM EDT
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>; Matthews, Rosalyn (CDC/DDNID/NCCDPHP/DPH) <aii9@cdc.gov>; Brunson, Juanita (CDC/DDNID/NCBDDD/DBDID) (CTR) <qrl8@cdc.gov>; White, Roshanna (CDC/DDID/NCIRD/OD) (CTR) <kqx3@cdc.gov>; Moore, Rashida (CDC/DDID/NCIRD/OD) (CTR) <ksq5@cdc.gov>; Harris Sharpe, Bria (CDC/DDNID/NCBDDD/DBDID) <qov0@cdc.gov>; Uddin, Rezwana (CDC/DDPHSIS/CSTLTS/DPIFS) <pyi1@cdc.gov>; Bermudez, Oscar (CDC/DDNID/NCBDDD/DBDID) (CTR) <rwk5@cdc.gov>; Johnson, Shyonna (CDC/DDNID/NCBDDD/DBDID) <qzf9@cdc.gov>
Subject: COVID-19 Partner Updates: August 04, 2021

Good afternoon Partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov. Thank you for your partnership.

Best regards,
Rezwana Uddin

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

August 4, 2021

CDC Resources

- **CDC Issues Eviction Order in Areas of Substantial and High Transmission:** CDC Director Dr. Rochelle Walensky signed an order determining the evictions of tenants for failure to make rent or housing payments could be detrimental to public health control measures to slow the spread of SARS-CoV-2. This order will expire on October 3, 2021 and applies in United States counties experiencing substantial and high levels of community transmission levels of SARS-CoV-2.
- **Overall US COVID-19 Vaccine Distribution and Administration Update as of Tue, 03 Aug 2021 06:00:00 EST**: CDC's COVID Data Tracker has updated maps, charts, and data for various vaccine-related metrics.
- **Laws and Regulations**: CDC has updated the most recent laws and regulations related to the COVID-19 pandemic.
- **Staffing Resources**: Recent update of the map shows CDC deployments and field staff.
- **Cruise Ship Color and Commercial Travel Status**: CDC has updated guidance for fully vaccinated people based on new evidence on the Delta variant.
- **What to Consider When Planning to Operate a COVID-19 Vaccine Clinic**: CDC shares strategies jurisdictions can use to plan, optimize, and maximize operations at all types of temporary COVID-19 vaccination clinics.
- **Families & Children**: CDC has updated guidance for parents, families, and organizations that care for children.
- **CDC Science Agenda for COVID-19**: CDC has updated a guide intended to strengthen the public health actions, guidance, and policy essential to limit the spread and impact of SARS-CoV-2 and ultimately end the COVID-19 pandemic.

Upcoming Meetings

- **CDC All-State, Tribal, Local, and Territorial (STLT) Update Call:** Monday, August 9th, 2:00-2:45 PM ET, CDC hosts a weekly national call series to provide state, tribal, local, and territorial partners with the latest information on the COVID-19 outbreak and U.S. preparedness efforts. If you would like to register for this event, please click here.

Additional Resources

- **Beyond School Supplies: Back to School Reminders & Readiness**
- **Find a COVID-19 vaccine near you:** Vaccines.gov is live – helping to make it easier for individuals to access COVID-19 vaccines. Powered by the trusted Vaccine Finder brand - Vaccines.gov is available in English and Spanish and will help connect Americans with locations offering vaccines near them.
    - **Individuals in the U.S. can now utilize a text messaging service to locate vaccine locations, available in both English and Spanish.** Individuals can text their ZIP code to 438829 (GETVAX) and 822862 (VACUNA) to find three locations nearby that have vaccines available.

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Friday, August 06, 2021 3:56 PM EDT
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>; Matthews, Rosalyn (CDC/DDNID/NCCDPHP/DPH) <aii9@cdc.gov>; Brunson, Juanita (CDC/DDNID/NCBDDD/DBDID) (CTR) <qrl8@cdc.gov>; White, Roshanna (CDC/DDID/NCIRD/OD) (CTR) <kqx3@cdc.gov>; Moore, Rashida (CDC/DDID/NCIRD/OD) (CTR) <ksq5@cdc.gov>; Harris Sharpe, Bria (CDC/DDNID/NCBDDD/DBDID) <qov0@cdc.gov>; Bermudez, Oscar (CDC/DDNID/NCBDDD/DBDID) (CTR) <rwk5@cdc.gov>; Johnson, Shyonna (CDC/DDNID/NCBDDD/DBDID) <qzf9@cdc.gov>
Subject: COVID-19 Partner Updates: August 06, 2021

Good afternoon Partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov. Thank you for your partnership.

Best regards,
Rezwana Uddin

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
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EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

August 6, 2021

Friday Feature: Race to End COVID-19 Partner Playbook

In collaboration with partners, CDC has developed a Race to End COVID Partner Playbook for planning and conducting community-based COVID-19 testing and vaccination events at racetracks. Race to End COVID events are envisioned as partnerships between state, tribal, local, and territorial (STLT) health departments, the National Association for Stock Car Auto Racing (NASCAR), and/or local racetracks, whether NASCAR-affiliated or independently owned.

An effective public health response to the COVID-19 pandemic involves the whole community, including the local, state, and/or tribal health authority and, potentially, members of the private sector. Public-private partnerships may offer a good way to promote public health messages and inform health behaviors to slow the spread of COVID-19. Please see the playbook for more details.

MMWR

- **Rapid Increase in Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — Mesa County, Colorado, April–June 2021.** Link here.
- **Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021.** Link here.
- **Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥65 Years — COVID-NET, 13 States, February–April 2021.** Link here.

CDC Resources

Science and Data

- **CDC Science Agenda for COVID-19**: CDC has updated a guide intended to strengthen the public health actions, guidance, and policy essential to limit the spread and impact of SARS-CoV-2 and ultimately end the COVID-19 pandemic.
- **COVID Data Tracker Recent Updates - 2021-08-05 - The Vaccination Among People with Disabilities tab displays information on the number of vaccinated adults with disabilities in the United States:** CDC reports findings from a Household Pulse Survey of adults aged ≥18 years led by the U.S. Census Bureau, in partnership with multiple other federal statistical agencies, to measure household experiences during the COVID-19 pandemic.
- **COVID-19 and Animals:** Updated guidance on understanding the risk of animals spreading SARS-CoV-2, the virus that causes COVID-19, to people as well as spread from people to animals.

Work and School

- **Guidance for COVID-19 Prevention in Kindergarten (K)-12 Schools:** CDC has updated guidance for K-12 schools to recommend universal indoor masking and testing for fully vaccinated people in situations of known recent exposure to COVID-19.
- **Interim Guidance for Case Investigation and Contact Tracing in K-12 Schools:** CDC has updated guidance for K–12 schools and institutions of higher education, including considerations for people fully vaccinated against COVID-19 and situations when K–12 students are not considered close contacts.

- **What to do if a Student Becomes Sick at School or Reports a New COVID-19 Diagnosis Flowchart:** CDC shares guidance for situations when students show signs of infectious illness consistent with COVID-19, or confirmation of negative and/or positive COVID-19 test results.

Healthcare

- **What to Consider When Planning to Operate a COVID-19 Vaccine Clinic:** CDC shares strategies jurisdictions can use to plan, optimize, and maximize operations at all types of temporary COVID-19 vaccination clinics.

Community

- **Families with Vaccinated and Unvaccinated Members:** Updated guidance for families protecting unvaccinated members, those who have a condition or are taking medications that weaken their immune system, and choosing safer activities for the family.
- **CDC Issues Eviction Order in Areas of Substantial and High Transmission:** CDC Director Dr. Rochelle Walensky signed an order determining the evictions of tenants for failure to make rent or housing payments could be detrimental to public health control measures to slow the spread of SARS-CoV-2. This order will expire on October 3, 2021 and applies in United States counties experiencing substantial and high levels of community transmission levels of SARS-CoV-2.
- **Laws and Regulations:** CDC has updated the most recent laws and regulations related to the COVID-19 pandemic.
- **Families & Children:** CDC has updated guidance for parents, families, and organizations that care for children.

Upcoming Meetings

- **CDC All-State, Tribal, Local, and Territorial (STLT) Update Call:** Monday, August 9th, 2:00-2:45 PM ET, CDC hosts a weekly national call series to provide state, tribal, local, and territorial partners with the latest information on the COVID-19 outbreak and U.S. preparedness efforts. If you would like to register for this event, please click here.
- **Clinical Laboratory COVID-19 Response Calls:** Monday, August 9th, 3:00-4:00 PM ET, CDC's Division of Laboratory Systems hosts a biweekly call to discuss hot topics and to solicit the laboratory community's questions about the national response to the COVID-19 pandemic. To attends this call on August 9th, please click here and enter the following password: 048861a! To submit a question for consideration, email DLSinquiries@cdc.gov. For additional information, please contact LOCS@cdc.gov.
- **Understanding the Role of School Nurses in Supporting School Safety Before, During, and After an Emergency:** Tuesday, August 10th, 2:00-3:00 PM ET, the U.S. Department of Education (DOE), in partnership with multiple other educational agencies, will host a webinar with the National Association of School Nurses to highlight and discuss the role school nurses have in supporting overall school safety, security, emergency management, and preparedness before, during, and after an emergency. If you would like to register for this event, please click here.

Additional Resources

- **Back to School Toolkit | WECANDOTHIS.HHS.GOV**
- **Guide to On-Site Vaccination Clinic for Schools | WECANDOTHIS.HHS.GOV**
- **Beyond School Supplies: Back to School Reminders & Readiness**
- **Find a COVID-19 vaccine near you:** Vaccines.gov is live – helping to make it easier for individuals to access COVID-19 vaccines. Powered by the trusted Vaccine Finder brand -Vaccines.gov is available in English and Spanish and will help connect Americans with locations offering vaccines near them.
    - **Individuals in the U.S. can now utilize a text messaging service to locate vaccine locations, available in both English and Spanish.** Individuals can text their ZIP code to 438829 (GETVAX) and 822862 (VACUNA) to find three locations nearby that have vaccines available.

ELC PERFORMANCE MEASURES GUIDANCE FOR PROJECT E: ENHANCING DETECTION

CDC-RFA-CK19-1904

CDC EPIDEMIOLOGY AND LABORATORY CAPACITY FOR PREVENTION AND CONTROL OF EMERGING INFECTIOUS DISEASES

August 2021

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Introduction and Purpose

The goal of the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) is to support state, local, and territories' public health efforts to reduce morbidity and associated deaths caused by a wide range of infectious disease threats. The ELC provides annual funding, strategic direction, and technical assistance to domestic jurisdictions for strengthening core capacities in epidemiology, laboratory, and health information systems activities. In addition to strengthening core infectious disease capacities nationwide, this cooperative agreement also supports a myriad of specific infectious disease programs and projects and provides special appropriations in response to infectious disease emergencies (e.g., H1N1, Ebola, and Zika).

As part of the "Paycheck Protection Program and Health Care Enhancement Act of 2020 (P.L. 116-139, Title I)", the ELC awarded a total of $10.25 billion to recipient jurisdictions in a program-initiated component funding under the Emerging Issues (E) Project of CK19-1904, "ELC Enhancing Detection" supplement. In early 2021, an additional $19.11 billion from the "Coronavirus Response and Relief Supplemental Appropriations Act of 2021, H.R. 133", was provided to ELC recipients to provide additional critical support to jurisdictions as they continue to address COVID-19 within their communities. These funds are intended to provide critical resources to state, local, and territorial health departments in support of a broad range of COVID-19/SARS-CoV-2 testing and epidemiologic surveillance related activities, including the establishment of modernized public health surveillance systems. The work supported by ELC Enhancing Detection and the Enhancing Detection Expansion builds upon previous COVID-19 awards (ELC CARES and ELC Community-based Surveillance). These funds support the public health response to COVID-19 and lay the foundation for the future of public health surveillance.

This guidance provides information on performance measures for recipients of these supplemental funds. To reduce reporting burden on recipients, the performance measures for ELC Enhancing Detection and ELC Enhancing Detection Expansion encompass work being conducted for those receiving funds for ELC CARES and Community-based Surveillance.

The performance measures are intended to be used by ELC and recipients to help:

- Support continuous monitoring and examine opportunities to improve performance and implementation of activities
- Demonstrate accountability to stakeholders (e.g., funders, public) by showing how ELC funds are being spent
- Clarify ELC project expectations and priorities

The ELC realizes that there are limitations to using performance measures to evaluate the scope of public health work being conducted by the jurisdictions. For example, without a consideration of contextual factors, measures do not always fully represent how strongly or poorly a recipient is doing. Thus, it is important to have other ways of collecting project information to demonstrate performance (i.e., workplan/milestone updates, progress calls, success stories). The ELC will rely on a combination of these sources of information to assess progress more comprehensively throughout the duration of the project.

Organization of Guidance

For each measure, the following elements are described:

- *Measure:* Name of measure
- *Applicable recipients:* Recipients the measure applies to
- *Rationale:* Provides the context and reasoning for monitoring this measure
- *Data elements:* Specific variables that will be reported by recipient or monitored by ELC
- *Additional guidance:* Additional information to help understand the measure such as definitions for specific terms, inclusion/exclusion criteria, limitations to the measure, and other applicable information
- *Target:* Recommended recipient target for this measure, where applicable. Targets are used to provide guidance to recipients on the desired level of performance from ELC. They will also be used in discussions between ELC and recipients to identify gaps and opportunities to provide technical assistance.
- *Recommended data source:* Source the recipient or ELC may use to retrieve data
- *Reporting frequency:* Specifies how often the measure will be reported
- *Reporting mechanism:* Describes how data will be reported

Intended Use of Guidance

Please take some time to review the guidance and share it with the appropriate staff members in your jurisdiction who are involved in the implementation of these activities. Ensure that you and your staff members understand each measure and how it applies to your jurisdiction. Some of these measures will be monitored through data reporting that recipients already submit to CDC. ELC recommends that you develop a plan for how you will collect, organize, and synthesize this information for reporting.

While ELC has made every effort to consolidate data submission intervals, please note that some measures require more frequent reporting than others. Furthermore, due to the relatively long (30 month) project period, recipients should anticipate and work with ELC to re-evaluate and potentially modify some measures to accommodate shifts in priorities during the timeframe of this project and to improve the ability to monitor performance. Some additional data collection for other measures may be required, and some measures may eventually become obsolete. ELC will make every effort to keep these changes minimal.

If you have questions related to these performance measures, please contact elcevaluation@cdc.gov, or your ELC Project Officer.

Updates in Guidance

The updated version of the guidance includes several updates and revisions that ELC recommends awardees pay particular attention to:

- **Measure E.10:** Percent of regularly reporting ILINet providers and the number of patient visits captured in ILINet each week both within and outside the Core Based Statistical Areas (CBSAs).
    - Numerator has been updated to the number of CBSA's with at least **200** patient visits each week from regularly reporting ILINet providers per 100,000 population
    - The target has been updated to at least **200** patient visits per 100,000 population within each CBSA, captured in ILINet each week after 12 months.
- **Measure E.12:** Number of healthcare organizations engaged to implement electronic case reporting (eCR)
    - Question 1 has been modified to only include the types of recruitment for **new** in-jurisdiction providers to onboard to eCR rather than the quantity.
    - Three new questions:
        - Did you confirm that your answer to question 1 is consistent with the monitoring question available on the Site Overview monitoring form? (Y/N)
        - Please share any successful recruitment strategies or any challenges to recruitment.
        - If you offered incentives to healthcare organizations for participating in eCR, what has been the impact of those incentives?
    - Former Question 3 (now Question 5): New categories added to the levels of engagement in eCR between public health and healthcare organizations
        - Testing for COVID-19 only
        - In production and parallel reporting for COVID-19 only
        - In production with no manual reporting for COVID-19 only
        - Testing for all conditions
        - In production and parallel reporting for all conditions
        - In production with no manual reporting for all conditions
- **NEW MEASURE - Measure E.12a:** Number of conditions published to production in Reportable Conditions Knowledge Management System (RCKMS).
- **Measure E.14:** Demonstration of automatic processing of electronic initial case reports (eICRs) in the jurisdiction integrated surveillance system(s)
    - Rather than providing a numerator and denominator, the recipient will indicate the percent of eICRs that are received by the jurisdiction and populated into the system without entering an error queue in the production environment for each surveillance system where applicable.
    - Two new questions:
        - Did you confirm that your answers for question 1 are consistent with the monitoring question available on the Site Overview monitoring form? (Y/N)
        - Please provide any qualitative information about your progress on processing eICRs into the surveillance system. Are there any successes, challenges, or status changes that you would like to share?
- **Measure E.15:** Proportion of test orders and results processed through Electronic Test Orders and Results Reporting (ETOR) at the PHL (this measure only applies to tests conducted at the public health laboratory)
    - This measure has been broken out to examine test orders and results by web portal versus direct and indirect systems integration.

- **Measure E.17:** Caseload, number of cases per case investigator and number of contacts per contact tracer during the data collection period
    - "Number of cases sent to the case investigation team" has been removed
- **Measure E.19:** Timeliness of contact tracing during the data collection period
    - "Number of contacts notified" has been added
    - "Number of contacts notified between 1 and 3 days of case interview" has been removed
    - "Number of contacts notified after 3 days of case interview" has been removed
- **Measure E.20:** Effectiveness of contact tracing to interrupt the transmission of COVID-19 during the data collection period
    - "Number of contacts that agree to have their symptoms monitored" has been removed
- **Measure E.29:** Number of SARS-CoV-2 specimens sent to CDC for sequencing per month
    - These data will be collected from an existing source, and recipients will not be required to report.
- **Appendix C:** PM reporting timeline for measures reported via REDCap for Year 2
    - **All data collection and data submission dates have been updated.**

Measure E.1: Median number of days from specimen collection date to date of report of final test result for COVID-19/SARS-CoV-2 molecular diagnostic tests

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	Laboratory turnaround time can impact public health's ability to respond to events in a timely manner. Whether or not tests are being conducted in a timely manner may help identify areas for improvement or point to gaps in the process to help achieve more timely detection and reduce the spread of COVID-19. Public health may have limited control over tests conducted by non-PHL laboratories/community testing sites and the quality of specimens sent to public health. However, since the majority of COVID-19/SARS-CoV-2 testing is performed outside of the PHL, assessing all laboratories ability to perform timely testing and reporting is a critical component in the success of our public health response. These data will be used to guide discussions between ELC and the recipient on how to work together to improve testing timeliness, where needed.
Data Elements	For the PHL: 1. Median number of days and range from **specimen collection date** to **receipt of specimen at the laboratory** for COVID-19/SARS-CoV-2 molecular tests conducted in the PHL a. Minimum b. Median c. Maximum d. Percent of specimens **received at the PHL** for COVID-19/SARS-CoV-2 molecular testing **within 2 days of the specimen collection date** i. Numerator: The number of specimens that were received at the PHL for COVID-19/SARS-CoV-2 molecular testing within 2 days of the specimen collection date ii. Denominator: The total number of specimens that were received at the PHL for COVID-19/SARS-CoV-2 molecular testing 2. Median number of days and range **from receipt of specimen** to **date of report of final test result** for COVID-19/SARS-CoV-2 molecular tests conducted in the PHL a. Minimum b. Median c. Maximum d. Percent of specimens for which **final test results were reported** for COVID-19/SARS-CoV-2 molecular testing **within 2 days** of the **date the specimen was received** at the PHL i. Numerator: The number of specimens for which final test results were reported for COVID-19/SARS-CoV-2 molecular testing within 2 days of the date the specimen was received at the PHL ii. Denominator: The number of specimens for which final test results were reported for COVID-19/SARS-CoV-2 molecular testing at the PHL For non-PHL laboratories/community testing sites: 3. Median number of days and range from specimen collection date to date of report of final test result for COVID-19/SARS-CoV-2 molecular tests conducted outside of the PHL a. Median b. Minimum

	c. Maximum d. Proportion of specimens for which final test results were reported for COVID-19/SARS-CoV-2 molecular testing within 4 days of the specimen collection date for tests conducted outside of the PHL i. Numerator: The number of specimens for which final test results were reported for COVID-19/SARS-CoV-2 molecular testing within 4 days of the specimen collection date for tests conducted outside of the PHL ii. Denominator: The number of specimens for which final test results were reported for COVID-19/SARS-CoV-2 molecular testing outside of the PHL
Additional Guidance	This measure applies to molecular tests conducted covering the entire jurisdiction. If the date of report of final test result is missing, please use the date the test result was determined. The median number of days and range should include weekend days. *Specimen collection to receipt of specimen:* This includes the time from collection of specimen to receipt of the specimen in the laboratory. *Receipt of specimen to final test result:* This includes the time from receipt of specimen, obtaining laboratory test results, and then reporting the result to public health.
Target	≤ 2-day from specimen collection to receipt of specimen. ≤ 2-day from receipt of specimen to date of report of final test result.
Recommended Data Source	LIMS
Reporting Frequency	Quarterly
Reporting Mechanism	☒ REDCap for PHLs ☒ CDC currently has this data for non-PHL laboratories/community testing sites and there is no need to report it at this time.

Measure E.2: Number of COVID-19/SARS-CoV-2 tests completed by test type, race/ethnicity, and result

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	A major purpose of this funding is to ensure a robust testing program for COVID-19/SARS-CoV-2 is in place. Recipients are expected to expand testing capacity, including working with non-PHL laboratories/community testing sites, to enable the jurisdiction to test sufficient numbers of its population in accordance with CDC guidelines and in alignment with a jurisdiction's testing plan. This measure looks at the volume of COVID-19/SARS-CoV-2 testing conducted across a jurisdiction and may be used in conjunction with percent of positive molecular tests to indicate whether a jurisdiction is sufficiently testing its population. Volume will also be assessed by race/ethnicity to determine whether all racial/ethnic groups are being testing
Data Elements	1. Number of COVID-19/SARS-CoV-2 molecular tests conducted, total and by race/ethnicity 2. Number of COVID-19/SARS-CoV-2 serology tests conducted, total and by race/ethnicity 3. Number of COVID-19/SARS-CoV-2 antigen tests conducted, total and by race/ethnicity 4. Number of COVID-19/SARS-CoV-2 molecular tests conducted that were positive 5. Number of COVID-19/SARS-CoV-2 serology tests conducted that were positive 6. Number of COVID-19/SARS-CoV-2 antigen tests conducted that were positive 7. Number of individuals planned to be tested (molecular)
Additional Guidance	This measure is about the total number of tests conducted. Numbers are inclusive of all tests conducted in your jurisdiction regardless of testing site. We understand there may or may not be a substantial discrepancy between the number of tests conducted and number of individuals tested; however, at this point in time, there is no way to differentiate between these two numbers through the CELR line-level data received by CDC. We encourage jurisdictions to de-duplicate test results whenever possible in order to better understand the burden of COVID-19 within the population. There are limitations to using percent positivity as an indicator of adequate testing capacity, and results will be contextualized with other factors. For example, a high percentage of positive test results may indicate that testing is occurring among a disproportionately high-risk population, or there is a high prevalence of COVID-19/SARS-CoV-2 overall circulating within the population. The percent of positive test results among all molecular test results may also be used to help gauge whether a jurisdiction has sufficient testing capacity in place, especially when it is applied to specific populations (e.g. high-risk demographics) and geographical areas (e.g. densely populated urban areas) *Number of tests conducted:* These include all tests (molecular, antigen, serology) and all test results (positive, negative and indeterminant). *Number of individuals planned to be tested:* This information is collected via the Jurisdictional Testing Plans as mandated by legislative language.

Target	≥ 2% of population tested per month (diagnostic testing) for the first year of funding during the remainder of calendar year 2020. While the target applies to diagnostic testing only, jurisdictions should evaluate and implement appropriate use of serology to better understand their population. This target may change over time.
Recommended Data Source	LIMS (#1-3) Jurisdictional Testing Plans (#4)
Reporting Frequency	Monthly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Measure E.3: Proportion of COVID-19/SARS-CoV-2 laboratory test results submitted to CDC with complete information

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	Assuring a rapid and thorough public health response to the COVID-19 pandemic necessitates comprehensive laboratory testing data. These data contribute to understanding disease incidence and trends, availability and use of testing resources, and identification of supply chain issues for reagents and other material. Particularly important for identifying and addressing health disparities, ascertaining race/ethnicity among cases is a high priority in the guidance and that efforts should focus on those variables. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities. The intent of this measure is to look at the extent to which laboratory test result information being submitted to CDC through the CELR line-level data is complete, resulting in a more detailed and timelier national picture of testing surveillance. ELC understands that completeness of these data may be reliant on the ordering provider; these data will be used to guide discussions between ELC and the recipient on how to work with ordering providers and clinical labs to improve data completeness.
Data Elements	For tests conducted within the PHL: 1. Proportion of COVID-19/SARS-CoV-2 laboratory test results submitted to CDC with complete information a. Numerator: Number of laboratory test results with complete information b. Denominator: Number of laboratory test results For tests conducted at non-PHL laboratories/community testing sites: 2. Proportion of COVID-19/SARS-CoV-2 laboratory test results submitted to CDC with complete information a. Numerator: Number of laboratory test results with complete information b. Denominator: Number of laboratory test results
Additional Guidance	This includes tests for all results. *Complete information:* A COVID-19/SARS-CoV-2 laboratory report with these critical data elements (as defined here: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf) completed and sent to CDC will be considered "complete" for the following data elements: 1. Test order identifier (universal service identifier/universal service description) 2. Test result 3. Test Result date 4. Accession #/Specimen ID (filler order number namespace/filler order number OID) 5. Age 6. Patient race 7. Patient ethnicity 8. Patient gender 9. Patient residence zip code 10. Patient residence county 11. Ordering provider name and NPI (as applicable) 12. Ordering provider zip

	13. Performing Laboratory name or CLIA number, if known 14. Performing Laboratory zip code 15. Specimen Source - use appropriate LOINC, SNOMED-CT, SPM4 codes, or equivalently detailed alternative codes 16. Date specimen collected (date format) 17. Test report date
Target	ELC plans to baseline completeness percentages for all data elements and use that information to develop strategies for improvement. The ELC acknowledges that current percentages for completeness may be low.
Recommended Data Source	LIMS
Reporting Frequency	Quarterly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Measure E.4: Biosafety outreach and guidance provided by PHLs and/or the health department to COVID-19/SARS-CoV-2 testing sites

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	Safety of testing for COVID-19/SARS-CoV-2, in both laboratory and non-laboratory testing sites (e.g., prisons, nursing homes, drive-through testing sites), is an important concern. Public health departments are expected to conduct outreach and engage with testing facilities to improve safety of testing. This measure looks at the extent and breadth of outreach and engagement efforts on improving safety in non-PHL laboratories/community testing sites to help ensure that testing is done safely to protect personnel involved in collecting and processing specimens.
Data Elements	1. Please describe what external outreach steps are being taken to provide consultation and training on biosafety. 2. Do you have a dedicated team in the PHL to address issues around laboratory safety, including inventory management of PPE, specimen management, diagnostic and surveillance testing, and reporting results? (Yes/No) a. If no, do you have plans to develop such a team? (Yes/No) 3. Do you have a biosafety officer (BSO)? (Yes/No) a. If yes, is your BSO part-time or full-time? 4. Do you have a biosafety outreach officer (BOO) to provide biosafety guidance to external institutions? (Yes/No) a. If no, do you have plans to hire one? (Yes/No) b. If yes, is your BOO part-time or full-time? 5. Does your BSO/BOO/biosafety team engage **non-PHL laboratories**? (Yes/No) a. If yes, how does your BSO/BOO/biosafety team engage non-PHL laboratories* (select all that apply)? i. Provides in-person training • If yes, what kind of in-person training did you provide? (Open-ended) ii. Provides virtual training • If yes, what kind of virtual training did you provide? (Open-ended) iii. Facilitates access to training opportunities iv. Facilitates routine conference calls/discussions v. Conducts site visits vi. Supplies biosafety materials to laboratories for reading vii. Shares videos with biosafety guidance (YouTube) viii. Other (please specify) b. If your team does not engage non-PHL laboratories, why not? (open-ended) 6. Percent of non-PHL laboratories performing testing for COVID-19/SARS-CoV-2 with which the PHL has engaged in any outreach a. Numerator: Number of non-PHL laboratories performing testing for COVID-19/SARS-CoV-2 with which the PHL has engaged in any outreach b. Denominator: Number of non-PHL laboratories performing testing for COVID-19/SARS-CoV-2 7. Does your PHL/Health Department/Infection Prevention and Control team** engage **non-traditional testing sites**? (Yes/No)

	a. If yes, how has your PHL/health department/Infection Prevention and Control team engaged non-traditional testing sites (select all that apply)? i. Provides in-person training • If yes, what kind of in-person training did you provide? (Open ended) ii. Provides virtual training • If yes, what kind of virtual training did you provide? (Open ended) iii. Facilitates access to training opportunities iv. Facilitates routine conference calls/discussions v. Conducts site visits vi. Supplies biosafety materials to laboratories for reading vii. Shares videos with biosafety guidance (YouTube) viii. Other (please specify) b. If your team does not engage non-traditional testing sites, why not? (open-ended)
Additional Guidance	This measure should include only sites performing any COVID-19/SARS-CoV-2 testing, not collection sites. Sites performing POC testing are considered testing sites. *A clinical laboratory is defined by CLIA as any facility which performs laboratory testing on specimens obtained from humans for the purpose of providing information for health assessment and for the diagnosis, prevention, or treatment of disease. **Depending on the structure of public health within the jurisdiction, non-traditional testing sites may be monitored by the health department/infection prevention rather than the PHL. Please engage with the health department if the PHL in your jurisdiction does not communicate directly with non-traditional testing sites. *Outreach:* Outreach can include training (virtual and in-person), communications (e-mail, phone calls, newsletters, flyers, site visit, routine meetings. Additional guidance on biosafety practices around handling and processing COVID-19/SARS-CoV-2 specimens is provided here: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html APHL Biosafety and Biosecurity Resources: https://www.aphl.org/programs/preparedness/Pages/Biosafety-Biosecurity-Resources.aspx
Target	
Recommended Data Source	
Reporting Frequency	Twice per year
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.5: Percent of COVID-19 cases submitted to CDC that include complete and meaningful responses for key data elements.

Applicable Recipients	All states, NYC, DC, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	The intent of this measure is to monitor the completeness of case surveillance data that jurisdictions submit to CDC. The analysis will also include a review of data with a meaningful response, defined as responses other than 'unknown', in order to understand the challenges in reporting this data and identify potential areas for improvement. Over time, efficient detection and reporting strategies (e.g., eCR, ELR, NNDSS MMGs), and additional staffing for case investigation and disease control should improve this data. Jurisdictions should strive to ensure that maximum completeness and validity, as well as meaningful data are achieved for the key data elements listed below.
Data Elements	1. Percent completeness* of priority 1 and priority 2 data elements. a. Numerator: Number of COVID cases with complete data b. Numerator: Number of COVID cases with missing data c. Denominator: Total number of COVID cases submitted to CDC 2. Percent of data with a meaningful response for priority 1 *and* priority 2 data elements. a. Numerator: Number of COVID cases with responses other than 'unknown' for priority 1 and 2 data elements b. Denominator: Total number of COVID cases submitted to CDC *Priority 1 Data Elements:* a. Race b. Ethnicity c. Healthcare Occupation d. Hospitalization *Priority 2 Data Elements:* e. Onset date
Additional Guidance	Initial reports should strive to capture and send basic demographic data and case status without delay. It is understood that other data elements that require more case follow-up to occur (e.g. interview, access to med records, etc.) may be delayed. Priority 2 data elements will be evaluated for completeness after jurisdictions submit priority 1 data elements consistently for several submissions. *Completeness: It is important to note that in this context, completeness for ***Priority 1 Data elements*** is an analysis of data that has passed validation checks. Because of built-in validation checks, the data reported must be valid to be accepted. Any invalid data reported for ***Priority 1 Data elements*** will be coded as 'missing'. Resources to support jurisdictional health departments submit COVID-19 case data to CDC:

	Information for Health Departments on Reporting Cases of COVID-19 | CDC COVID PUI Form: May 2020: https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf Jan 2021: https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/COVID19-Worksheet-CSV-annotated-20201Jan15.pdf COVID Message Mapping Guide: https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html
Target	≥ 90% for each data element Jurisdictions should strive for high levels of completeness, validity, and 'meaningful' responses for all data elements.
Recommended Data Source	Data quality reports produced from case surveillance data received at CDC
Reporting Frequency	Monthly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Measure E.6: Proportion of COVID-19 cases with individual-level data submitted to CDC

Applicable Recipients	All states, NYC, DC, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	Aggregate counts submitted by jurisdictions to CDC limit CDC's ability to understand disease trends and patterns. This measure captures improvement in data quality related to electronic data flows. The intent of this measure is to monitor the extent to which jurisdictions provide case-level data on COVID-19 cases to CDC by comparing to the aggregate case counts.
Data Elements	1. Proportion of COVID-19 cases with individual-level data submitted to CDC a. Numerator: Cases with individual-level case information received at CDC b. Denominator: Aggregate case counts
Additional Guidance	https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf A link to the COVID-19 MMG will be provided once available.
Target	≥ 98%
Recommended Data Source	1. Numerator: NNDSS and DCIPHER 2. Denominator: Aggregate case counts
Reporting Frequency	Monthly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Measure E.7: Median number of days from date of first positive specimen collection (or when not available, diagnosis date) to date COVID-19 case is reported to CDC

Applicable Recipients	All states, NYC, DC, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	The intent of this measure is to monitor improvements in the timeliness of COVID-19 case reporting to CDC. Recipients are expected to work with reporters to improve the speed with which COVID-19 cases are identified and reported to public health and the speed with which initial notification is provided to CDC. Timely data ensures that public health has up-to-date information on which to base decisions and actions.
Data Elements	1. Median number of days from date of first positive specimen collection (or when not available, diagnosis date) to date COVID-19 case is reported to CDC
Additional Guidance	To the best of the jurisdiction's ability, initial reports should strive to capture and send basic demographic data and case status without delay. It is understood that other data elements that require more case follow up to occur (e.g. interview, access to med records, etc.) may be delayed. If both date of diagnosis and specimen collection date are available, the earlier of the two dates will be used for the calculation. https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html
Target	≤ 5 days
Recommended Data Source	Calculations based on COVID-19 case notifications to CDC through NNDSS and DCIPHER.
Reporting Frequency	Monthly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Measure E.8: Percent of facilities reporting emergency department (ED) visits to the National Syndromic Surveillance Program (NSSP).

Applicable Recipients	All states, DC
Rationale	Syndromic surveillance provides public health with a timely system for detecting, understanding, and monitoring health events, including COVID-19. Recipients are expected to work with EDs in their jurisdiction to increase the number submitting syndromic surveillance data or increase the ED data transmitted to NSSP. The intent of this measure is to monitor the extent to which syndromic surveillance coverage of ED visits increases over time. From a jurisdiction and national perspective, full coverage of ED visits ensures that valid conclusions can be drawn for all geographic and population areas and that important findings are not missed due to coverage gaps.
Data Elements	1. Percent of facilities that are reporting emergency department (ED) visits to the National Syndromic Surveillance Program (NSSP). a. Numerator: The number of non-federal emergency departments that sent at least one valid message in production to NSSP in the last 12 months b. Denominator: Total number of non-federal emergency departments
Additional Guidance	Source for total number of ED visits can be an estimation from American Hospital Association or a state-specific source.
Target	Recipients should aim to have > 90% of facilities reporting by the end of 2022
Recommended Data Source	NSSP calculations of ED visit coverage
Reporting Frequency	Quarterly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Measure E.9: Completeness of priority data elements in ED visits reported to NSSP

Applicable Recipients	All states, DC, NYC and Los Angeles County
Rationale	Recipients are expected to work with facilities submitting ED data to improve data element completeness. The intent of this measure is to monitor the completeness of ED visit data, focusing on NSSP Priority 1 and 2 data elements. Increased completeness of information in the syndromic surveillance records improves public health's ability to detect and describe health events and the affected population groups and geographic areas.
Data Elements	1. Completeness of priority1 and 2 data elements in ED visits reported to NSSP a. Numerator: Number of ED visits with complete data b. Denominator: Total number of ED visits reported to NSSP *Priority 1 Data Elements:* • Admit_Reason_Code • Admit_Reason_Description • C_Chief_Complaint • Chief_Complaint_Text • Diagnosis_Code • Diagnosis_Description • C_Patient_Age • C_Patient_Age_Years • Patient_Zip • C_Biosense_Facility_ID • C_Facility_ID • Facility_Type_Code • Sending_Facility_ID • Treating_Facility_ID • C_Unique_Patient_ID • Visit_ID • Arrived_Date_Time • Admit_Date_Time • C_Visit_Date • C_Visit_Date_Time • C_Death • C_FacType_Patient_Class • C_Patient_Class • Patient_Class_Code *Priority 2 Data Elements:* • Chief_Complaint_Code • Diagnosis_Type • Administrative_Sex • Age_Reported • Age_Units_Reported • C_Patient_County • Ethnicity_Code

	• Ethnicity_Description • Patient_City • Patient_Country • Medical_Record_Number • Patient_State • Race_Code • Sending_Facility_ID_Source • First_Patient_ID • Message_Profile_ID • Message_Structure • Message_Type • Processing_ID • Trigger_Event • Version_ID • Message_Date_Time • Recorded_Date_Time • Discharge_Date_Time • Discharge_Disposition
Additional Guidance	Please review pages 27-28 of the BioSense Platform User Manual for Data-Quality-on-Demand-Programs (https://www.cdc.gov/nssp/biosense/docs/Data-Quality-On-Demand_User_Manual.pdf) for a list of key data elements.
Target	≥ 90% completeness
Recommended Data Source	NSSP Data Quality Dashboard
Reporting Frequency	Quarterly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Measure E.10: Percent of regularly reporting ILINet providers and the number of patient visits captured in ILINet each week both within and outside the Core Based Statistical Areas (CBSAs).

Applicable Recipients	All states, NYC, DC, Chicago, Puerto Rico, and US Virgin Islands. Other recipients may enroll providers if interested.
Rationale	The Outpatient Influenza-like Illness Surveillance Network, or ILINet, consists of volunteer sentinel outpatient providers, urgent care centers, and emergency departments. Providers who participate in the ILINet program collect and report information about the number of influenza-like illness (ILI) visits to their practice/facility each week. Mild to moderate COVID-19 illness presents with symptoms similar to ILI, so ILINet is now also being used to track trends of mild COVID-19 illness and allows for comparison with prior influenza seasons. There are currently more than 2,900 ILINet sentinel providers covering all 50 states, Puerto Rico, the District of Columbia, and the U.S. Virgin Islands. Data reported by ILINet providers provide a national picture of ILI activity in the U.S. Expanding the geographic distribution of ILINet providers and increasing their reporting frequency, as well as volume of patient visits, will improve our ability to detect and monitor community spread of SARS-CoV-2 and influenza. Establishing or maintaining one or more regularly reporting ILINet sites within each CBSA that, in aggregate, see at least 200 patients per 100,000 population each week, will help each jurisdiction obtain more complete geographic coverage for syndromic surveillance for respiratory illnesses. For non-CBSA areas within a state, ILINet sites and patient visits should be commensurate with population size.
Data Elements	1. Percent of CBSA's with at least 200 patient visits per 100,000 population captured in ILINet each week a. Numerator: Number of CBSA's with at least 200 patient visits each week from regularly reporting ILINet providers per 100,000 population b. Denominator: Total number of CBSA's 2. Average number of patient visits reported each week by regularly reporting ILINet sites that are **not** within the CBSAs a. Non-CBSA area population estimate (state population- population of all CBSAs) b. Average number of patient visits per week from regularly reporting providers not in the CBSA 3. Percent of enrolled ILINet providers that regularly report a. Numerator: Number of regularly reporting ILINet providers b. Denominator: Number of enrolled ILINet providers
Additional Guidance	*Core-Based Statistical Area:* Metropolitan and Micropolitan Statistical Areas are collectively referred to as Core-Based Statistical Areas[1]. They are defined by the Office of Management and Budget (OMB) and consist of the county or counties or equivalent entities associated with at least one urban core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core. *ILINet provider types:* Providers in many types of practices may be ILINet providers, including: • Emergency medicine

[1] https://www.census.gov/topics/housing/housing-patterns/about/core-based-statistical-areas.html

	• Family practice • Infectious disease • Internal medicine • OB/GYN • Pediatrics • Student health • Urgent care
Target	• Within each CBSA, at least 200 patient visits per 100,000 population captured in ILINet each week after 12 months • For non-CBSA areas of a state, maintain the number of providers and patient visits commensurate with the population. • 80% of ILINet sites routinely report each quarter. “Routinely report” is defined as reporting at least 12 out of 13 weeks in the quarter.
Recommended Data Source	ILINet
Reporting Frequency	Quarterly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Measure E.11: Percent of labs reporting influenza and COVID-19/ SARS-CoV-2 via PHLIP 2.5.1 to CDC and the percent completeness of key data elements for respiratory virus specimens tested at the public health laboratory (PHL).

Applicable Recipients	All states, NYC, DC, Guam, and Puerto Rico
Rationale	Improving the completeness and validity of laboratory reporting for respiratory viruses will help CDC gain a better understanding of the community and seasonal spread of COVID-19/SARS-CoV-2 vis-à-vis other respiratory viruses. Laboratory reporting for respiratory viruses, including SARS-CoV-2/COVID-19, influenza, RSV and others, must have complete and valid data for all key data elements to inform epidemiologic case investigations and follow up and to monitor trends in virus circulation. Submitting all public health laboratory reports for respiratory virus testing to CDC will ensure that PHL data can be used most effectively. This measure focuses on laboratory reporting for all respiratory virus specimens tested at the public health laboratory. ELC will collect a complementary measure (E.3) that focuses on reporting for COVID-19/ SARS-CoV-2 specimens tested at all laboratories, including at the public health laboratory and clinical laboratories.
Data Elements	1. Percent of labs reporting influenza and COVID-19/ SARS-CoV-2 via PHLIP 2.5.1 a. Numerator: Number of labs reporting influenza and COVID-19 via PHLIP 2.5.1 b. Denominator: Total number of PHLs 2. Percent of labs reporting other respiratory viruses via PHLIP 2.5.1 a. Numerator: Number of labs reporting other respiratory viruses via PHLIP 2.5.1 b. Denominator: Total number of PHLs 3. Percent completeness* of the following key data elements reported to CDC for Influenza and COVID-19/SARS-CoV2 specimens tested at the PHL: • Patient DOB (or age if DOB is not available) • Patient race/ethnicity • Patient zip code or county of residence (or zip code or county of submitting facility) • Specimen collection date • Virus test results • Level of care (inpatient/outpatient), when possible • Illness onset date, when possible • Specimen source, when possible • Gender, when possible Additional data element for respiratory specimens submitted by ILINet providers: • ILINet provider ID a. Numerator: Number of influenza specimens with complete* data for each key data element above. b. Denominator: Total number of influenza specimens reported c. Numerator: Number of COVID-19/ SARS-CoV-2 specimens with complete* data for each key data element above. d. Denominator: Total number of COVID-19/ SARS-CoV-2 specimens reported
Additional Guidance	*PHLIP:* The Public Health Laboratory Interoperability Project (PHLIP) is a collaborative effort between the Association of Public Health Laboratories, CDC, and state public health

	laboratories (PHLs) to advance automated electronic data flows from PHLs to CDC.[2] *Completeness: It is important to note that in this context, completeness is an analysis of data that has passed validation checks. Because of built-in validation checks, the data reported must be valid to be accepted. However, blank (missing) data is also accepted.
Target	• 100% of labs reporting influenza and COVID-19 to CDC are using PHLIP 2.5.1. • 100% of labs reporting other respiratory viruses to CDC are using PHLIP 2.5.1 • Reports for all respiratory virus testing at the public health laboratory include data that are at least 80% complete* for each key data element.
Recommended Data Source	PHLIP
Reporting Frequency	Quarterly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

[2] https://www.aphl.org/programs/informatics/Documents/INF_2013May15_ELSM-Overview.pdf

Measure E.12: Number of healthcare organizations engaged to implement electronic case reporting (eCR)

Applicable Recipients	All recipients
Rationale	Jurisdictions must demonstrate that they are making electronic case reporting implementation with healthcare organizations a priority focus area through this funding. Recipients are expected to recruit and work with healthcare organizations in their jurisdictions that submit reportable condition reports to implement electronic case reporting. The intent of this measure is to monitor the extent to which the number of healthcare organizations submitting electronic case reports to the jurisdiction increases over time. From a jurisdiction and national perspective, full coverage of healthcare organizations ensures that all cases of reportable conditions are identified for public health action.
Data Elements	1. How are you recruiting new in-jurisdiction providers to onboard to eCR? (Select all that apply.) ☐ Sending recruitment letters or e-mails ☐ Hosting or participating in recruitment group calls or eCR webinars to in-jurisdiction providers ☐ Targeted discussions (calls with one or more healthcare organizations, HIE, or HIN for recruitment) ☐ Passive recruitment – accepting providers who reach out to the eCR team ☐ Not recruiting (if this is checked, must provide a date for when recruitment will begin in question 1a) 1a. If not currently recruiting, what date will you start recruiting? (D-M-Y) 2. Did you confirm that your answer to question 1 is consistent with the monitoring question available on the Site Overview monitoring form? (Y/N) 3. Please share any successful recruitment strategies or any challenges to recruitment. 4. List priority healthcare organizations for **recruitment** who have not yet implemented eCR at this time. Ideally, include at least 15 organizations and accompanying information listed below. List organizations you have prioritized for eCR recruitment and implementation. Indicate whether you have reached out to recruit this organization. Do not include any organizations already in testing or live with eCR. (Please enter the information in the spreadsheet template provided in REDCap.) • Organization name • Name of EHR vendor (if known) • Date last contacted 5. For healthcare organizations actively **engaged** in eCR with the public health agency, please indicate the following for level of engagement. (Please enter the information in the spreadsheet template provided in REDCap.) • Testing for COVID-19 only • In production and parallel reporting for COVID-19 only • In production with no manual reporting for COVID-19 only • Testing for all conditions • In production and parallel reporting for all conditions • In production with no manual reporting for all conditions 6. If you offered incentives to healthcare organizations for participating in eCR, what has been the impact of those incentives?

Additional Guidance	The agreed upon priority list of healthcare organizations in the jurisdiction will be used at quarterly calls between jurisdiction and the ELC HIS Implementation and Monitoring Team to track status of organization's implementation progress. Questions 4 and 5 will be reported using the spreadsheet template available for download in REDCap. Question 5 is cumulative. Recipients may update the engagement list (in Excel) and status each quarter of reporting. Healthcare organizations may change status over time.
Target	Quarterly reporting on engagement status
Recommended Data Source	CDC will assist with providing an initial list of healthcare organizations in the jurisdiction if desired.
Reporting Frequency	Quarterly
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.12a: Number of conditions published to production in Reportable Conditions Knowledge Management System (RCKMS).

Applicable Recipients	All recipients
Rationale	Using this RCKMS allows public health jurisdictions to define reporting criteria, and helps healthcare organizations using electronic case reporting send the appropriate initial case reports to respective public health agencies. Increasing the number of reportable conditions published to production in RCKMS ensures efficient and timely disease surveillance, ultimately leading to more timely identification of clusters or outbreaks of disease and resulting in more rapid public health response.
Data Elements	1. Per the guidance, each jurisdiction should have at least 36 conditions authored each quarter, for a total of 144 conditions authored to production by the end of the year. How many conditions has your jurisdiction currently published to production in RCKMS?
Additional Guidance	
Target	36 conditions authored each quarter, for a total of 144 conditions authored to production by the end of the year
Recommended Data Source	
Reporting Frequency	Quarterly
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.13: Proportion of state reportable cases with an electronic initial case report (eICR) submitted

Applicable Recipients	All recipients
Rationale	Recipients are expected to work with healthcare organizations in their jurisdictions that submit reportable condition reports to increase the number submitting reports electronically. The intent of this measure is to monitor the extent to which cases in the jurisdiction have associated electronic case reports – either case was started by an eICR, an eICR was received and helped define the case status, or eICR received provided additional data to support the case. From a jurisdiction and national perspective, submission of electronic reports that are timely and complete will allow for more efficient and speedy public health action.
Data Elements	1. Percent of state reportable cases with an electronic initial case report (eICR) submitted during the last 6 months a. Numerator: Number of reportable cases with at least one associated electronic initial case report (see additional guidance below) b. Denominator: Total number of reportable cases known by the jurisdiction from all reporting mechanisms for all state reportable conditions
Additional Guidance	For 1a: This is not the number of electronic initial case reports (eICRs) received, but the unique number of case reports that have **one or more** eICR associated with them (e.g deduplicated eICRs) Jurisdiction must maintain production connection with AIMS to receive eICRs
Target	50% by August 2021; overall target > 90%
Recommended Data Source	
Reporting Frequency	Twice per year
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.14: Demonstration of automatic processing of electronic initial case reports (eICRs) in the jurisdiction integrated surveillance system(s)

Applicable Recipients	All recipients
Rationale	Recipients are expected to ensure that their surveillance systems have capability to accept, process and present the data in electronic initial case reports (eICRs) and reportability responses (RRs) for use by users of the surveillance system. The intent of this measure is to monitor the surveillance system(s) ability to fully process the electronic case report data. Increased capacity to process electronic data improves public health's ability to identify and response to health events and the affected population groups and geographic areas.
Data Elements	1. List each surveillance system that is used to manage cases of reportable conditions a. For each surveillance system, indicate the percent of eICRs that are received by the jurisdiction and populated into the system without entering an error queue in the production environment. b. What are the start and end dates for this metric? i. What is the start date for this metric? (Month, day, year) ii. What is the end date for this metric? (Month, day, year) 2. Did you confirm that your answers for question 1 are consistent with the monitoring questions available on the Site Overview monitoring form? (Y/N) 3. Please provide any qualitative information about your progress on processing eICRs into the surveillance system. Are there any successes, challenges, or status changes that you would like to share?
Additional Guidance	Data from RR are needed to process eICR. Report measure for each surveillance system being used for managing reportable conditions. Conditions may vary by jurisdictions.
Target	Processing of > 50% of eICRs by the surveillance system
Recommended Data Source	
Reporting Frequency	Twice per year
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.15: Proportion of test orders and results processed through Electronic Test Orders and Results Reporting (ETOR) at the PHL (this measure only applies to tests conducted at the public health laboratory)

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County
Rationale	Electronic Test Orders and Results (ETOR) enable laboratories and healthcare providers to electronically exchange standardized test orders and results. Recipients are expected to work on enhancing laboratory test ordering and reporting capability with this project. The volume of orders and results data exchanged through ETOR by jurisdiction provides CDC an understanding of ETOR implementation occurring across the nation.
Data Elements	1. Number of **test orders** processed through Electronic Test Orders and Results (ETOR) established through the PHL LIMS and/or a centralized platform and/or web portal a. Number of test orders received by the PHL through a web portal b. Number of test orders sent or received by the PHL through direct systems integration ETOR c. Number of test orders sent or received by PHL through indirect systems integration ETOR d. Number of all test orders sent or received by the PHL 2. Number of **test results** processed through Electronic Test Orders and Results (ETOR) established through the PHL LIMS and/or a centralized platform and/or web portal a. Number of test results received by the PHL through a web portal b. Number of test results sent or received by the PHL through direct systems integration ETOR c. Number of test results sent or received by PHL through indirect systems integration ETOR d. Number of all test results sent or received by the PHL
Additional Guidance	This measure only applies to tests conducted at the public health laboratory. *Number of test orders/results exchanged through a web portal:* Includes all orders received and results sent by the laboratory using a web portal. The web portal needs to be directly integrated to the LIMS to be considered valid for counting as "received and sent through a web portal". Please do not count tests which are transferred from portal to LIMS or vice versa by staff using mechanisms such as copy pasting or exporting to files by portal and upload to LIMS or other similar means for both orders and result reporting). *Number of test orders/results exchanged through direct systems integration ETOR:* Includes all orders received and results sent by the laboratory through direct systems integration. Systems (EHR and LIMS) are integrated, and data is exchanged using HL7 messaging or other file formats. Data translation for integration is managed through integration engines such as Rhapsody, Mirth, within the PHL No manual data entry is involved in sending or receiving data. *Number of test orders/results exchanged through indirect systems integration ETOR:* Includes all orders received and results sent by the laboratory through indirect systems integration. Sending and receiving systems (EHR and LIMS) exchange data using an

	external system such as a centralized platform. This external system translates the messages for integration. No manual work is involved in sending or receiving data. *Number of test results/orders:* This includes all test orders/results exchanged by the laboratory through all mechanisms (e.g., paper form, PDF Form, Email, through phone, mail, web portal, HL7 based message.
Target	None at this time.
Recommended Data Source	LIMS
Reporting Frequency	Twice per year
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.16: Systems/programs at the PHL with ETOR interfaces

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County
Rationale	Electronic Test Orders and Results (ETOR) implementation is aimed at process automation within public health laboratories. This allows enhanced testing capacity by load management and reduction of errors due to manual data entry. The number of different programs/ systems connected electronically with healthcare providers is an indicator of the amount of process automation within the laboratory.
Data Elements	1. List of systems and/or programs within your public health laboratory that currently have fully implemented ETOR interfaces with any healthcare provider.
Additional Guidance	This measure only applies to systems/programs within the public health laboratory. Please list system/program if ETOR has been fully established with at least one healthcare provider. *Systems/programs:* This could include how the public health laboratory is categorized administratively or based on how LIMS implementations are divided.E.g., Infectious Disease Program, Microbiology Laboratory, Newborn Screening Laboratory, Pathology Laboratory. Recipients are encouraged to provide a list of systems/programs within their public health laboratory at the start of measurement period. *Healthcare providers:* Hospitals, Hospital systems, Physicians' offices or other entities receiving services from the public health laboratory. *Fully Implemented ETOR:* Systems where at least 80% of routine orders and/or results are exchanged electronically using web portal, direct or indirect integration
Target	None at this time.
Recommended Data Source	Administrative System
Reporting Frequency	Annually
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.17: Caseload, number of cases per case investigator and number of contacts per contact tracer during the data collection period

Applicable Recipients	All recipients
Rationale	This measure is essential for monitoring capacity and identifying case investigation and contact tracing staffing needs. This data will help provide important information about variations in workload over time and across jurisdictions.
Data Elements	1. Number of cases reported to the health department (confirmed and, if possible, probable) 2. Number of case Investigators 3. Number of contacts identified through case investigations 4. Number of contact tracers
Additional Guidance	If exact numbers are difficult to obtain, please provide the best estimate for these data elements and provide an explanation in the note section. Case investigators and contact tracers are not expected to be mutually exclusive or spend 100% of their time on one these tasks. It is understood that case investigators may perform some contact tracing activities and vice versa. *Definitions:* Total number of cases should include all confirmed and, if possible, probable. “Number of case investigators” is the total number of staff who were assigned cases to contact for an interview “Number of contacts” is the total number of contacts identified through case interviews. “Number of contact tracers” is the total number of staff assigned to follow up on contacts *Potential Calculations (performed by ELC):* 1. Caseload per case investigator 2. Caseload per contact tracer
Target	No target
Recommended Data Source	Case investigation management system, Contact tracing management system
Reporting Frequency	Monthly (Schedule included in Appendix C of the guidance)

Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.18: Timeliness, completeness, and effectiveness of case interviews among the cases sent for case investigation during the data collection period

Applicable Recipients	All recipients
Rationale	The intent of this measure is to monitor the timeliness of completion of case interviews following the report of a case to the health department. Conducting timely case interviews increases the likelihood of quickly identifying and notifying contacts, allowing for more timely detection of additional COVID-19 cases. Rapid case follow- up is essential to mitigate the spread of disease.
Data Elements	1. Number of cases that completed an interview 2. Number of cases interviewed within 1 day of report to case investigations team 3. Number of cases that provided at least one contact 4. Number of cases that were successfully contacted but did not complete an interview 5. Number of cases that did not respond to contact attempts
Additional Guidance	If exact numbers are difficult to obtain, please provide the best estimate for these data elements and provide an explanation in the note section. *Definitions:* "Cases that completed an interview" is defined as the active engagement with a case or proxy to conduct an interview, beyond notification of positive result or scheduling a time for interview. This can also include interviews that do not result in contact tracing efforts based on prioritization algorithms. "Successfully contacted but did not complete interview" refers to a case who responded to outreach attempts from the health department but was unable to (or refused to) complete an interview "Did not respond to contact attempts" refers to when one or more attempt was made by the health department to contact the case, but the attempt was unsuccessful. *Potential calculations (performed by ELC):* 1. Percent of cases that completed an interview among the total cases sent to the health department 2. Percent of cases that completed an interview within 1 day of report among those who completed an interview 3. Percent of cases that did not complete an interview among those that were successfully contacted 4. Percent of cases that provided contacts among those that complete an interview 5. The average number of contacts provided by cases that completed an interview
Target	The target for this measure is still under development; there is a need to see what is realistic and how this target needs to change over time, depending on epidemiology and capacity. There is no expectation that 100% of cases would be interviewed.

Recommended Data Source	Case investigation data system
Reporting Frequency	Monthly (Schedule included in Appendix C of the guidance)
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.19: Timeliness of contact tracing during the data collection period

Applicable Recipients	All recipients
Rationale	The intent of this measure is to monitor the timeliness of contact notification following a case report to the health department. Identifying and notifying contacts of cases in a timely manner allows for detection and mitigation of possible transmission.
Data Elements	1. Total number of contacts notified 2. Number of contacts notified within 1 day of case interview
Additional Guidance	If exact numbers are difficult to obtain, please provide the best estimate for these data elements and provide an explanation in the note section. *Definitions:* "Notified" means that a person is informed of their potential exposure to a COVID-19 case. Method of notification is not defined and can vary depending on notification methods (text, phone, email, other). Notification does not necessarily require an interview.
Target	The target for this measure is still under development; there is a need to see what is realistic and how this target needs to change over time, depending on epidemiology and capacity. There is currently no expectation that 100% of contacts would be notified within 1 day.
Recommended Data Source	Contact tracing data system
Reporting Frequency	Monthly (Schedule included in Appendix C of the guidance)
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.20: Effectiveness of contact tracing to interrupt the transmission of COVID-19 during the data collection period

Applicable Recipients	All recipients
Rationale	Contacts enrolling in symptom monitoring program and the capacity to reach contacts to recommend quarantine or isolation and monitor symptoms is important to interrupt the transmission of CoVID-19. The number of cases that were known to be contacts is an important metric to collect because new cases that are not identified as contacts in the previous 14 days could indicate spread of COVID-19 in the community that is unknown to the health department. This could reduce the effectiveness of case investigations and contact tracing efforts.
Data Elements	1. Number of new cases that were identified (or known) as contacts in the previous 14 days
Additional Guidance	If exact numbers are difficult to obtain, please provide the best estimate for these data elements and provide an explanation in the note section. *Potential calculations (performed by ELC):* 1. Percent of new cases that were identified (or known) as contacts in the previous 14 days among the number of cases.
Target	The target for this measure is still under development; there is a need to see what is realistic and how this target needs to change over time, depending on epidemiology and capacity. There is currently no expectation that 100% of contacts would agree to symptom monitoring.
Recommended Data Source	Case surveillance and contact tracing data system
Reporting Frequency	Monthly (Schedule included in Appendix C of the guidance)
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.21: Timeline of the case investigation process from specimen collection to contact notification during the data collection period

Applicable Recipients	All recipients
Rationale	The timeliness of sample collection to contact notification to mitigate the spread of CoVID-19 is dependent on several different points within the case investigation process. These different points can be used to identify areas where contact tracing is being delayed.
Data Elements	1. Median and range for the number of days between specimen collection and report of case to the health department 2. Median and range for the number of days between the report of the case to the health department to a case interview completion 3. Median and range of the number of days between when a case interview is completed to when any identified contacts were notified
Additional Guidance	
Target	No target at this time.
Recommended Data Source	Laboratory reports, case surveillance and contact tracing systems
Reporting Frequency	Monthly (Schedule included in Appendix C of the guidance)
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.22: Among contacts notified, proportion tested for COVID-19/SARS-CoV-2 at least once, within 14 days of notification during the data collection period

Applicable Recipients	This measure will no longer be collected.
Rationale	Obtaining information on the extent of testing among contacts is important because it reflects both testing capacity and public health intervention to reduce the spread of COVID-19. Monitoring the extent of testing conducted within contact tracing process is important for better understanding how contact tracing programs are implemented and evolve over time, across jurisdictions.
Data Elements	1. Number of contacts tested for COVID-19/SARS-CoV-2 at least once, within 14 days of notification out of the number of contacts notified
Additional Guidance	"Testing" can be by self-report or lab result received (assuming negative lab results come to recipient). Tested using a diagnostic test, for current/active infection, not antibody testing. Antibody testing should not be included in this measure. Testing capacity and testing protocols vary across recipients, so it may be difficult to compare this measure across recipients. Some contacts may be appropriately managed without testing, so this measure does not reflect the percent of contacts who were appropriately managed. Some testing may be difficult to capture, if the contact is tested on their own or if there are gaps in reporting of testing to the health department (by testing agencies or the contact).
Target	No target at this time.
Recommended Data Source	Contact tracing data system
Reporting Frequency	Monthly (Schedule included in Appendix C of the guidance)
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.23: Number of health department staff who can perform healthcare infection control assessments at the state and local level

Applicable Recipients	All recipients
Rationale	Strengthening the infection prevention and control expertise can influence a health department's ability to respond to COVID-19 and other infectious diseases outbreaks. Tracking the number of people who can perform infection control assessments in healthcare settings is an essential component of monitoring progress and identify areas for improvement or point to gaps in IPC workforce development at the state and local level.
Data Elements	1. Number of staff who can independently and capably perform an infection control assessment in healthcare facilities, provide prevention and outbreak response recommendations to facilities, and follow-up with facilities to ensure gaps have been mitigated. a. Number of state HD staff b. Number of local HD staff c. Number of other staff (e.g., staff working at medical schools, nursing schools, regional teams, partnerships etc.)
Additional Guidance	Health department staff can include hired and/or contracted by the HD. Please refer to the REDCap user guide on HAI/AR Performance Measured for step-by-step instructions on completing this form.
Target	N/A
Recommended Data Source	N/A
Reporting Frequency	Twice per year
Reporting Mechanism	☒ REDCap (**HAI/AR Performance Measures 2020 - 2021 (BP2)** REDCap Project) ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.24: Number of proactive healthcare infection control assessments conducted by the health department or designee for COVID-19.

Applicable Recipients	All recipients
Rationale	The health department plays a critical role in responding to possible COVID-19 HAI/AR outbreaks. Understanding the proactive assessments conducted allows CDC and the HDs to track IPC issues requiring the greatest public health support. Beyond the infection control assessments, HDs should follow up after the assessment to support healthcare settings in implementing recommendations.
Data Elements	1. Number of healthcare facilities where a proactive (prevention-based) infection control assessment was conducted by the health department or designee, by method: a. Remote (e.g., Tele-ICAR, video-ICAR) b. On-site
Additional Guidance	Provision of remote/onsite assistance to assess infection control issues may be done directly by the Recipient or through the support of a local health department, academic partner, contractor, consultant, or other entity (designee) for which the Recipient can assure the quality of services provided. Prevention-based assessments require use of a structured form for data collection, such as CDC tele-ICAR tool (or similar state/local developed tool). Proactive infection control assessments are those that focus on facilities considered to be at high risk for COVID-19 outbreaks, with the goal of improving infection control practices to reduce transmission of COVID-19. This type of infection control assessment is distinct from response-driven infection control assessments that are focused on facilities where COVID-19 or other HAI/AR infections outbreaks have been identified. Please refer to the REDCap user guide on HAI/AR Performance Measured for step-by-step instructions on completing this form.
Target	N/A
Recommended Data Source	N/A
Reporting Frequency	Twice per year
Reporting Mechanism	☒ REDCap (**HAI/AR Performance Measures 2020 - 2021 (BP2)** REDCap Project) ☐ CDC currently has this data and there is no need to report it currently.

Measure E.25: Number of COVID-19 outbreaks and responses in healthcare settings

Applicable Recipients	All recipients
Rationale	Rapid and structured response is critical to the successful containment of COVID-19 in all healthcare settings. An understanding of this information can help CDC and HD quantify the extent of the issue and assess whether timely and efficient response is implemented.
Data Elements	1. Number of possible COVID-19 outbreaks that met the threshold for additional investigation 2. Of the possible COVID-19 outbreaks, number for which any response was provided
Additional Guidance	Response refers to a series of actions on the part of public health authorities to assess specific, acute HAI/AR risks and prevent further harm. Response efforts may take the form of consultation regarding IPC activities, remote or on-site assessments, or other IPC technical assistance (e.g. cohorting or testing strategies, return to work criteria, PPE optimization, mitigating staffing shortages), to facilities with COVID-19 infections among residents/patients or HCP. Note that definition of “outbreak”, “responded to” and “specified time period” is defined in the REDCap reporting template. Please refer to the REDCap user guide on HAI/AR Performance Measured for step-by-step instructions on completing this form.
Target	N/A
Recommended Data Source	N/A
Reporting Frequency	Twice per year
Reporting Mechanism	☒ REDCap (**HAI/AR Performance Measures 2020 - 2021 (BP2)** REDCap Project) ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.26: Number of new or enhanced laboratory technologies procured, maintained, or implemented to improve laboratory response capacity

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	When PHLs have the capacity to conduct multiple types of tests in a timely manner, public health is better able to detect SARS-CoV-2, respond to areas of increased incidence of COVID-19, and identify populations that require more thorough mitigation measures. Current funding opportunities allow PHLs to bolster their laboratory technology, including adding new equipment, maintaining existing equipment, and managing service agreements for both new and existing equipment. These data will serve initially as a baseline for current testing capacity in terms of technology and will allow CDC to monitor how funds have been used to build on that technology over the course of the project.
Data Elements	1. Have any of the following automated and/or high-throughput laboratory platforms, service agreements, and/or reagents been procured by your public health laboratory using Strengthening PHL Preparedness funds? Please select "yes" for all platforms that apply. If platform is not listed in the table, please add to "Other".

	Platforms	Number of platforms	Service Agreements	Reagents /Supplies
Bruker MALDI-TOF Microflex System	☐	(drop down menu 1,2)	Number for Newly Acquired Equipment (drop down 0,1,2) Number for Existing Equipment (drop down 0,1,2)	☐
KingFisher FLEX (96 well Deep Head) System	☐	(drop down menu 1,2)	Number for Newly Acquired Equipment (drop down 0,1,2) Number for Existing Equipment (drop down 0,1,2)	☐
Sequencer - MinION - Illumina Iseq100 - GridION - MiniSeq - NextSeq - Others (please specify)	☐	(drop down menu 0, 1,2,3,4 or more)	Number for Newly Acquired Equipment (drop down 0,1,2,3,4 or more) Number for Existing Equipment (drop down 0,1,2,3,4 or more)	☐
Extraction platform - Qiagen EZ1 Advanced XL - Roche MagNAPure 24 - Roche MagNA Pure 96 - Others (please specify)	☐	(drop down menu 0, 1,2,3)	Number for Newly Acquired Equipment (drop down 0,1,2,3) Number for Existing Equipment (drop down 0,1,2,3)	☐
Other _____ (Should include other instruments such as liquid handlers/robotics)	☐	(drop down menu 1,2,3)	Number for Newly Acquired Equipment (drop down 0,1,2,3) Number for Existing Equipment (drop down 0,1,2,3)	☐

<table>
<tr><td></td><td>2. Have any of the following bioinformatics enhancements been procured by your public health laboratory using Strengthening PHL Preparedness funds? Select all that apply. If not applicable, please leave blank and provide explanation in the comments.
<table>
<tr><td>Computer(s)</td><td>☐</td><td>1, 2, 3, 4 or more</td></tr>
<tr><td>Storage (hardware or cloud based)</td><td>☐</td><td>Description (e.g. Linux, Google, AWS, etc.)</td></tr>
<tr><td>Bioinformatics analysis software</td><td>☐</td><td>Description (e.g. BioNumerics, etc)</td></tr>
<tr><td>Other bioinformatics enhancements</td><td colspan="2">☐ Description</td></tr>
</table></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Additional Guidance</td><td>For E.26, “Newly Acquired” refers to purchases made with Project E (Emerging Issues): Strengthening PHL Preparedness (CK19-1904). "Existing" refers to equipment or supplies purchased using other (federal, state, etc.) funds.

For E.26.1, “Other” may include instruments such as liquid handlers/robotics or other extraction and sequencing equipment not provided in the drop-down menu.</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Target</td><td>Recipients must meet the following targets where applicable:
1. Procure a mass spectrometer, Bruker MALDI-TOF, Kingfisher FLEX (96 well Deep Head)
2. Procure Next Generation sequencing (NGS) technologies for implementation of genetic sequencing to further characterize pathogens, toxins, and emerging infectious diseases
3. Procure nucleic acid extraction equipment and/or necessary maintenance agreements</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Recommended Data Source</td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Reporting Frequency</td><td>Semi-annual</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Reporting Mechanism</td><td>☒ REDCap
☐ CDC currently has this data and there is no need to report it at this time.</td></tr>
</table>

Measure E.27: Number of biothreat samples shipped to designated LRN reference laboratory or CDC

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	By sending samples for further characterization of biothreat samples, PHLs help strengthen response capabilities by contributing to laboratory testing infrastructure. CDC will use this measure to monitor the amount of funding recipients need to adequately ship samples when necessary.
Data Elements	1. Were any samples sent to a LRN reference laboratory? (Yes/No/Not Applicable) a. If yes, how many samples were sent to a LRN reference laboratory? 2. Were any samples sent to CDC? (Yes/No) a. If yes, how many samples were sent to CDC?
Additional Guidance	Shipment of biothreat isolates or specimens to an LRN reference laboratory or to CDC for further rule out testing or characterization is acceptable.
Target	
Recommended Data Source	
Reporting Frequency	Quarterly
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.28: Enhancing laboratory information infrastructure for LRN testing methodologies

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	Enhancement and expansion of laboratory information infrastructure between local, state, and national laboratories will enable faster, dynamic, and more complete data exchange and reporting. With more efficient reporting practices, public health is better able to detect SARS-CoV-2, respond to areas of increased incidence of COVID-19, and identify populations that require more thorough mitigation measures. These data inform CDC on how LRN methodologies are being prioritized in the context of information exchange.
Data Elements	1. Has your laboratory implemented ELR for LRN testing methodologies? (Yes/In Progress/No/Not Applicable) a. If no, please explain limitations or challenges in implementing ELR for LRN testing methodologies. 2. What enhancements have been accomplished within your laboratory information system infrastructure within this reporting period using Strengthening PHL Preparedness funds? 3. Please explain the plan for enhancements for the reporting period.
Additional Guidance	
Target	Implementation of ELR for LRN testing methodologies, when applicable
Recommended Data Source	
Reporting Frequency	Semi-annual
Reporting Mechanism	☒ REDCap ☐ CDC currently has this data and there is no need to report it at this time.

Measure E.29: Number of SARS-CoV-2 specimens sent to CDC for sequencing per month

Applicable Recipients	All states, NYC, DC, Philadelphia, Houston, Los Angeles County, American Samoa, Guam, Marshall Islands, Northern Mariana Islands, Federated States of Micronesia, Palau, Puerto Rico, and US Virgin Islands
Rationale	As SARS-CoV-2 continues to evolve and more variants of the virus are identified, the ability for laboratories to sequence SARS-CoV-2 specimens allows public to identify where those variants exist and how public health should respond. PHLs should aim to increase the number of SARS-CoV-2 specimens sent to CDC for sequencing for that effort. This performance measure will indicate growth of sequencing and facilitate the use of genomic sequence data in the response to SARS-CoV-2 and other emerging pathogens on a national level.
Data Elements	1. The number of SARS-CoV-2 specimens sent to CDC for sequencing each month. The following information must be submitted for cases: a. Viral Ct value b. Host control Ct (RNase or whatever is used in the assay) c. Sample collection date d. Patient information: i. Residence by country and (where relevant) state and county ii. Race/ethnicity iii. Age in years iv. Gender vi. Hospitalized (yes/no/unknown) vii. Death (yes/no/unknown) viii. Optional: Other relevant information
Additional Guidance	The number of specimens sent to CDC should be counted starting from February 2021. This measure still applies to all jurisdictions, including those with very few or no COVID cases. It is understood these jurisdictions may or may not make targets.
Target	Minimum: 20 specimens sent to CDC per month Based on population size, the ultimate target by state is listed in Appendix 2 of this doc: NS3-Submission-Guidance.pdf (aphl.org)
Recommended Data Source	LIMS
Reporting Frequency	Monthly
Reporting Mechanism	☐ REDCap ☒ CDC currently has this data and there is no need to report it at this time.

Appendix A. Reporting mechanism by measure

ID	Measure	REDCap	CDC has data and will share with recipients
E.1	Median number of days from specimen collection date to date of report of final test result for COVID-19/SARS-CoV-2 molecular diagnostic tests	X	X
E.2	Number of COVID-19/SARS-CoV-2 tests completed by test type, race/ethnicity, and result		X
E.3	Proportion of COVID-19/SARS-CoV-2 laboratory test results submitted to CDC with complete information		X
E.4	Biosafety outreach and guidance provided by PHLs and/or the health department to COVID-19/SARS-CoV-2 testing sites	X	
E.5	Percent of COVID-19 cases submitted to CDC that include complete and meaningful responses for key data elements.		X
E.6	Proportion of COVID-19 cases with individual-level data submitted to CDC.		X
E.7	Median number of days from date of first positive specimen collection (or when not available, diagnosis date) to date COVID-19 case is reported to CDC		X
E.8	Percent of facilities reporting emergency department (ED) visits to the National Syndromic Surveillance Program (NSSP).		X
E.9	Completeness of priority data elements in ED visits reported to NSSP		X
E.10	Percent of regularly reporting ILINet providers and the number of patient visits captured in ILINet each week both within and outside the Core Based Statistical Areas (CBSAs)		X
E.11	Percent of labs reporting influenza and COVID-19/ SARS-CoV-2 via PHLIP 2.5.1 to CDC and the percent completeness of key data elements for respiratory virus specimens tested at the public health laboratory (PHL)		X
E.12	Number of healthcare organizations engaged to implement electronic case reporting (eCR)	X	
E.12a	Number of conditions published to production in Reportable Conditions Knowledge Management System (RCKMS).	X	
E.13	Proportion of state reportable disease cases with an electronic initial case report (eICR) submitted	X	
E.14	Demonstration of automatic processing of electronic initial case reports (eICRs) in the jurisdiction integrated surveillance system(s)	X	
E.15	Proportion of test orders and results processed through Electronic Test Orders and Results Reporting (ETOR) at the PHL (this measure only applies to tests conducted at the public health laboratory)	X	
E.16	Systems/programs at the PHL with ETOR interfaces	X	
E.17	Caseload, number of cases per case investigator and number of contacts per contact tracer during the data collection period	X	
E.18	Timeliness, completeness, and effectiveness of case interviews among the cases sent for case investigation during the data collection period	X	
E.19	Timeliness of contact tracing during the data collection period	X	
E.20	Effectiveness of contact tracing to interrupt the transmission of COVID-19 during the data collection period	X	

ID	Measure	REDCap	CDC has data and will share with recipients
E.21	Timeline of the case investigation process from specimen collection to contact notification during the data collection period	X	
E.22	Among contacts notified, proportion tested for COVID-19/SARS-CoV-2 at least once, within 14 days of notification during the data collection period	X	
E.23	Number of health department staff who can perform healthcare infection control assessments at the state and local level	X	
E.24	Number of proactive healthcare infection control assessment and response (ICAR) conducted by the health department or designee for COVID-19.	X	
E.25	Number of COVID-19 outbreaks and responses in healthcare settings	X	
E.26	Number of new or enhanced laboratory technologies procured, maintained, or implemented to improve laboratory response capacity	X	
E.27	Number of biothreat samples shipped to designated LRN reference laboratory or CDC	X	
E.28	Enhancing laboratory information infrastructure for LRN testing methodologies	X	
E.29	Number of SARS-CoV-2 specimens sent to CDC for sequencing per month		X

Appendix B. Reporting frequency (for recipient-reported measures only)

ID	Measure	Reporting Frequency
E.1	Median number of days from specimen collection date to date of report of final test result for COVID-19/SARS-CoV-2 molecular diagnostic tests	Quarterly
E.4	Proportion of COVID-19/SARS-CoV-2 testing sites that received biosafety guidance and conducted laboratory risk assessments	Twice per year
E.12	Number of healthcare organizations engaged to implement electronic case reporting (eCR)	Quarterly
E.12a	Number of conditions published to production in Reportable Conditions Knowledge Management System (RCKMS).	Quarterly
E.13	Proportion of state reportable disease cases with an electronic initial case report (eICR) submitted	Twice per year
E.14	Demonstration of automatic processing of electronic initial case reports (eICRs) in the jurisdiction integrated surveillance system(s)	Twice per year
E.15	Proportion of test orders and results processed through Electronic Test Orders and Results Reporting (ETOR) at the PHL (this measure only applies to tests conducted at the public health laboratory)	Twice per year
E.16	Systems/programs at the PHL with ETOR interfaces	Annually
E.17	Caseload, number of cases per case investigator and number of contacts per contact tracer during the data collection period	Monthly
E.18	Timeliness, completeness, and effectiveness of case interviews among the cases sent for case investigation during the data collection period	Monthly
E.19	Timeliness of contact tracing during the data collection period	Monthly
E.20	Effectiveness of contact tracing to interrupt the transmission of COVID-19 during the data collection period	Monthly
E.21	Timeline of the case investigation process from specimen collection to contact notification during the data collection period	Monthly
E.22	Among contacts notified, proportion tested for COVID-19/SARS-CoV-2 at least once, within 14 days of notification during the data collection period	Monthly
E.23	Number of health department staff who can perform healthcare infection control assessments at state and local level	Twice per year
E.24	Number of proactive healthcare infection control assessment and response (ICAR) conducted by the health department or designee for COVID-19.	Twice per year
E.25	Number of COVID-19 outbreaks and responses in healthcare settings	Twice per year

ID	Measure	Reporting Frequency
E.26	Number of new or enhanced laboratory technologies procured, maintained, or implemented to improve laboratory response capacity	Twice per year
E.27	Number of biothreat samples shipped to designated LRN reference laboratory or CDC	Quarterly
E.28	Enhancing laboratory information infrastructure for LRN testing methodologies	Twice per year

Appendix C. PM reporting timeline for measures reported via REDCap for Year 2

Area	Measure #	Frequency	Data Collection Period	Data Submission Period
Strengthening laboratory testing	**E.1, E.27**	Q1	May 1 - Jul 31, 2021	Jul 31 - Aug 31, 2021
		Q2	Aug 1 - Oct 31, 2021	Oct 31 - Nov 30, 2021
		Q3	Nov 1, 2021 - Jan 31, 2022	Jan 31 - Feb 28, 2022
		Q4	Feb 1 - Apr 30, 2022	Apr 30 - May 31, 2022
	E.4, E.26, E.28	Twice per year	May 1 - Oct 31, 2021	Oct 31 - Nov 30, 2021
		Twice per year	Nov 1, 2021 - Apr 30, 2022	Apr 30 - May 31, 2022
Advancing electronic data exchange	**E.12, E.12a**	Q1	May 1 - Jul 31, 2021	Jul 31 - Aug 31, 2021
		Q2	Aug 1 - Oct 31, 2021	Oct 31 - Nov 30, 2021
		Q3	Nov 1, 2021 - Jan 31, 2022	Jan 31 - Feb 28, 2022
		Q4	Feb 1 - Apr 30, 2022	Apr 30 - May 31, 2022
	E.13, E.14, E.15	Twice per year	May 1 - Oct 31, 2021	Oct 31 - Nov 30, 2021
		Twice per year	Nov 1, 2021 - Apr 30, 2022	Apr 30 - May 31, 2022
	E.16	Once per year	As of July 31, 2021	Jul 31 - Aug 31, 2021
Enhancing investigation, response and prevention	**E.17, E.18, E.19, E.20, E.21, E.22**	Month 1	Jul 1 - Jul 31, 2021	Jul 31 - Aug 14, 2021
		2	Aug 1 - Aug 31, 2021	Aug 31 - Sep 14, 2021
		3	Sep 1 - Sep 30, 2021	Sep 30 - Oct 14, 2021
		4	Oct 1 - Oct 31, 2021	Oct 31 - Nov 14, 2021
		5	Nov 1 - Nov 30, 2021	Nov 30 - Dec 14, 2021
		6	Dec 1 - Dec 31, 2021	Dec 31, 2021 - Jan 14, 2022
		7	Jan 1 - Jan 31, 2022	Jan 31 - Feb 14, 2022
		8	Feb 1 - Feb 28, 2022	Feb 28 - Mar 14, 2022
		9	Mar 1 - Mar 31, 2022	Mar 31 - Apr 14, 2022
		10	Apr 1 - Apr 30, 2022	Apr 30 - May 14, 2022
		11	May 1 - May 31, 2022	May 31 - Jun 14, 2022
		12	Jun 1 - Jun 30, 2022	Jun 30 - Jul 14, 2022
	E.23, E.24, E.25 (Infection Prevention and Control)	Twice per year	Jan 1 - Jul 31, 2021	Due date Sep 30, 2021
		Twice per year	Aug 1 - Dec 31, 2021	Due date Jan 31, 2022

From: HHS IEA (OS/IEA) <HHSIEA@hhs.gov>
Sent: Thursday, August 05, 2021 10:07 PM EDT
To: HHS IEA (OS/IEA) <HHSIEA@hhs.gov>
Subject: HHS COVID-19 Update - 8/5

Dear Partner:

HHS Office of Intergovernmental and External Affairs COVID-19 update for August 5, 2021:

Highlights from President Biden's August 3rd Remarks on Fighting the COVID-19 Pandemic

- **Delta Variant and Transmissibility:** President Biden stated that because the Delta variant is highly transmissible, it is causing a new wave of cases, accounting for over 80% of cases in the United States today, with a likelihood of an increase in cases in the future. Biden states that the predicted increase is "a largely preventable tragedy that will get worse before it gets better."
- **COVID-19 and Vaccines:** Biden stated that the best way to protect yourself from COVID-19 is to get vaccinated; if vaccinated, it is highly unlikely to get COVID-19 and, if you contract the virus, you will likely experience mild symptoms if any. The data shows that the vast majority of cases, hospitalizations, and deaths due to COVID-19 are from the unvaccinated population. Biden commented, "The best line of defense against the virus is the vaccine… We have a pandemic of the unvaccinated."
- **Data of Increased Vaccination:** Biden reported a 55 percent increase in the average number of new people getting vaccinated every day in the past two weeks, and the highest seven-day total in a month. The eight states with the highest current case rates have seen a doubling of the number of people newly vaccinated each day. Biden declared that "we have to continue our aggressive efforts to vaccinate the unvaccinated."
- **Federal Steps to Incentivize Vaccination:** Biden outlined steps taken by his administration and other government-affiliated organizations to increase vaccinations. Places that have offered $100 to get vaccinated have seen an uptick of 25 percent of daily vaccination rates. Biden reiterated his plan to reimburse small- and medium-sized businesses who give paid time off to their employees to get vaccinated, to work with the Pentagon on adding COVID-19 to required vaccines for troops, and to require healthcare workers in the Department of Veterans Affairs to be vaccinated. Biden stated that these restrictions are "tough, unpopular steps to keep people safe and our economy strong."
- **States' Lack of Action on COVID:** President Biden stated that many states' harmful laws on mask mandates is disappointing and harmful; seven states have both banned mask mandates statewide and in schools while many students are not yet eligible to be vaccinated. The president cited these measures and accompanying low vaccination rates as the cause of the rise of cases, citing Florida and Texas as accounting for a third of all new cases. Biden declared that "COVID-19 is a national challenge, and we must come together — we have to come together — all of us together, as a country, to solve it."
- **Vaccination Abroad:** Biden stated that a global attack on the virus is in the United States' national interest. New, potentially more dangerous variants (such as the Delta variant) can mutate outside of the United States and threaten the country if a global approach is not taken. Biden highlighted American action in global vaccination, announcing that he will purchase and donate 500 million doses from Pfizer; he also stated that the U.S. has domestically manufactured 110 million doses for global vaccination. Biden reiterated that he's "been very clear-eyed that we need to attack this virus globally, not just at home, because it's in America's self-interest to do so."

Highlights from the White House COVID-19 Response Team Briefing

Jeff Zients

- **Update on Progress in the Fight Against COVID:** Mr. Zients highlighted how, driven by the Delta variant, cases are continuing to rise, especially among the unvaccinated. Zients states that over the past seven days, seven states — among the leaders in unvaccinated percentage — accounted for half of the new cases and hospitalizations despite holding less than a quarter of US population; vaccines are the best way to protect against COVID. Vaccinations are on the rise; the past 24 hours served as the greatest number of vaccinations in a single day since July 3 and the daily average of vaccinations has increased for the fourth week in a row. Zients said that "clearly Americans are seeing the impact of being unvaccinated and unprotected and they respond by doing their part, rolling up their sleeve, and getting vaccinated."
- **Action on Vaccination Requirements:** Mr. Zients reiterated President Biden's call for federal workers and contractors to get vaccinated and notes the further requests for similar requirements in the private sector. Zients stated that over 650 colleges and universities are requiring students and staff on campus to be vaccinated and nationwide, over 100 hospitals and healthcare systems are requiring healthcare professionals to be vaccinated. "America's businesses, large and small, universities and medical schools, and many other institutions are stepping up on vaccination requirements and our message is quite simple: we support these vaccination requirements to protect workers, communities, and the country," Zients said.
- **COVID-19 Surge Response Teams:** Mr. Zients stated that the COVID-19 Surge Response Teams are in 16 states and addressing each state's specific needs, whether that is increased testing, mobile vaccination clinics, or hospital capacity. Zients noted the hundreds of federal employees deployed to the states that are assisting in combatting COVID. "Our whole of government response," Zients said, "will continue its relentless efforts to end this pandemic and deliver progress each and every day."

Dr. Walensky

- **COVID-19 Case Update:** Dr. Walensky stated that on August 3, the CDC reported 103,455 new cases of COVID with a 7-day average of about 89,463 cases per day, representing an increase of 43.3% from last week. Hospitalizations and deaths from this week compared to the last increased significantly; deaths rose 39.3 percent. Walensky stated that 83% of counties within the United States are experiencing moderate or high transmission. Those at high risk remain people who have not yet been vaccinated. Walensky said that "now is the time to get vaccinated. We know these vaccines are working and we know that they save lives."

Dr. Fauci

- **Vaccine Hesitancy and Concern Over Development Speed:** In response to Americans worried about the speed of the development of the vaccine, Dr. Fauci outlined the various ways in which the vaccine is safe and not rushed: the investment of logistics and resources, the decades of prior research (both in platform technology and immunogen), the non-sequential investment in vaccine development, and the reuse of clinical trial sites originally built for HIV and influenza further sped the development. Fauci said that the vaccine "did not go too

fast; it was a major investment both in the logistics, the resources, and the clinical and basic research."

Dr. Murthy

- **Vaccine Efficacy:** Dr. Murthy stated that the COVID-19 vaccines protect against the Delta variant, both at reducing the risk of infection and the severity if infected. Murthy said that "breakthrough infections of vaccinated people are the exception, not the rule."
- **Meeting of Living Surgeons General:** Yesterday, Dr. Murthy met with the living former surgeons general to discuss the vaccination effort with equity being at the forefront. The meeting covered health misinformation, ensuring that communities of color and rural areas are not left behind, and engaging with trusted community messengers. Murthy stated that "this gathering of surgeons general reflected the diversity of our nation, and it was emblematic of what we have to do together to defeat the virus."

Testing and Treatment

FDA Testing Updates: As of August 3, 398 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 279 molecular tests and sample collection devices, 87 antibody and other immune response tests and 32 antigen tests. There are 53 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, six antigen over-the-counter (OTC) at-home tests and two molecular OTC at-home tests. The FDA has authorized 13 antigen tests and eight molecular tests for serial screening programs. The FDA has also authorized 595 revisions to EUA authorizations.

Funding

FEMA COVID-19 Funeral Assistance Tops $888 Million: FEMA announced that COVID-19 funeral assistance has now increased to over $888 million to more than 135,000 people to assist with COVID-19-related funeral costs for deaths occurring on or after Jan. 20, 2020. The assistance, easing financial stress, comes from the Coronavirus Response and Relief Supplemental Appropriations Act of 2021 and the American Rescue Plan Act of 2021. Eligibility determinations are not driven by state/location; instead, they are based on when the applicant submits all required documentation.

Information for Specific Populations

CDC Issues Eviction Order in Areas of Substantial and High Transmission: CDC announced that Director Dr. Rochelle Walensky signed an order on August 3rd determining the evictions of tenants for failure to make rent or housing payments could be detrimental to public health control measures to slow the spread of SARS-CoV-2, the virus that causes COVID-19. This order will expire on October 3, 2021 and applies in United States counties experiencing substantial and high levels of community transmission levels of SARS-CoV-2: This temporary protection from eviction in counties with heightened levels of community transmission exists in order to respond to recent, unexpected developments in the trajectory of the COVID-19 pandemic, including the rise of the Delta variant. It is intended to target specific areas of the country where cases are rapidly increasing, which likely would be exacerbated by mass evictions.

CDC Extends Order at the Southern and Northern Land Borders: The Centers for Disease Control and Prevention (CDC) has issued an order under Sections 362 and 365 of the Public Health Service Act, and associated implementing regulations, that temporarily suspends the introduction of certain noncitizens. The order is based on the Director's determination that introduction of such noncitizens, regardless of their country of origin, migrating through Canada and Mexico into the United States creates a serious danger of the introduction of COVID-19 into the United States, and the danger is so increased by the introduction of such noncitizens that a temporary suspension is necessary to protect the public health. Unaccompanied noncitizen children already excepted under a July 16, 2021, order, remain excepted from the order's coverage.

Readout of the Sixth Covid-19 Health Equity Task Force Meeting: HHS released a readout on Friday, July 30's, sixth COVID-19 Health Equity Task Force meeting to consider interim recommendations addressing future pandemic preparedness. Task Force Members discussed and voted favorably on interim recommendations, including but not limited to exploring strategies that meet local and regional staffing needs during pandemic response, expanding adequate and evidence-based healthcare access and funding infrastructure to treat patients in congregate settings, establishing and adjusting national standards as well as strategically target funding for water, sewage, and air quality to where it's needed, based on data from reliable equity indicators.

What to Consider When Planning to Operate a COVID-19 Vaccine Clinic: CDC released information regarding what to consider when planning to operate a COVID-19 vaccine clinic. The informational sheet provides guidance to conduct a gap analysis to determine specific geographic areas and specific populations that may benefit from additional sites to improve access to vaccination, work with community leaders and trusted members of the community to help with the success of vaccination clinics, and assess the optimal time to activate a vaccination site and consider the benefits of focused vaccination efforts. The page also page also provides a checklist of best practices for vaccination clinics held at satellite, temporary, or off-site locations.

Know What to Expect at Your Child's K- 12 School or Child Care Program: CDC released information for parents on what to expect for K-12 school or childcare programs. The page provides information for factors that a child's school or care program may consider, prevention strategies for these programs, and vaccination and masking.

CMS Updates

Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Rates Final Rule (CMS-1752-F): CMS announced that, on August 2, 2021, it issued the final rule for fiscal year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS). The final rule updates Medicare payment policies and rates for operating and capital-related costs of acute care hospitals and for certain hospitals and hospital units excluded from the IPPS for FY 2022. The policies in this IPPS and LTCH PPS final rule build on key priorities to close health care equity gaps and support greater access to life-saving diagnostics and therapies during the COVID-19 public health emergency (PHE) and beyond. To continue to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments and to minimize any potential payment disruption immediately following the end of the PHE, CMS is extending the New COVID-19 Treatment Add-on Payment for eligible COVID-19 products through the end of the fiscal year in which the PHE ends.

Research

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings: CDC released an *MMWR* on the outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings in Barnstable County, Massachusetts in July, 2021. This report was released as an *MMWR* Early Release on July 30. Variants of SARS-CoV-2 continue to emerge. The B.1.617.2 (Delta) variant is highly transmissible. In July 2021, following multiple large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; 346 (74%) occurred in fully vaccinated persons. Testing identified the Delta variant in 90% of specimens from 133 patients. Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not. Jurisdictions might consider expanded prevention strategies, including universal masking in indoor public settings, particularly for large public gatherings that include travelers from many areas with differing levels of SARS-CoV-2 transmission. CDC Director Rachelle Walensky, MD, MPH, released an accompanying statement on the MMWR.

COVID-19 Vaccine Safety in Adolescents Aged 12–17: CDC released an *MMWR* on COVID-19 vaccine safety in adolescents aged 12–17 in the United States from December 14, 2020 - July 16, 2021. This report was released as an *MMWR* Early Release on July 30. In preauthorization trials of the Pfizer-BioNTech COVID-19 vaccine, adolescents aged 12–17 years reported local and systemic mild and moderate reactions. Myocarditis has been observed after vaccination with mRNA vaccines in post authorization monitoring. Local and systemic reactions after vaccination with Pfizer-BioNTech vaccine were commonly reported by adolescents aged 12–17 years to U.S. vaccine safety monitoring systems, especially after dose 2. A small proportion of these reactions are consistent with myocarditis. Mild local and systemic reactions are common among adolescents following Pfizer-BioNTech vaccine, and serious adverse events are rare. The Advisory Committee on Immunization Practices conducted a risk-benefit assessment and continues to recommend the Pfizer-BioNTech COVID-19 vaccine for all persons aged ≥12 years.

Full-dose Blood Thinners Reduce the Need for Organ Support in Moderately Ill COVID-19 Patients, but Not in Critically Ill Patients: NIH released a report on full-dose blood thinners reducing the need for organ support in moderately ill COVID-19 patients, but not critically ill patients. In April 2020, hospitalized COVID-19 patients received either a low or full dose of heparin, a blood thinner, for up to 14 days after enrollment. By December 2020, interim results indicated that full-dose anticoagulation did not reduce the need for organ support and may even cause harm in critically ill patients. However, one month later, interim results indicated that full doses of heparin likely benefited moderately ill patients. The full study can be viewed here.

Long-Term Study of Brain Development Records Pandemic Life: NIH released a report on the analysis of adolescent brains to examine the long-term health impacts caused by the COVID-19 pandemic and shutdowns. Through surveys and tests, the study, from Adolescent Brain Cognitive Development (ABCD) Study and funded by NIH, is capturing the impact of the COVID-19 pandemic on children using an MRI.

Case Forecasts: This week's national ensemble predicts that 350,000 to 1,800,000 new cases will likely be reported in the week ending August 28, 2021. Over the last several weeks, more reported cases have fallen outside of the forecasted prediction intervals than expected. This suggests that current forecast prediction intervals may not capture the full range of uncertainty. Because of this, case forecasts for the coming weeks should be interpreted with caution. View previous case forecasts.

Hospitalization Forecasts: This week's national ensemble predicts that the number of new daily confirmed COVID-19 hospital admissions will likely increase over the next 4 weeks, with 6,700 to 24,000 new confirmed COVID-19 hospital admissions likely reported on August 30, 2021. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of daily confirmed COVID-19 hospital admissions will likely increase in 38 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported hospital admissions are uncertain or predicted to remain stable in the other states and territories. View previous hospitalization forecasts.

Death Forecasts: This week's national ensemble predicts that the number of newly reported COVID-19 deaths will likely increase over the next 4 weeks, with 2,300 to 9,100 new deaths likely reported in the week ending August 28, 2021. The national ensemble predicts that a total of 624,000 to 642,000 COVID-19 deaths will be reported by this date. The state- and territory-level ensemble forecasts predict that over the next 4 weeks, the number of newly reported deaths per week will likely increase in 17 jurisdictions, which are indicated in the forecast plots below. Trends in numbers of future reported deaths are uncertain or predicted to remain stable in the other states and territories. View previous death forecasts.

Top Military Medical Doctor Predicts Coronavirus Longevity: DoD released a report on the analysis of COVID-19 longevity according to director of Defense Health Agency, Army Lt. Gen. Ronald J. Place. Place stated his belief that COVID-19 and other such coronaviruses likely will stay in the environment and continue to mutate. Vaccines serve as the way to protect oneself from this lingering threat.

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
Washington, D.C.

Emergency Preparedness & Response

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Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021

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Although laboratory evidence suggests that antibody responses following COVID-19 vaccination provide better neutralization of some circulating variants than does natural infection (*1*,*2*), few real-world epidemiologic studies exist to support the benefit of vaccination for previously infected persons. This report details the findings of a case-control evaluation of the association between vaccination and SARS-CoV-2 reinfection in Kentucky during May–June 2021 among persons previously infected with SARS-CoV-2 in 2020. Kentucky residents who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated (odds ratio [OR] = 2.34; 95% confidence interval [CI] = 1.58–3.47). These findings suggest that among persons with previous SARS-CoV-2 infection, full vaccination provides additional protection against reinfection. To reduce their risk of infection, all eligible persons should be offered vaccination, even if they have been previously infected with SARS-CoV-2.*

Kentucky residents aged ≥18 years with SARS-CoV-2 infection confirmed by positive nucleic acid amplification test (NAAT) or antigen test results† reported in Kentucky's National Electronic Disease Surveillance System (NEDSS) during March–December 2020 were eligible for inclusion. NEDSS data for all Kentucky COVID-19 cases were imported into a REDCap database that contains laboratory test results and case investigation data, including dates of death for deceased patients reported to public health authorities (*3*). The REDCap database was queried to identify previously infected persons, excluding COVID-19 cases resulting in death before May 1, 2021. A case-patient was defined as a Kentucky resident with laboratory-confirmed SARS-CoV-2 infection in 2020 and a subsequent positive NAAT or antigen test result during May 1–June 30, 2021. May and June were selected because of vaccine supply and eligibility requirement considerations; this period was more likely to reflect resident choice to be vaccinated, rather than eligibility to receive vaccine.§ Control participants were Kentucky residents with laboratory-confirmed SARS-CoV-2 infection in 2020 who were not reinfected through June 30, 2021. Case-patients and controls were matched on a 1:2 ratio based on sex, age (within 3 years), and date of initial positive SARS-CoV-2 test (within 1 week). Date of initial positive test result refers to the specimen collection date, if available. The report date in NEDSS was used if specimen collection date was missing. Random matching was performed to select controls when multiple possible controls were available to match per case (*4*).

Vaccination status was determined using data from the Kentucky Immunization Registry (KYIR). Case-patients and controls were matched to the KYIR database using first name, last name, and date of birth. Case-patients were considered fully vaccinated if a single dose of Janssen (Johnson & Johnson) or a second dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) was received ≥14 days before the reinfection date. For controls, the same definition was applied, using the reinfection date of the matched case-patient. Partial vaccination was defined as receipt of ≥1 dose of vaccine, but either the

* https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#CoV-19-vaccination

† https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

§ May and June were selected for two primary reasons. First, when vaccination supplies were low, some previously infected persons were deferring vaccination for 90 days to allow never-infected persons priority for available vaccine; however, by May 2021, deferral for 90 days was no longer a reason for those infected in 2020 to remain unvaccinated. Second, although vaccination eligibility was initially restricted based on age, comorbidities, and occupation, by April 5, 2021, all Kentucky residents aged ≥16 years became eligible for vaccination (https://chfs.ky.gov/agencies/dph/covid19/Cv19VaccineFAskedQ.pdf). Thus, vaccination status in May or June 2021 might more accurately reflect choice rather than eligibility to be vaccinated.

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Summary

What is already known about this topic?

Reinfection with human coronaviruses, including SARS-CoV-2, the virus that causes COVID-19, has been documented. Currently, limited evidence concerning the protection afforded by vaccination against reinfection with SARS-CoV-2 is available.

What is added by this report?

Among Kentucky residents infected with SARS-CoV-2 in 2020, vaccination status of those reinfected during May–June 2021 was compared with that of residents who were not reinfected. In this case-control study, being unvaccinated was associated with 2.34 times the odds of reinfection compared with being fully vaccinated.

What are the implications for public health practice?

To reduce their likelihood for future infection, all eligible persons should be offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection.

vaccination series was not completed or the final dose was received <14 days before the case-patient's reinfection date. Using conditional logistic regression, ORs and CIs were used to compare no vaccination and partial vaccination with full vaccination among case-patients and controls. SAS (version 9.4; SAS Institute) was used for matching and statistical analyses. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶

Overall, 246 case-patients met eligibility requirements and were successfully matched by age, sex, and date of initial infection with 492 controls. Among the population included in the analysis, 60.6% were female, and 204 (82.9%) case-patients were initially infected during October–December 2020 (Table 1). Among case-patients, 20.3% were fully vaccinated compared with 34.3% of controls (Table 2). Kentucky residents with previous infections who were unvaccinated had 2.34 times the odds of reinfection (OR = 2.34; 95% CI = 1.58–3.47) compared with those who were fully vaccinated; partial vaccination was not significantly associated with reinfection (OR = 1.56; 95% CI = 0.81–3.01).

Discussion

This study found that among Kentucky residents who were previously infected with SARS-CoV-2 in 2020, those who were unvaccinated against COVID-19 had significantly higher likelihood of reinfection during May and June 2021. This finding supports the CDC recommendation that all eligible persons be offered COVID-19 vaccination, regardless of previous SARS-CoV-2 infection status.

Reinfection with SARS-CoV-2 has been documented, but the scientific understanding of natural infection-derived immunity is still emerging (*5*). The duration of immunity resulting from natural infection, although not well understood, is suspected to persist for ≥90 days in most persons.** The emergence of new variants might affect the duration of infection-acquired immunity, and laboratory studies have shown that sera from previously infected persons might offer weak or inconsistent responses against several variants of concern (*2,6*). For example, a recent laboratory study found that sera collected from previously infected persons before they were vaccinated provided a relatively weaker, and in some cases absent, neutralization response to the B.1.351 (Beta) variant when compared with the original Wuhan-Hu-1 strain (*1*). Sera from the same persons after vaccination showed a heightened neutralization response to the Beta variant, suggesting that vaccination enhances the immune response even to a variant to which the infected person had not been previously exposed. Although such laboratory evidence continues to suggest that vaccination provides improved neutralization of SARS-CoV-2 variants, limited evidence in real-world settings to date corroborates the findings that vaccination can provide improved protection for previously infected persons. The findings from this study suggest that among previously infected persons, full vaccination is associated with reduced likelihood of reinfection, and, conversely, being unvaccinated is associated with higher likelihood of being reinfected.

The lack of a significant association with partial versus full vaccination should be interpreted with caution given the small numbers of partially vaccinated persons included in the analysis (6.9% of case-patients and 7.9% of controls), which limited statistical power. The lower odds of reinfection among the partially vaccinated group compared with the unvaccinated group is suggestive of a protective effect and consistent with findings from previous studies indicating higher titers after the first mRNA vaccine dose in persons who were previously infected (*7,8*).

The findings in this report are subject to at least five limitations. First, reinfection was not confirmed through whole genome sequencing, which would be necessary to definitively prove that the reinfection was caused from a distinct virus relative to the first infection. Although in some cases the repeat positive test could be indicative of prolonged viral shedding or failure to clear the initial viral infection (*9*), given the time between initial and subsequent positive molecular tests among participants in this study, reinfection is the most likely explanation. Second, persons who have been vaccinated are possibly less likely to get tested. Therefore, the association of reinfection and lack of vaccination might be overestimated. Third, vaccine doses administered at federal or out-of-state sites are

¶ 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

** https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

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TABLE 1. Demographic characteristics of COVID-19 patients with reinfection (case-patients) and COVID-19 patients who were not reinfected (control participants) — Kentucky, May–June 2021

Characteristic	No. (%) Case-patients* (n = 246)	Control participants† (n = 492)
Age group, yrs		
18–29	46 (18.7)	89 (18.1)
30–39	37 (15.0)	83 (16.9)
40–49	43 (17.5)	80 (16.3)
50–59	44 (17.9)	88 (17.9)
60–69	27 (11.0)	51 (10.4)
70–79	28 (11.4)	58 (11.8)
≥80	21 (8.5)	43 (8.7)
Sex		
Female	149 (60.6)	298 (60.6)
Month of initial infection in 2020		
March	0 (0)	3 (0.6)
April	7 (2.8)	11 (2.2)
May	2 (0.8)	2 (0.4)
June	4 (1.6)	11 (2.2)
July	8 (3.3)	17 (3.5)
August	8 (3.3)	13 (2.6)
September	13 (5.3)	22 (4.5)
October	36 (14.6)	78 (15.9)
November	72 (29.3)	141 (28.7)
December	96 (39.0)	194 (39.4)

* Case-patients were eligible for inclusion if initial infection occurred during March–December 2020, and a subsequent positive nucleic acid amplification or antigen test result was received during May–June 2021 (using date of specimen collection). Cases for analyses were restricted to persons aged ≥18 years at time of reinfection.
† Controls were matched by sex, age (within 3 years), and time of initial infection diagnosis (within 7 days).

not typically entered in KYIR, so vaccination data are possibly missing for some persons in these analyses. In addition, inconsistencies in name and date of birth between KYIR and NEDSS might limit ability to match the two databases. Because case investigations include questions regarding vaccination, and KYIR might be updated during the case investigation process, vaccination data might be more likely to be missing for controls. Thus, the OR might be even more favorable for vaccination. Fourth, although case-patients and controls were matched based on age, sex, and date of initial infection, other unknown confounders might be present. Finally, this is a retrospective study design using data from a single state during a 2-month period; therefore, these findings cannot be used to infer causation. Additional prospective studies with larger populations are warranted to support these findings.

These findings suggest that among persons with previous SARS-CoV-2 infection, full vaccination provides additional protection against reinfection. Among previously infected Kentucky residents, those who were not vaccinated were more than twice as likely to be reinfected compared with those with full vaccination. All eligible persons should be offered vaccination, including those with previous SARS-CoV-2 infection, to reduce their risk for future infection.

TABLE 2. Association of SARS-CoV-2 reinfection* with COVID-19 vaccination status — Kentucky, May–June 2021

Vaccination status	No. (%) Case-patients	Control participants	OR (95% CI)†
Not vaccinated	179 (72.8)	284 (57.7)	2.34 (1.58–3.47)
Partially vaccinated¶	17 (6.9)	39 (7.9)	1.56 (0.81–3.01)
Fully vaccinated§	50 (20.3)	169 (34.3)	Ref
Total	**246 (100)**	**492 (100)**	—

Abbreviations: CI = confidence interval; NAAT = nucleic acid amplification test; OR = odds ratio; Ref = referent group.
* All case-patients (reinfected) and control participants (not reinfected) had previous SARS-CoV-2 infection documented by positive NAAT or antigen test results during March–December 2020. Reinfection was defined as receipt of positive NAAT or antigen test results during May 1–June 30, 2021.
† Estimated based on conditional logistic regression.
§ Case-patients were considered partially vaccinated if ≥1 dose of vaccine was received, but the vaccination series was either not completed or the final dose was received <14 days before their reinfection date. For control participants, the same criteria were applied, using the matched case-patient's reinfection date.
¶ Case-patients and control participants were considered fully vaccinated if a complete COVID-19 vaccine series was received ≥14 days before the case-patient's reinfection date.

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Rapid Increase in Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — Mesa County, Colorado, April–June 2021

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On May 5, 2021, the Colorado Department of Public Health and Environment (CDPHE) identified the first five COVID-19 cases caused by the SARS-CoV-2 B.1.617.2 (Delta) variant in Mesa County in western Colorado (population 154,933, <3% of the state population). All five initial cases were associated with school settings. Through early June, Mesa County experienced a marked increase in the proportion of Delta variant cases identified through sequencing: the 7-day proportion of sequenced specimens identified as B.1.617.2 in Mesa County more than doubled, from 43% for the week ending May 1 to 88% for the week ending June 5. As of June 6, more than one half (51%) of sequenced B.1.617.2 specimens in Colorado were from Mesa County. CDPHE assessed data from surveillance, vaccination, laboratory, and hospital sources to describe the preliminary epidemiology of the Delta variant and calculate crude vaccine effectiveness (VE). Vaccination coverage in early May in Mesa County was lower (36% of eligible residents fully vaccinated) than that in the rest of the state (44%). Compared with that in all other Colorado counties, incidence, intensive care unit (ICU) admissions, and COVID-19 case fatality ratios were significantly higher in Mesa County during the analysis period, April 27–June 6, 2021. In addition, during the same time period, the proportion of COVID-19 cases in persons who were fully vaccinated (vaccine breakthrough cases) was significantly higher in Mesa County compared with that in all other Colorado counties. Estimated crude VE against reported symptomatic infection for a 2-week period ending June 5 was 78% (95% confidence interval [CI] = 71%–84%) for Mesa County and 89% (95% CI = 88%–91%) for other Colorado counties. Vaccination is a critical strategy for preventing infection, serious illness, and death from COVID-19. Enhanced mitigation strategies, including masking in indoor settings irrespective of vaccination status, should be considered in areas with substantial or high case rates.

Whole genome sequencing is performed in the CDPHE laboratory on specimens submitted as part of sentinel surveillance (38 sites across Colorado, including one acute care hospital in Mesa County), as well as for cluster and outbreak response and on suspected variants (reverse transcription–polymerase chain reaction [RT-PCR]–positive specimens with S-gene target failure associated with the B.1.1.7 lineage) (*1*). The Colorado Electronic Disease Reporting System (CEDRS), a surveillance system managed by CDPHE, was used to identify reported confirmed or probable cases of COVID-19 occurring from April 27, the date of illness onset for the first Delta variant case in Mesa County, to June 6, when sequencing identified B.1.617.2 as the dominant variant in Colorado (*2*). The Colorado Immunization Information System (CIIS) was used to verify COVID-19 vaccination status; vaccine breakthrough infections were identified using personally identifying information to match cases in CEDRS to CIIS entries* (*3*). Crude VE against reported symptomatic infection was estimated and compared among Mesa County and all other Colorado counties using a screening method outlined by the World Health Organization† as a rapid tool to assess whether a vaccine is performing as expected (*4*). To better determine settings where the Delta variant was spreading, outbreak data

* SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after they have completed all recommended doses of the primary series for a Food and Drug Administration–authorized COVID-19 vaccine.

† Crude VE was estimated as (1-[{PCV/(1-PCV)}/{PPV/(1-PPV)}]) following World Health Organization interim guidance on conducting VE evaluations in the setting of new SARS-CoV-2 variants where PCV is the observed percentage of cases in persons who are vaccinated and PPV is the percentage of a comparable group in the population who are vaccinated. The PPV used in the calculations for Mesa County and other Colorado counties was from May 7, 2021, approximately 2 weeks before the anticipated onset for cases included in the PCV estimate. PPV included only vaccine-eligible persons and PCV was limited to symptomatic persons who were vaccine-eligible.

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during April 22–June 26 were obtained from the CDPHE outbreak database, which contains information on all reported COVID-19 outbreaks in Colorado and outbreak line lists.[§] Residential care facility vaccination data were obtained from EMResource, a capacity planning tool used by CDPHE for facility-level reporting of aggregate COVID-19 vaccinations. Incidence of SARS-CoV-2 infection and proportions of outcomes and vaccination rates among patients living in Mesa County and all other Colorado counties were compared and p-values were calculated using chi-square or Fisher's exact tests. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[¶]

During April 27–June 6, a total of 1,945 COVID-19 cases were reported in Mesa County through CEDRS (incidence = 1,255 per 100,000). Compared with that in all other Colorado counties, incidence, overall ICU admissions, and overall case fatality ratios were significantly higher in Mesa County (Table). In addition, the proportion of breakthrough cases was significantly higher in Mesa County than in all other Colorado counties. In Mesa County, the proportion of persons aged ≥65 years with COVID-19 who were fully vaccinated (27.5%) was significantly higher than that in all other Colorado counties (17.4%). The crude VE against reported symptomatic infection for a 2-week period ending June 5 was 78% (95% CI = 71%–84%) for Mesa County and 89% (95% CI = 88%–91%) for all other Colorado counties.[**]

Among 18,475 sequenced specimen results reported in Colorado through June 6, a total of 783 infections with the Delta variant were identified; more than one half (400; 51.1%) of these occurred among Mesa County residents, even though the county accounts for <3% of the state's population. Symptomatic illness was reported in 304 (76.0%) of the 400 Delta variant infections in Mesa County residents and 251 (65.5%) of 383 Delta variant infections in other counties. The 7-day percentage of sequenced sentinel specimens identified as SARS-CoV-2 B.1.617.2 in Mesa County increased from 43% for the week ending May 1 to 88% for the week ending June 5 (Figure). During the 5-week period, 67% (51 of 76) of sentinel surveillance specimens in Mesa County were identified as B.1.617.2 compared with 15% (248 of 1,637) of specimens from all other Colorado counties sequenced over the same time frame.

During April 22–June 26, a total of 37 COVID-19 outbreaks were reported in Mesa County; 13 (35%) in residential care facilities, 11 (30%) in schools, two (5%) in correctional facilities, and 11 (30%) in other settings. Twelve outbreaks, including seven in residential care facilities, had at least one Delta variant case. Average vaccination coverage in these seven residential facilities was 87% among residents (range = 50%–97%) and 50% among staff members (range = 6%–69%); attack rates among residents ranged from 0% to 54.6% (median = 1.2%) and among staff members from 2.2% to 25.5% (median = 10.0%). Five of these seven outbreaks involved at least one case in a fully vaccinated resident or staff member.[††]

Discussion

The Delta variant is highly transmissible; within 5 weeks of first identification, the Delta variant became the dominant SARS-CoV-2 variant in Mesa County, Colorado and is also now the predominant variant in the United States (*5*). Higher ICU admissions and case fatality ratios in Mesa County compared with those in the rest of the state are consistent with previous reports that infections with the Delta variant might result in more severe outcomes (*6*,*7*). The slightly lower crude VE estimate against symptomatic infection in Mesa County may lend support to previous findings that COVID-19 vaccines provide modestly lower protection against symptomatic infection with the Delta variant (*8*). Alternatively, because the Delta variant was circulating at higher levels in Mesa County than in other Colorado counties, the lower VE in Mesa County might reflect the much higher exposure to circulating virus among vaccinated persons.

The findings in this report are subject to at least four limitations. First, lack of genetic sequencing for all SARS-CoV-2 isolates likely affected estimated rates and proportions; the number of outbreaks involving the Delta variant might be underreported for this reason. Second, sentinel surveillance might not provide a fully representative sample of sequence types in Colorado because the specimens originate from hospitals and likely include more specimens from inpatients and

[§] An outbreak in a residential care facility (skilled nursing facility, assisted living residence, intermediate care facility, or group home) is defined as the occurrence of two or more confirmed cases of COVID-19 among residents and staff members in a facility within 14 days, or one confirmed case and two or more probable cases of COVID-19 among residents and staff members in a facility within 14 days. Until May 31, 2021, the definition of a school outbreak was defined as two or more confirmed COVID-19 cases among students, teachers, and staff members from separate households within 14 days in a single classroom, cohort, or activity or other close contact in the school setting; or one confirmed case and two or more probable cases of COVID-19 among students, teachers, and staff members from separate households within 14 days in a single classroom, cohort, or activity or other close contact in the school setting. Starting June 1, the definition changed from two or more to five or more cases of COVID-19, of which at least one patient has had a positive molecular amplification test or antigen test, among students, teachers, and staff members from separate households within 14 days in a single classroom, cohort, or activity or other close contact in the school setting.

[¶] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

[**] For Mesa County, PPV was 36.2% and PCV was 11.0%. For other Colorado counties, PPV was 44.2% and PCV was 7.9%.

[††] A fully vaccinated person is one who has completed all recommended doses of an FDA–authorized COVID-19 vaccine, including Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) ≥14 days before a positive SARS-CoV-2 test result.

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TABLE. Age-specific incidence, clinical outcomes, and vaccination status among COVID-19 cases in Mesa and other counties — Colorado, April 27–June 6, 2021

Characteristic	Mesa County	Other Colorado counties	p-value[†]
Total COVID-19 cases, no.	**1,945**	**35,494**	—
Age group, yrs			
0–17	477	7,603	—
18–64	1,246	25,466	—
≥65	222	2,425	—
Overall incidence*	1,255	633	<0.001
Age group, yrs			
0–17	1,408	620	<0.001
18–64	1,377	714	<0.001
≥65	726	297	<0.001
Hospital admission, no./No. (%)	142/1,945 (7.3)	2,448/35,494 (6.9)	0.49
Age group, yrs			
0–17	3/477 (0.6)	97/7,603 (1.3)	0.22
18–64	69/1,246 (5.5)	1,554/25,466 (6.1)	0.42
≥65	70/222 (31.5)	797/2,425 (32.9)	0.69
ICU admission among hospitalized patients, no./No. (%)	49/142 (34.5)	583/2,448 (23.8)	0.004
Age group, yrs			
0–17	1/3 (33.3)	17/97 (17.5)	0.45
18–64	25/69 (36.2)	356/1,554 (22.9)	0.01
≥65	23/70 (32.9)	210/797 (26.4)	0.24
Overall CFR, no./No. (%)	29/1,945 (1.5)	299/35,494 (0.8)	0.003
Age group, yrs			
0–17	1/477 (0.2)	2/7,603 (0.03)	0.16
18–64	7/1,246 (0.6)	101/25,466 (0.4)	0.37
≥65	21/222 (9.5)	196/2,425 (8.1)	0.47
CFR, hospitalized patients, no./No. (%)	22/142 (15.5)	198/2,448 (8.1)	0.002
Age group, yrs			
0–17	1/3 (33.3)	1/97(1.0)	0.06
18–64	5/69 (7.2)	55/1,554 (3.5)	0.11
≥65	16/70 (22.9)	142/797 (17.8)	0.29
Fully vaccinated[§,¶], no./No. (%)	136/1,945 (7.0)	1,715/35,397 (4.8)	<0.001
Age group, yrs			
0–17	2/477 (0.4)	10/7,591 (0.1)	0.16
18–64	73/1,246 (5.9)	1,283/25,381 (5.1)	0.21
≥65	61/222 (27.5)	422/2,425 (17.4)	<0.001

Abbreviations: CFR = case fatality ratio; ICU = intensive care unit.
* Cases per 100,000 population.
† Calculated using chi-square test or Fisher's exact test.
§ A fully vaccinated person is one who has completed all recommended doses of a Food and Drug Administration–authorized COVID-19 vaccine, including Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) ≥14 days before a positive SARS-Co-V-2 test result.
¶ Vaccination status was missing for 97 persons.

emergency department patients compared with specimens from other testing sites. Third, the screening method provides rapid crude VE estimates that do not control for possible effects of confounding or clustering. Some of the differences between VE and severity of illness in Mesa County and that in other counties might be due to differences in the age distribution of patients and the inclusion of cases associated with outbreaks in congregate settings. However, CDPHE estimates that fewer than 10% of cases during the time period occurred in congregate settings. Finally, differences in vaccination coverage in some of these populations might be an additional confounding factor when estimating crude VE at the county and state levels. VE studies with more rigorous methods and the power to estimate protection against severe outcomes are needed to better understand the potential impact of the Delta variant.

Vaccination is a critical strategy for preventing infection, serious illness, and death associated with SARS-CoV-2 (including the Delta variant). Additional targeted prevention strategies (e.g., masking in indoor settings irrespective of vaccination status) and adherence to prevention strategies (e.g., surveillance testing and infection prevention and control procedures) are prudent in areas with high circulation of the Delta variant and in higher risk settings, such as residential care facilities.

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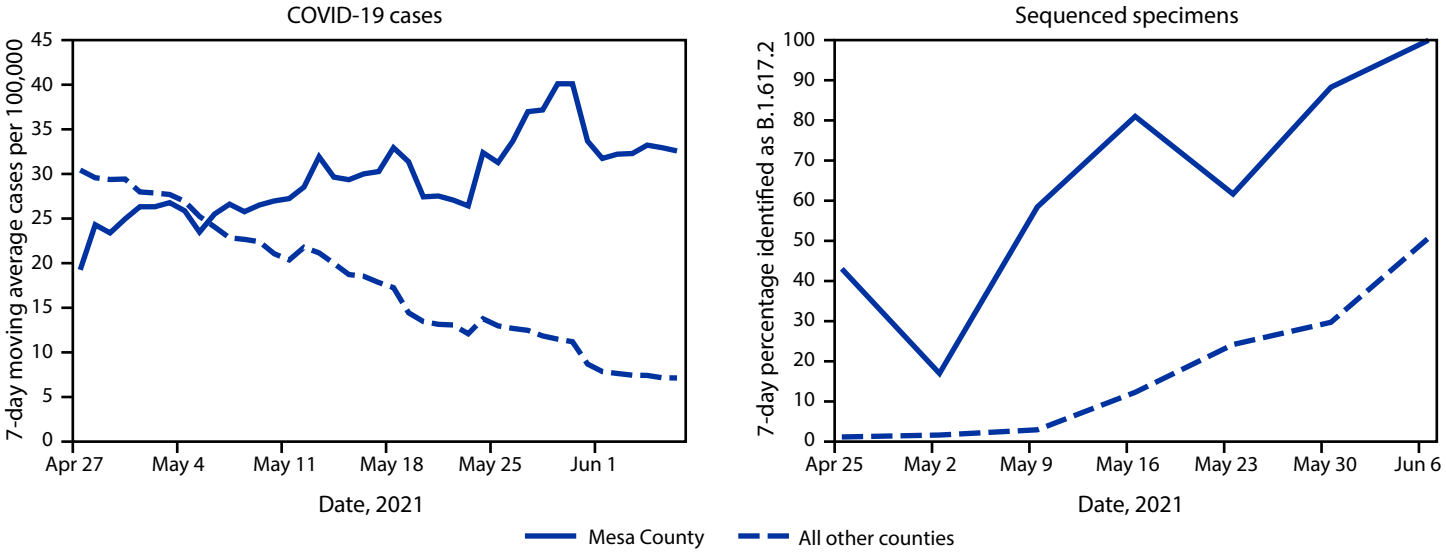
FIGURE. Number of COVID-19 cases and proportion of B.1.617.2 (Delta) variant infections in Mesa and other counties — Colorado, April 27–June 6, 2021



Summary

What is already known about this topic?

The highly transmissible B.1.617.2 (Delta) variant of SARS-CoV-2 has become the predominant circulating U.S. strain.

What is added by this report?

During April–June 2021, COVID-19 cases caused by the Delta variant increased rapidly in Mesa County, Colorado. Compared with that in other Colorado counties, incidence, intensive care unit admissions, COVID-19 case fatality ratios, and the proportion of cases in fully vaccinated persons were significantly higher in Mesa County. Crude vaccine effectiveness against symptomatic infection was estimated to be 78% for Mesa County and 89% for other Colorado counties.

What are the implications for public health practice?

Vaccination is critical for preventing infection, serious illness, and death associated with SARS-CoV-2 infection (including the Delta variant). Multicomponent prevention strategies, such as masking in indoor settings irrespective of vaccination status as well as optimal surveillance testing and infection prevention and control, should be considered in areas of high incidence.

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Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥65 Years — COVID-NET, 13 States, February–April 2021

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Clinical trials of COVID-19 vaccines currently authorized for emergency use in the United States (Pfizer-BioNTech, Moderna, and Janssen [Johnson & Johnson]) indicate that these vaccines have high efficacy against symptomatic disease, including moderate to severe illness (*1*–*3*). In addition to clinical trials, real-world assessments of COVID-19 vaccine effectiveness are critical in guiding vaccine policy and building vaccine confidence, particularly among populations at higher risk for more severe illness from COVID-19, including older adults. To determine the real-world effectiveness of the three currently authorized COVID-19 vaccines among persons aged ≥65 years during February 1–April 30, 2021, data on 7,280 patients from the COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) were analyzed with vaccination coverage data from state immunization information systems (IISs) for the COVID-NET catchment area (approximately 4.8 million persons). Among adults aged 65–74 years, effectiveness of full vaccination in preventing COVID-19–associated hospitalization was 96% (95% confidence interval [CI] = 94%–98%) for Pfizer-BioNTech, 96% (95% CI = 95%–98%) for Moderna, and 84% (95% CI = 64%–93%) for Janssen vaccine products. Effectiveness of full vaccination in preventing COVID-19–associated hospitalization among adults aged ≥75 years was 91% (95% CI = 87%–94%) for Pfizer-BioNTech, 96% (95% CI = 93%–98%) for Moderna, and 85% (95% CI = 72%–92%) for Janssen vaccine products. COVID-19 vaccines currently authorized in the United States are highly effective in preventing COVID-19–associated hospitalizations in older adults. In light of real-world data demonstrating high effectiveness of COVID-19 vaccines among older adults, efforts to increase vaccination coverage in this age group are critical to reducing the risk for COVID-19–related hospitalization.

COVID-NET includes data on laboratory-confirmed COVID-19–associated hospitalizations in 99 U.S. counties in 14 states, representing approximately 10% of the U.S. population.[†] COVID-NET cases were hospitalizations that occurred in residents of a designated COVID-NET catchment area who were admitted within 14 days of a positive SARS-CoV-2 test result. COVID-NET program personnel collected information on COVID-19 vaccination status (vaccine product received, number of doses, and administration dates) from state IISs for all sampled COVID-NET cases.[§] Some sites expanded collection of information on vaccination status to all reported COVID-NET cases, not only sampled cases, which were included for analysis if all cases in a single month had vaccination status available. Data from 13 sites were included for analysis; one site (Iowa) does not have access to the state IIS and cannot collect vaccination data.[¶] Population-level vaccination coverage was determined using deidentified person-level COVID-19 vaccination data reported to CDC by jurisdictions, pharmacies, and federal entities through the

[*] These authors contributed equally to this report.

[†] https://www.medrxiv.org/content/10.1101/2021.04.21.21255473v1

[§] COVID-NET methodology and sampling scheme: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html

[¶] COVID-NET data included in this analysis were from the following states: California, Colorado, Connecticut, Georgia, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah.

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IISs,** Vaccine Administration Management System,†† or direct data submission.§§

The study was restricted to adults aged ≥65 years and included the period February 1–April 30, 2021. The Janssen vaccine was authorized for use during the study period beginning March 15, 2021.¶¶ Patients were classified as 1) unvaccinated (no IIS record of vaccination), 2) partially vaccinated (1 dose of Moderna or Pfizer-BioNTech received ≥14 days before hospitalization or 2 doses, with the second dose received <14 days before hospitalization), or 3) fully vaccinated (receipt of both doses of Moderna or Pfizer-BioNTech with second dose received ≥14 days before hospitalization or receipt of a single dose of Janssen ≥14 days before hospitalization). Patients with only 1 dose of any COVID-19 vaccine received <14 days before hospitalization were excluded. Daily county-level coverage data for adults aged 65–74 and ≥75 years in the COVID-NET catchment area were estimated using population denominators from the U.S. Census Bureau; vaccination status was classified as described for hospitalized cases.*** For vaccine records missing county of residence, county of vaccine administration was used.

To estimate vaccine effectiveness and corresponding 95% CIs, methods were adapted based on previously published literature (*4*). Poisson regression was used to compare case counts by vaccination status (outcome) and the proportion of the population vaccinated and unvaccinated (offset).††† Data were stratified by age group because of the potential for confounding by age, and adjusted for COVID-NET site, time (number of weeks since the start of the study period as a categorical covariate), and monthly site-specific sampling frequency.§§§ Vaccine effectiveness was calculated as one minus the exponent of the estimated coefficient of the exposure (vaccination status) variable. For estimating effectiveness of full vaccination, partially vaccinated persons were excluded; for estimating effectiveness of partial vaccination, fully vaccinated persons were excluded. Vaccine product–specific estimates excluded persons who had received other COVID-19 vaccines. To account for the interval between infection and hospitalization, sensitivity analyses were conducted using a reference date 1 week and 2 weeks before admission, rather than admission date, for classification of vaccination status for cases (i.e., adding 7 and 14 days, respectively between last vaccine dose and hospital admission date); the same adjustment was included for population vaccination coverage. Statistical analyses were conducted using SAS software (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶¶¶

During February 1–April 30, 2021, among 7,280 eligible COVID-NET patients, 5,451 (75%) were unvaccinated, 867 (12%) were partially vaccinated, and 394 (5%) were fully vaccinated; 568 (8%) who received a single vaccine dose <14 days before hospitalization were excluded from the analysis (Table). Vaccination coverage in the population increased rapidly during this period among persons aged ≥65 years and varied by age and vaccine product (Figure 1). Among adults aged ≥65 years in the COVID-NET catchment area, full vaccination coverage from any of the three authorized vaccines ranged from 0.7% on February 1, 2021, to 72% on April 30, 2021.

Effectiveness of full vaccination in preventing hospitalization among adults aged 65–74 years was estimated at 96% (95% CI = 94%–98%) for Pfizer-BioNTech, 96% (95% CI = 95%–98%) for Moderna, and 84% (95% CI = 64%–93%) for Janssen vaccine products. Among adults aged ≥75 years, effectiveness of full vaccination was 91% (95% CI = 87%–94%) for Pfizer-BioNTech, 96% (95% CI = 93%–98%) for Moderna, and 85% (95% CI = 72%–92%) for Janssen vaccine products (Figure 2). Effectiveness of partial vaccination among adults aged 65–74 years was 84% (95% CI = 76%–89%) for Pfizer-BioNTech and 91% (95% CI = 87%–93%) for Moderna vaccine products. Among those aged ≥75 years, effectiveness

** IISs are confidential, computerized, population-based systems that collect and consolidate vaccination data from providers in 64 public health jurisdictions nationwide and can be used to track administered vaccines and measure vaccination coverage. https://www.cdc.gov/vaccines/covid-19/reporting/overview/IT-systems.html

†† https://www.cdc.gov/vaccines/covid-19/reporting/vams/program-information.html

§§ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/about-vaccine-data.html

¶¶ Emergency Use Authorization (EUA) for the Janssen (Johnson & Johnson) vaccine was granted by the Food and Drug Administration on February 26, 2021. EUA was granted for the Pfizer-BioNTech vaccine on December 11, 2020, and for the Moderna vaccine on December 18, 2020.

*** https://www.cdc.gov/nchs/nvss/bridged_race.htm

††† Population vaccine effectiveness is defined as the reduction in disease risk among vaccinated versus unvaccinated persons in the population. Vaccine effectiveness is typically estimated by examining the proportion of persons with disease among those who are vaccinated and the proportion of persons with disease among those who are unvaccinated. If these numbers are difficult to measure or estimate and only case vaccination information is available, then an alternative approach, called the "screening method," uses estimates of 1) the proportion of persons with disease who are vaccinated and 2) the proportion of persons in the population who are vaccinated. This analysis applied a variation of the screening method through a Poisson regression model, which allows the estimates to account for potential confounding. Specifically, the Poisson regression model uses case counts (both vaccinated and unvaccinated) as the outcome, vaccination status as the exposure variable, and the logarithms of the proportion of vaccinated and unvaccinated persons in the population as offsets. The Poisson model includes the potential confounders time and COVID-NET site as fixed effects because vaccination coverage data are available in each time-by-site stratum. A generalized estimating equation approach with autoregressive correlation structure accommodated daily variations of disease rates and vaccine coverage because this study occurred during a time of very rapid change. Finally, the adjusted vaccine effectiveness estimate was calculated as 1 - exp(β), in which β is the regression coefficient of the vaccination status exposure variable.

§§§ Sampling weights were created based on the probability of selection. Weights were adjusted for nonresponse; adjusted to population catchment totals based on combinations of surveillance site, time period of admission, age, sex, and race/ethnicity via raking procedures; and trimmed to reduce variability.

¶¶¶ 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

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TABLE. Hospitalized COVID-19 patients aged ≥65 years, by vaccination status and age group (N = 6,712)* — COVID-NET,† 13 states, February 1 –April 30, 2021

Vaccination status§,¶	No. of cases, by age group (yrs)		
	65–74	≥75	Total (≥65)
All patients (any vaccination status)	3,306	3,406	**6,712**
Unvaccinated patients	2,869	2,582	**5,451**
Vaccinated patients, by vaccine product			
Pfizer-BioNTech			
Partially vaccinated	188	379	**567**
Fully vaccinated	73	185	**258**
Moderna			
Partially vaccinated	104	196	**300**
Fully vaccinated	56	56	**112**
Janssen (Johnson & Johnson)**			
Fully vaccinated	16	8	**24**

Abbreviation: COVID-NET = Coronavirus Disease 2019–Associated Hospitalization Surveillance Network.

* Among 7,280 eligible COVID-NET patients, 568 patients (251 aged 65–74 years and 317 aged ≥75 years) who received only 1 dose of any COVID-19 vaccine <14 days before hospitalization were excluded from analysis.

† COVID-NET data included in this analysis were from the following states: California, Colorado, Connecticut, Georgia, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah.

§ Partially vaccinated patients received 1 dose of Moderna or Pfizer-BioNTech vaccine ≥14 days before hospitalization or 2 doses, with the second dose received <14 days before hospitalization.

¶ Fully vaccinated patients received both doses of Moderna or Pfizer-BioNTech vaccine, with second dose received ≥14 days before hospitalization, or receipt of a single dose of Janssen (Johnson & Johnson) vaccine ≥14 days before hospitalization.

** The Janssen vaccine was authorized for use after the study began; cases were included during March 15–April 30, 2021.

of partial vaccination was 66% (95% CI = 48%–77%) for Pfizer-BioNTech and 82% (95% CI = 76%–86%) for Moderna vaccine products. Sensitivity analyses accounting for interval between infection and hospitalization did not yield notably different vaccine effectiveness estimates, with point estimates varying by <1% for Pfizer-BioNTech and Moderna vaccine models. Point estimates for Janssen COVID-19 vaccine models varied by <10%, with few cases eligible for inclusion and wide CIs.

Discussion

In this analysis of 7,280 laboratory-confirmed COVID-19–associated cases among hospitalized adults aged ≥65 years, all three COVID-19 vaccine products currently authorized for use in the United States had high effectiveness in preventing laboratory-confirmed COVID-19–associated hospitalizations. The effectiveness of full vaccination with mRNA vaccines (Pfizer BioNTech and Moderna) was ≥91% and of Janssen was ≥84% among adults aged ≥65 years. These findings are consistent with estimates from other observational studies of the mRNA vaccines and provide an early estimate of the effectiveness of Janssen in preventing COVID-19–associated hospitalization (*1*–*3*,*5*). Although the method used in this analysis does not account for many important potential confounders and results should be interpreted with caution, taken together, these findings provide additional evidence that available vaccines are highly effective in preventing COVID-19–associated hospitalizations and demonstrate that performance of COVID-19 vaccines can be assessed using existing disease surveillance and immunization data.

This analysis provides an early estimate of the Janssen vaccine effectiveness in preventing hospitalization in older adults, adding to the limited observational data available assessing Janssen vaccine effectiveness.**** These findings are consistent with clinical trial efficacy data, which found an efficacy of 76.7% for prevention of moderate to severe disease ≥14 days after vaccination (*3*). The relatively few cases and low population vaccination coverage with Janssen in this analysis likely contributed to the wide CIs for the vaccine effectiveness estimate. In addition, given vaccine prioritization for populations at high risk, older adults receiving the Janssen product were more likely to be at lower risk and differ substantially from those receiving products available earlier in the vaccine rollout. Other observational studies have demonstrated variability in the effectiveness of partial vaccination with mRNA vaccines in preventing hospitalization, with point estimates of effectiveness of 64% to 91% (*5*,*6*). Variation in estimates of effectiveness of partial vaccination between Pfizer-BioNTech and Moderna in this analysis might represent confounding from differences among the persons receiving these products. Residents of long-term care facilities (LTCFs) were prioritized early in the vaccine rollout and were more likely to receive Pfizer-BioNTech than Moderna.†††† The underlying risk for severe illness from COVID-19 in this medically fragile population could contribute to lower vaccine effectiveness among LTCF residents than among the general population of older adults and to an apparently lower effectiveness of Pfizer-BioNTech. Moreover, if partial protection increases between the third and fourth week after receipt of the first dose, it is possible that the timing of the second Pfizer-BioNTech and Moderna doses (21 and 28 days after the first dose, respectively) could affect the observed effectiveness of partial vaccination. Therefore, these results should not be interpreted as definitive evidence of a difference in the effectiveness of partial vaccination between the two mRNA vaccines, but rather as an indication that further evaluation is warranted.

**** https://www.medrxiv.org/content/10.1101/2021.04.27.21256193v1

†††† Among COVID-NET patients living in LTCFs, more residents received Pfizer-BioNTech vaccine than received Moderna vaccine, consistent with state distribution through the federal Pharmacy Partnership for Long-Term Care Program. https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships-faqs.html

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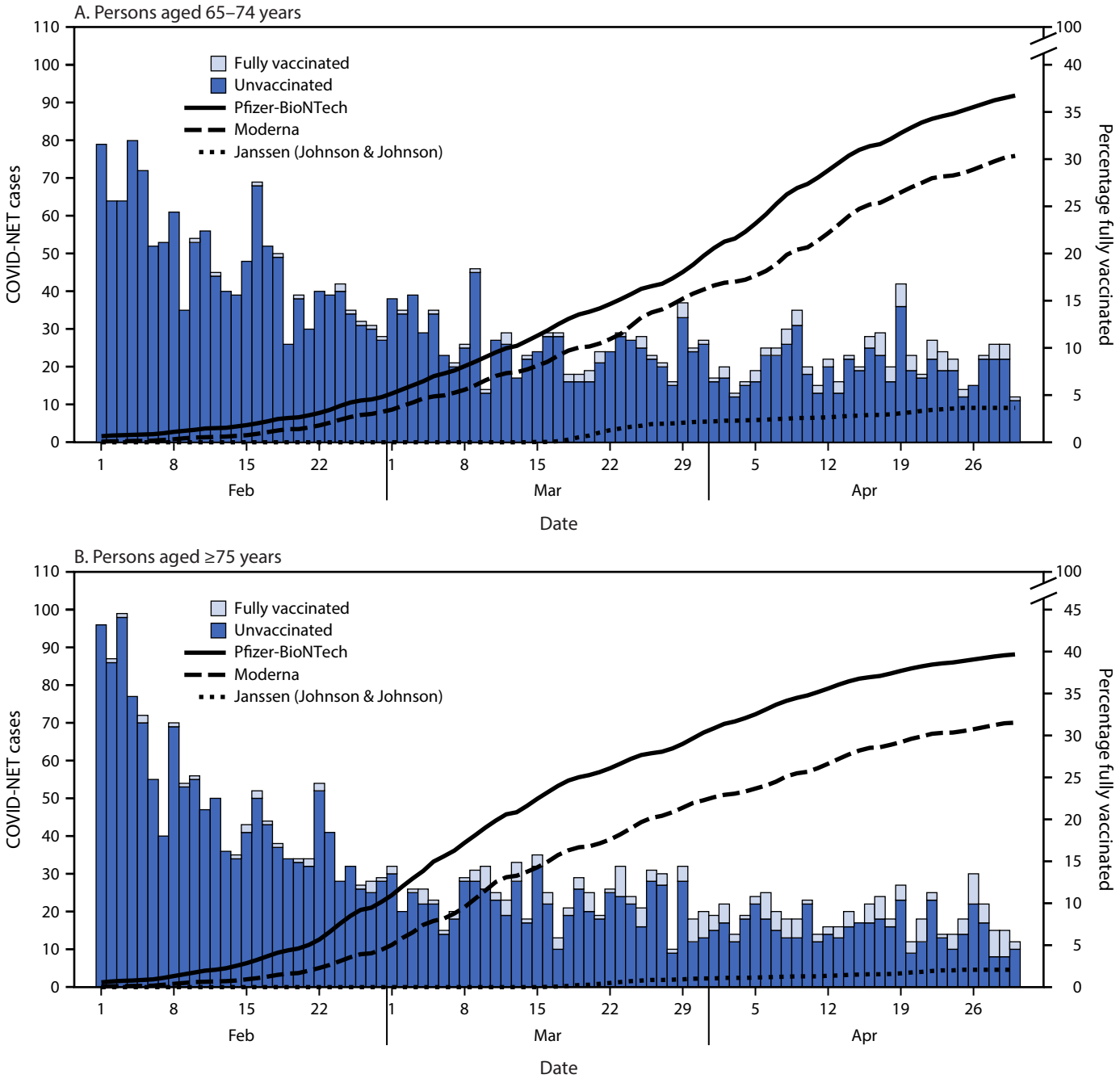
FIGURE 1. COVID-NET* cases and full vaccination coverage among persons aged 65–74 years (A) and persons aged ≥75 years (B) — 13 states, February 1–April 30, 2021



Abbreviation: COVID-NET = Coronavirus Disease 2019–Associated Hospitalization Surveillance Network.
* COVID-NET data included in this analysis were from the following states: California, Colorado, Connecticut, Georgia, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah.

The findings in this report are subject to at least four limitations. First, although adjustments were made for time and site, the analysis did not adjust for other potential confounders, such as chronic conditions, because person-level data were not available for the catchment population. In addition, although the analysis was stratified by age and adjusted for time and site, the heterogeneity of disease risk, vaccination coverage within each site, and differences in the populations who received different vaccine products might confound estimates of vaccine effectiveness. Second, the study period for this analysis

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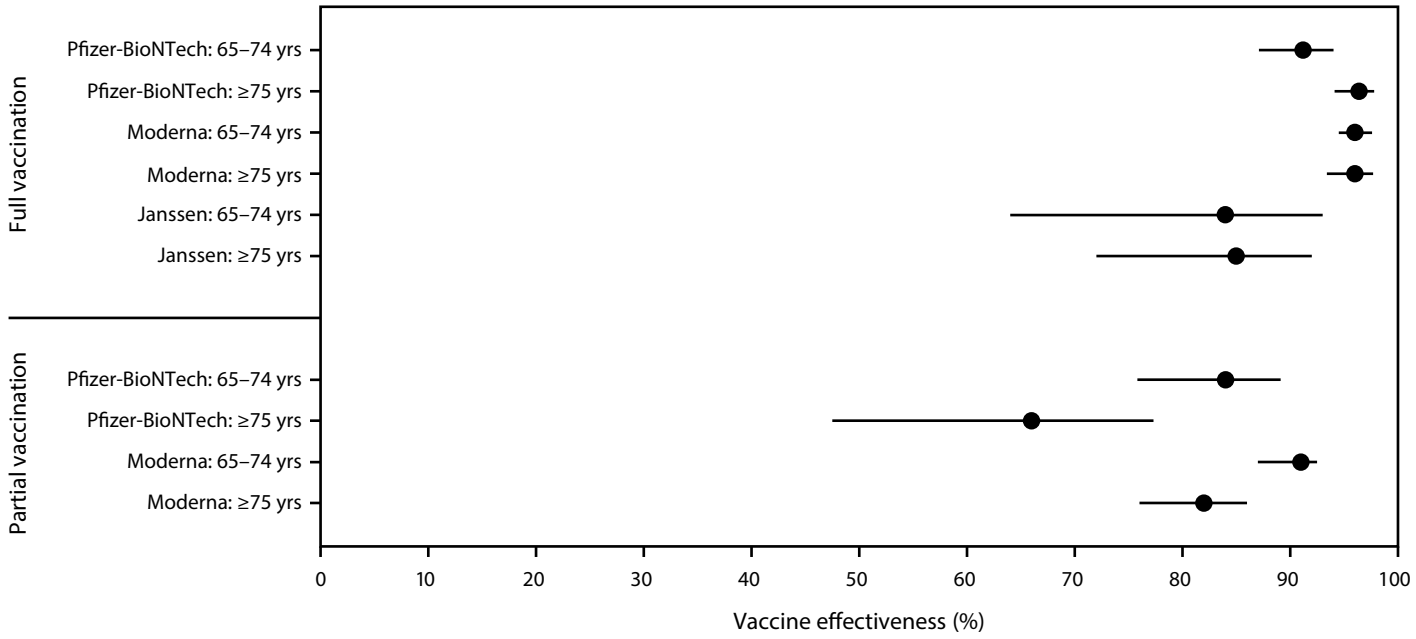
FIGURE 2. Estimates of vaccine effectiveness in preventing COVID-19–associated hospitalization among patients aged ≥65 years for the COVID-NET catchment area, by vaccine product and age group using the screening method — COVID-NET, 13 states,* February 1–April 30, 2021†



Abbreviation: COVID-NET = Coronavirus Disease 2019–Associated Hospitalization Surveillance Network; Janssen = Janssen (Johnson & Johnson).
* COVID-NET data included in this analysis were from the following states: California, Colorado, Connecticut, Georgia, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah.
† Confidence intervals indicated by error bars.

Summary

What is already known about this topic?

Clinical trials of COVID-19 vaccines currently authorized for emergency use in the United States (Pfizer-BioNTech, Moderna, and Janssen [Johnson & Johnson]) have shown high efficacy in preventing symptomatic (including moderate to severe) COVID-19.

What is added by this report?

Among adults aged 65–74 years, effectiveness of full vaccination for preventing hospitalization was 96% for Pfizer-BioNTech, 96% for Moderna, and 84% for Janssen COVID-19 vaccines; among adults aged ≥75 years, effectiveness of full vaccination for preventing hospitalization was 91% for Pfizer-BioNTech, 96% for Moderna, and 85% for Janssen COVID-19 vaccines.

What are the implications for public health practice?

Efforts to increase vaccination coverage are critical to reducing the risk for COVID-19–related hospitalization, particularly in older adults.

occurred before the predominance of the B.1.617.2 (Delta) variant; changes in circulating SARS-CoV-2 variants might affect vaccine effectiveness when assessed over time. Third, persons choosing to receive vaccine later in the rollout might have different risk characteristics than do those vaccinated earlier and might have experienced differences in access to vaccine products by time and location. Finally, this analysis was limited to adults aged ≥65 years, and the results are not generalizable to younger age groups.

This analysis found that all COVID-19 vaccines currently authorized in the United States are highly effective in preventing COVID-19–associated hospitalizations in older adults and also demonstrates the utility of this method in generating a relatively rapid assessment of vaccine performance in the setting of high-quality surveillance and vaccine registry data. Efforts to increase vaccination coverage are critical to reducing the risk for COVID-19–related hospitalization, particularly in older adults.

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Detection & Mitigation of COVID-19 in Confinement Facilities

Thursday, August 5, 2021

Welcome	Angelica O'Connor, ELC
Background	Ruby Qazilbash, Department of Justice
Purpose	
Required & optional activities	
Technical assistance	
Reporting requirements	Dr. Jason Snow, ELC
Grants management	
Questions	

Welcome

Angelica O'Connor

ELC Program Coordinator

Detection & Mitigation of COVID-19 in Confinement Facilities

Ruby Qazilbash

Associate Deputy Director, Bureau of Justice Assistance, U.S. Department of Justice

Background

- $700M made available through *American Rescue Plan Act of 2021*
- Project period: August 1, 2021 – July 31, 2024 (36 months)
- All 64 ELC recipients to respond to COVID-19 in confinement facilities*
  - *Defined as adult prisons and jails; juvenile confinement facilities; police lock-ups; and community confinement facilities
- Award formula = $\frac{\text{recipient's incarcerated population}}{\text{total national incarcerated population}}$

Purpose

- From March to June 2020, 11% of COVID tests in jails were positive
- By December 2020, state & federal prisoners' COVID positivity rate was four times higher than the general population
- As facilities now open for visitors and service/care providers, mitigation of new transmission of COVID must be addressed

Required Activity

1. Assist confinement facilities in establishing and implementing COVID diagnostic and screening testing programs for residents / detainees / inmates, staff, and visitors

Optional Activities

- Conduct COVID-19 testing and contact tracing within confinement facilities.
- Support facilities in planning and implementing recommended isolation and quarantine strategies including for confirmed and suspected cases and close contacts.
- Implement distancing policies and support staff training to maintain distancing practices.
- Support staffing strategies that reduce the risk of virus transmission (e.g., organize staff assignments so that the same staff are assigned to the same areas of the facility over time).
- Support transportation policies and practices consistent with recommendations to reduce transmission.
- Implement visitor policies consistent with recommendations to reduce virus risk.
- Implementation of infection control practices inside facilities.
- Develop and implement procedures and systems to improve confinement facility preparedness and response efforts.
- Coordinate preparedness and response efforts with state, local, tribal, and territorial public health departments to prevent, prepare for, and respond to COVID-19 within confinement facilities.
- Enhance/improve the practices of confinement facilities to mitigate the spread of COVID-19, and to reduce the risk of virus transmission and exposure to environmental health hazards.

Optional Activities (continued)

- Purchase of additional supplies to sanitize and clean the confinement facilities. Funding must not supplant existing expenditures on such supplies and can only be used to support enhanced cleaning efforts.

- Educate and train confinement facility staff and residents/detainees/inmates on sanitation and minimizing the spread of infectious diseases.

- Implement COVID-19 mitigation practices to minimize potential opportunities for exposure including video conferencing technology and other measures for attorney/client purposes, court appearances, family visiting, and programming.

- Based on state and local laws and regulations, and training and technical assistance provided by the DOJ, review and analyze policies and practices and implement policy and practice changes to safely reduce populations in confinement facilities to mitigate the spread of COVID-19. This could include creating policies and practices that may divert individuals from confinement, determine the optimal population for the facility given physical plant/structure and public health guidelines, and the revision of appropriate release practices. The DOJ will make training and technical assistance available to grantees to help ensure these activities comport with state and local laws and evidence-based practices and are administered solely by state and local correctional agencies.

Technical Assistance

- CDC guidance on the Management of COVID-19 in Correctional and Detention Facilities
- ELC as a source of regular program management and oversight support
- Bureau of Justice Assistance as a source of support with:
  - Technical assistance during workplan development, upon request
  - Workplans and budgets review alongside ELC team
  - Technical assistance during implementation, upon request
  - BJA hiring designated term position to assist recipients and their health departments

Detection & Mitigation of COVID-19 in Confinement Facilities

Jason Snow

Program Manager, ELC Cooperative Agreement

Allowable Costs (See guidance for full listing)

- Personnel (term, temporary, students, overtime, consultant and/or contract staff, etc.) related to testing and mitigation efforts.
- Laboratory equipment used for COVID-19 testing and necessary maintenance contracts.
- Collection supplies, test kits, reagents, consumables, and other necessary supplies for existing or new screening testing or onboarding new platforms to support testing.
- Personal Protective Equipment (PPE) (e.g., masks, gloves, gowns) for those collecting samples and/or conducting testing.
- Hardware and software necessary for reporting to public health and communication and coordination of follow up on any positive cases detected.
- Testing & mitigation effort outreach expenses
- Resident, inmate, or detainee needs resulting from COVID-19-related restricted access to and/or limited mobility within the facility
  - Includes communication access to/by family, legal representation, & service providers

Grants Management - Budget

- Funds will be awarded
  - In the *Project E: Emerging Issues* tab of the ELC budget workbook
  - On line 'E.1_O1' in the 'Other' cost category section

- At time of NOA issuance, funds will be accessible in the Payment Management System (PMS) and can be used, in accordance with guidance, during the 90-day period for preparing the workplan & budget.

Grants Management – Budget (continued)

- Within 90 days of receiving the NOA, submit your 'Budget Revision Amendment' in GrantSolutions. Your Amendment must include:
  - Revised budget using the ELC budget workbook that was provided in GrantSolutions as a Grant Note
  - Budget Information SF-424A using the form generated by ELC budget workbook or a PDF – **not the e-form in GrantSolutions**
  - Cover letter signed by the Authorized Official of record

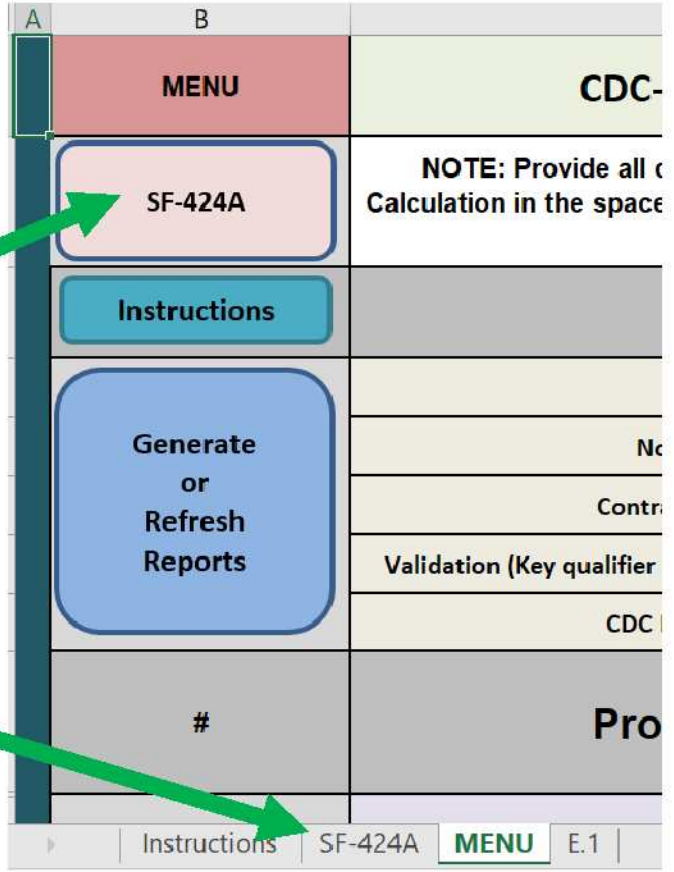
- If a recipient does not have written approval for an extension from CDC and misses the 90-day deadline for workplan and revised budget submission, their PMS account **may be restricted**.

Reminder - SF-424A

- Do not use the hyperlink for the SF-424A in GrantSolutions as it creates issues for award processing.

- ELC budget workbook
  1. Use the 'SF-424A' button on the 'Menu' page to generate.
  2. Go to the 'SF-424A' tab.
  3. Print the tab as a PDF.
  4. Upload in GrantSolutions under the 'SF-424A' in the amendment submission section.

Note: clicking the 'refresh and generate reports' button in Excel will create reports of *all* worksheets. Follow steps 1-4 here to generate a report for *only* this budget worksheet.



Grants Management - Workplan

- Within 90 days of receiving the NOA, submit your workplan into REDCap's 'Detection & Mitigation of COVID-19 in Confinement Facilities' portal.

- A letter signed by all ELC Governance Team members indicating that they have each contributed to and agreed upon the workplan *and* revised budget must be submitted in REDCap.

- Reminder: 1 required activity and up to 14 optional activities

Reporting Requirements

Authorized Official's signed Acknowledgement of Guidance letter through a GrantSolutions Grant Note	Due 5 days after NOA is received
Financial reporting	Due the 5th of each month, starting October 5th
Any applicable performance measures	TBD
Workplan, revised budget, & agreement letter signed by all ELC Governance Team members	Due 90 days after NOA is received, likely mid-November
Quarterly workplan/milestone progress reporting	Due quarterly, starting January 31st

Questions & Answers

Webinar recording and slides will be sent tomorrow, August 6th

Weekly Office Hours

To address recipients' questions and provide regular technical assistance, the DOJ and ELC will cohost weekly Office Hours.

Office hours will be held each Thursday, 4:00-5:00pm ET, August 26 through Thursday, September 23.

A recurring calendar invitation to these optional Office Hours will be sent from the ELC mailbox. Please not these Office Hours are intended for ELC recipients only.

Detection & Mitigation of COVID-19 in Confinement Facilities

Webinar Q&A Summary

If you'd like to listen to our full Q&A session, it begins at the 23-minute mark of the webinar recording.

The ELC will be providing funding directly to its 64 recipients. These recipients (i.e., state, large local, and territorial and freely associated state health departments) will then develop workplans and budgets that address the needs of their own jurisdictions' state, tribal, or locality's correctional and confinement facility's needs. Federal confinement facilities are not eligible to receive financial or programmatic support under this supplement.

The project period is August 1, 2021 – July 31, 2024. 85% of the total funding a recipient receives must go towards direct financial support for COVID-19 detection & mitigation efforts in confinement facilities (defined as any of these facilities), which also includes staffing to support supplement activities whether in the health department or confinement facility. 15% of the total funding a recipient receives must go towards expenses associated with reporting, managing, and other associated costs in launching and maintaining efforts under this supplement.

It is each ELC recipient's discretion how they prioritize selecting, distributing funding, and engaging with specific stakeholders (including state associations of counties, departments of corrections, state sheriff's associations, etc.); confinement facilities (defined as any of these facilities), and populations; the guidance does require, however, that recipients strive to support the largest extent of eligible confinement facilities as possible in their jurisdiction. The Department of Justice is available to provide technical assistance and support as recipients make these decisions.

Examples of costs that would be **in scope** for this award,
as asked about during the webinar:

- Hiring of infection prevention coordinators within confinement facilities
- Gloves, masks, gowns, and other PPE for those collecting samples/conducting testing
- Financial support to organizations that provide guidance and oversight to county detention facilities,
- Personnel to conduct testing or collect samples
- Ventilation upgrades that support the mitigation and prevention of COVID in confinement facilities
- Interoperable data systems for surveillance of testing efforts
- Telehealth systems to mitigate restricted access to and/or limited mobility within facilities, including communication access to/by family, legal representation, & service providers

Examples of costs that would be **out of scope** for this award,
as asked about during the webinar:

- Sick leave and/or personal time off required of confinement facility staff after exposure to a suspected or confirmed COVID case
- Direct incentives (e.g., monetary gift) to increase testing in confinement facilities
- Any costs to support isolation and/or quarantine of staff and/or residents of confinement facilities (including but not limited to food, paid leave, bill payment, medical supplies, etc.)
- Anti-human trafficking efforts, including but not limited to safe houses
- Clinical services of any kind, including administering vaccines and providing medical care

Additional examples of allowable costs can be found in the supplement's guidance. Where activities or costs overlap with other existing ELC supplements, workplans and budgets must clearly state how they are not duplicative (e.g., if including whole genome sequencing under this supplement, the recipient must provide evidence of how this does not duplicate *ELC AMD Sequencing and Analytics* activities). Spending can begin as soon as NOAs are granted.

Please contact your ELC Project Officer, the ELC mailbox (elc@cdc.gov) with any questions, concerns, or requests for technical assistance from the Department of Justice.

DETECTION AND MITIGATION OF COVID-19 IN CONFINEMENT FACILITIES
WEBINAR TRANSCRIPT

Cameron Warner: Today, we will be discussing the newest supplemental award administered through the ELC, Detection and Mitigation of COVID-19 in Confinement Facilities. This effort really represents a partnership between HHS and the Department of Justice that we hope will provide much needed support to confinement facilities. I want to thank our colleague and SMEs from the Department of Justice that are on the line for joining in particular Ruby Qazilbash. She's been a great partner to work with already.

Cameron Warner: I'll turn things over to her to cover the background and purpose of the funding and the activities and technical assistance. Then she'll turn it over to Jason for reporting requirements and grants management. Of course, we will also have time at the end for questions. Without further ado, here's Ruby.

Ruby Qazilbash: Thanks so much Cameron and Angelica. Good afternoon everyone Thank you so much for joining us. Today, perhaps you're joining today, or perhaps you're listening or watching a recording afterwards day today, which is Thursday August 5.

Ruby Qazilbash: It was recently announced, and why you're tuning in, by the White House that CDC is making $700 million available through the American Rescue Plan Act. And this is to respond specifically to the disproportionate impact of on the nation's confinement facilities. These funds are awarded, as you know, to the 64 current ELC cooperative agreement recipients. For those on today's webinar - or listening after the fact, who are not current recipients - ELC is the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases Program. At the CDC the 64 current ELC cooperative agreement recipients are the public health authorities in the states, the territories, District of Columbia, and the eight most populous U.S. local jurisdictions. And important to note that the formula for determining the allocation for these funds per recipient was determined by the recipient share of the total national custodial or incarcerated population.

Ruby Qazilbash: And then, with regard to confinement facilities, how are we defining them or what do we rely on? The guidance sites title 28 section 115.5 for the definition of confinement facilities and it includes adult prisons and jails, juvenile confinement facilities, police lockups, and community confinement facilities. But the guidance also really importantly outlines that state recipients must support units of local government within their jurisdiction to reach the fullest complement of confinement facilities within the state. In order to do that, cooperative agreement recipients of these funds will need to determine the best strategy. We hope to provide support for that. As we see it, this could include the recipient partnering with their public safety authority or state administering agencies - those are designated by the nation's governors and the states and territories; a component of the governor's or the mayor's office; a freestanding criminal justice planning entity; or a division of the state’s department of public safety. At the local level, criminal justice coordinating Councils might be the appropriate or an appropriate partnering authority.

Ruby Qazilbash: We really want to get up the purpose, and I'd like to say, on behalf of the Department of Justice, and specifically the Bureau of justice assistance, that we're really honored to be a partner of the ELC program at the CDC on this effort. We have seen the disproportionate impact of COVID on the nation's confinement facilities. From March to June of 2020, 11% of covert tests in jails were positive. By December of 2020, state and federal prisoners’ COVID positivity rate was four times higher than that of the general US population. Detainees -- residences of confinement facilities have been heavily impacted, our public safety staff who work in confinement facilities have been heavily impacted. These are congregate settings that we're talking about. Most of them, jails, prisons, community confinement facilities, juvenile detention facilities, these are 24-hour environments, with people living in them and people working all three shifts to staff them. As COVID entered and moved through facilities, leadership and staff implemented protocols, including testing upon booking, quarantining prior to entry into the general facility population, separating individuals that tested positive.

Ruby Qazilbash: Many facilities that didn't already have strong partnerships with public health authorities learned to work together pretty quickly to test, to track, to report, to coordinate vaccine distribution when vaccines became available… All working to keep people safe. There was immense impact on the daily operations of these facilities, both for people living in them, and certainly for people working in them. For many, there was a stop to a lot of things - to visitors, in-person programming, in-person court appearances. For many, there was extreme limitation on movement within facilities to keep people safe. So as facilities are now beginning to open back up again to visitors, to service and care providers, mitigation of new transmission of COVID has really got to be addressed and that is what the intention is of this funding.

Ruby Qazilbash: It's really important to note that, under this guidance, there is one required activity and 14 optional activities that are outlined within the guidance. All activities pertain to COVID-19 detection and mitigation. The funds do not support vaccinations or clinical care. The, as listed here, the required activity is to assist confinement facilities in establishing and implementing COVID diagnostic and screening testing programs for the people who live, work, and visit these facilities.

Ruby Qazilbash: The first set of optional activities include conducting COVID-19 testing and contact tracing, supporting facilities in planning and implementing recommended isolation and quarantine strategies, implementing distancing policies and training staff on them, supporting staffing transportation and visiting strategies that reduce the risk of virus transmission, implementation of infection control practices inside the facilities and coordinating those preparedness and response efforts with the relevant state, local, tribal, or territorial public health departments, and enhancing and improving the practices of confinement facilities to mitigate the spread of COVID. There are other optional activities that really have more to do with mitigation, I would say: purchase of additional supplies around sanitizing and cleaning, educating and training staff - as well as residents/detainees -on sanitation. We're interested to see the plans that you all come up with, but some ideas that we've listed here are ways that you can implement mitigation practices to minimize potential opportunities for exposure. That could mean implementation of technology to make things that need to happen able to happen, such as measures for attorney client purposes for court appearances, to facilitate family and other visiting, as well as programming, that's really taken a hit during the lockdown and facilities. Lastly here, importantly, recommendations from the national academies of sciences special report: jurisdictions can implement mitigation strategies that reduce the size of the population in custody and part as a way to achieve greater physical distance between individuals within facilities. And this can include creating and implementing policies and practices that may divert people from confinement, to determine and take strategies to determine the optimal population for the facility given its particular physical plant or structure and the current public health guidelines locally, and then revising release practices to achieve a reduction in the number of people confined within those facilities. It's important to know that this last option will obviously need to take state and local laws and regulations into account.

Ruby Qazilbash: With regard to technical assistance, we want to make a distinction of where and from whom recipients and sub recipients will and can receive it. So, as these are CDC awards, ELC will continue as the source or regular program management and oversight, so including compliance with terms and conditions, the award fiscal performance, and programmatic oversight. The Bureau of Justice Assistance is for the provision of technical assistance: to do things like help inform partnerships to ensure that the funds get to the confinement facilities that they're intended to reach as expeditiously as possible. We'll also review work plans and budgets, alongside the ELC team, and will provide ongoing technical assistance during implementation. I'm going to pass the baton to Dr. Jason Snow, who's going to review those allowable costs and then other aspects of grants management for these awards.

Jason Snow: Thank you very much. Ruby. Good afternoon, this is Jason Snow. I'm the ELC Program Manager. The ELC, in coordination with our colleagues in the Office of Grants Services, are completing a process this week of finalizing our End of Year - also referred to EOY - notice of awards. Awards have already started going out today, and they will continue on a rolling basis through the first part of next week. As in prior

years, our End of Year awards are made up using fallout funds from various programs and projects under the ELC, to augment funds that were previously provided in the last month in the budget period three funding. Part of the end of your awards this year consist of special COVID funds to support two different projects. The first project is this one, the Detection and Mitigation of COVID-19 in Confinement Facilities award. The second project that you will find in your budget is going to be the Accelerating Data Modernization in Jurisdictions award, which was issued under the project C2 Data Modernization tab of the ELC budget workbook. There's a separate webinar scheduled for next Wednesday August 11 at 3pm which will cover that particular award in more detail.

Jason Snow: In the guidance document on pages two and three, you will find a listing of allowable costs. This slide contains some, but not all, the costs listed in the guidance. As you develop your work plan and budget, common allowable costs would likely include hiring staff or supporting the reallocation of existing staff to conduct testing and or overseeing mitigation efforts. For mitigation efforts, please ensure the details are included in the work plan and in the budget justification section. This is a broad category and not all possible mitigation strategies might be within scope for this particular award. Laboratory equipment is another likely cost to include in the budget. However, if a similar piece of equipment was included in a prior ELC budget, such as in enhancing detection and enhancing detection expansion, or the recently awarded reopening schools award, please indicate in the budget justification for this award how the lab equipment request differs and does not duplicate from prior requests. With the hardware and software necessary for reporting positive cases to public health and related follow up. Please keep in mind that a strong budget justification in this area would incorporate how these lab systems and health information system enhancements will assess, not only for the immediate COVID response, but for ongoing public health surveillance. Additionally, details around how these systems would ensure capture and transmission of key data elements such as race and ethnicity, are important to include. Similar to the comment made about staffing for costs around testing and mitigation outreach expenses, please specify the mitigation efforts that will be addressed when completing the budget justification for these associated costs. Included in the outreach category could be items such as health communications and educational efforts that are tailored for residence inmates, detainees, correctional officers, other facility staff, as well as family members and other visitors. The last item on this list pertains to residents and maintaining needs resulting from restricted access due to COVID-19. Should questions arise around possible associated costs, please feel free to reach out to your ELC project officer, who can connect you to the appropriate DOJ subject matter expert as well as for determination if the request would be in scope.

Jason Snow: For the Detection and Mitigation of COVID-19 in Confinement Facilities award, you will find the awarded amount under your project the emerging issues tab in the ELC budget workbook. When the end of year notices of awards are issued and released, your ELC project officer will release the associated grant note in GrantSolutions. It will be in this grant note that you will find your budget workbook, which is an excel file, along with the ELC funding spreadsheet, which shows the various sources across categories that are pertinent to the end of year funding. Once the award is released and issued, the entirety of this award will be made available to the recipients in the payment management system for immediate use. As with prior ELC awards, please note that funds must be used in accordance with the guidance. Any questions about if a cost is within scope should be directed to your ELC project officer to ensure that funds are being used appropriately and will not end up having to be paid back from non-federal sources at a later date.

Jason Snow: On July 27, CDC published the guidance for this award in GrantSolutions as a grant note. We also sent out an email the week prior on July 22 that provided recipients with advanced copy of this guidance. The guidance can also be found on our website under the resources section and then look under the ELC COVID-19 supplemental words guidance section. On both the cover page and page with the section header background and purpose, you will find a reminder that this award can be found under your project E emerging issues on the ELC budget workbook. It will be on the same tab that you will need to complete your budget for revision. Within 90 days from the time the recipient receives the notice of award, you work plan and budget must be completed and submitted to CDC. To submit budget revisions, you will do so through the budget revision amendment option in GrantSolutions. As part of the budget revision amendment, please include your ELC budget workbook in the original excel format. Please do not submit a word, PDF, or budget that does not

utilize the ELC budget workbook that was provided in a grant note at time of award. Doing so will result in the action being returned. Also, when completing the budget revision, do not use the hyperlink in grant solutions to create a SF424-a online. Doing so creates issues on the CDC side when processing or revise notice of award. ELC budget workbooks will generate the SF424a PDF once the budget has been completed.

Jason Snow: This is a screenshot of the menu tab on an ELC budget workbook. Once the budget has been completed and you've checked the summary table at the bottom to ensure that your requested total matches your approved total - which comes from the original award line of E 101, go to your menu. In the upper left you will find the SF424a button. Select this, and the budget workbook will take all the requested line items and generate the SF424a for you. Next, go to the SF424a tab which could be found at the bottom of the workbook, just left of the menu tab. On the SF424a tab, you can print a PDF to create the file that will be needed to upload into GrantSolutions as part of your budget revision amendment.

Jason Snow: Within 90-days, recipients are going to need to go into REDCap and complete the workplan. As Ruby mentioned previously, there is one required activity, which is to assist facilities in establishing and implementing diagnostic and screening testing programs for residents, detainees, staff, and visitors. In cases where this activity has already been addressed, recipients would simply need to note in the workplan, using the implementation plan section, providing the details on how this has been addressed to date and the plans for continued support through the project period. The remaining 14 activities are optional and should be addressed as needed and appropriate to meet the needs within the recipient's jurisdiction. By the 90-day response window, recipients will need to submit a budget revision into GrantSolutions that includes a completed ELC budget workbook in the original excel format, a PDF of the workplan - which could be printed off from REDCap once completed - and a letter of support that is signed by the ELC governance team members. And please remember this letter needs to be on agency letterhead.

Jason Snow: This slide provides a summary of the various due dates for this award. The acknowledgement letter must be signed by the authorizing official on record in GrantSolutions. It must be submitted in GrantSolutions as a grant and within five days of the notice of award being issued. As of today, actually right before this webinar, I have already seen numerous grant notices come through that have either followed the early release of the guidance, by way of the ELC mailbox, or after OGS published the guidance in GrantSolutions on July 27. If you've already submitted the letter when the notice of award was officially issued and released to you, you do not need to resubmit. Those proactive early submissions will still meet the five-day requirement. Financial Reporting on this award will start October 5 and will continue monthly. As with prior ELC COVID awards monthly reporting is required until all funds are extended. Workplan completion in REDCap and budget completion in the ELC budget workbook - that will be available in GrantSolutions as a grant note after the award is issued – are both due within 90 days from the issuance of the award. Please remember to make your workplan, ELC governance team letter, and the completed ELC budget workbook in the original excel format, as a budget revision amendment in GrantSolutions. The performance measures for this award are still being discussed and developed. When we finalize this information, any reporting requirements will be shared with recipients. Quarterly workplan monitoring will begin and align with the ELC budget period three, quarterly reporting cycle, which is January 2022. And if I recall correctly, the next slide opens up our question-and-answer portion.

Cameron Warner: As Jason mentioned, if we're unable to answer your question today or questions arise as you complete your work plan and revised budget, the ELC and Department of Justice will be hosting weekly office hours beginning August 26 at 4pm. The office hours will be held every Thursday through September 23 and are intended for direct recipients of ELC funds. With that being said, again, please feel free to use the chat or the Q&A boxes for questions.

[Q&A Period]

Jason Snow: I want to thank everyone for your attendance, for wonderful questions. I especially want to thank Ruby and her collaboration and partnership in both helping get this award made possible, and then also the ongoing continued support as we continue over the next three years, making sure these funds reach the intended population and serve our public health interest in the confinement facilities. Thank you very much, have a wonderful rest of the day and we'll be in touch soon.

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Dec. 30 (incl. MMWRs, HHS Therapeutics Update, CDC All STLT Call, and more)
Date:	Thursday, December 30, 2021 2:09:35 PM
Attachments:	image001.png image002.png UPDATE HHS Allocation of bam ete and REGEN-COV therapeutics.pdf MMWR Weekly - December 29 2021.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- MMWR – Vol. 70, No. 51-52 [Links, Attachment]
  - The **December 31** edition of CDC's Morbidity and Mortality Weekly Report (MMWR) includes the following COVID-related articles:
    - COVID-19 Vaccine Safety in Children Aged 5–11 Years — United States, November 3–December 19, 2021
    - Interim Estimate of Vaccine Effectiveness of BNT162b2 (Pfizer-BioNTech) Vaccine in Preventing SARS-CoV-2 Infection Among Adolescents Aged 12–17 Years — Arizona, July–December 2021
    - Characteristics and Clinical Outcomes of Children and Adolescents Aged <18 Years Hospitalized with COVID-19 — Six Hospitals, United States, July–August 2021
    - Evaluation of a Test-To-Stay Strategy in Transitional Kindergarten Through Grade 12 Schools — Los Angeles County, California, August 16–October 31, 2021
    - Evaluation of Test-To-Stay Strategy on Secondary and Tertiary Transmission of SARS-CoV-2 in K–12 Schools — Lake County, Illinois, August 9–October 29, 2021
    - Investigation of a SARS-CoV-2 B.1.1.529 (Omicron) Variant Cluster — Nebraska, November–December 2021
- HHS Update: Allocation of bam/ete and REGEN-COV therapeutics [Link, Attachment]
  - Yesterday, **December 29**, the U.S. Department of Health and Human Services (HHS) announced a pause in allocations of bamlanivimab/etesevimab and REGEN-COV COVID-

19 therapeutics to states or territories within regions of the country that have greater than 80% prevalence of the Omicron variant based on CDC NOWCAST data. The purpose of this pause is to ensure effective product is available in most sites.
    - Please see attached for the full update. You may email COVID19Therapeutics@HHS.gov with questions regarding the allocation of bam/ete and REGEN-COV.
- Reminder: CDC All-STLT Update Call Series – Register for 2022 Calls Before 1/3/22 [Link]
    - On **January 3, 2022**, CDC's weekly COVID-19 All-STLT Update call will be moving to a new Zoom link. Before that date, please register here to ensure your access to the 2022 call series. Please note that your unique participant link will be the same for all calls in the series through December 2022; you do not need to register for each individual call. Calls will be held on Mondays from 2:00–2:45 pm ET (unless otherwise notified).
    - Call registrants will also be added to CDC's partner update distribution list. Partner update emails are disseminated every Monday, Wednesday, and Friday afternoon, and are the same updates included below in our "Standing Updates" section.
- Lights, Camera, Action: The Future of Public Health Summit Series – Summit #2 [Link]
    - The CDC Foundation and other public health agencies are hosting a four-part virtual summit to advance recommendations for a modernized U.S. public health system. Registration is now open for the second summit, *Creating an Interoperable and Modern Data and Technology Infrastructure,* occurring on **January 25, 2022 at 11:00 am EST**. Speakers will include CDC's Deputy Director for Public Health Science and Surveillance, Dr. Daniel Jernigan, HHS's National Coordinator for Health Information Technology, Dr. Micky Tripathi and other prominent leaders in the field. Learn more and register for the Summit here.

Standing Updates

- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
    - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
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Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 70 / No. 51-52
December 31, 2021

COVID-19 Vaccine Safety in Children Aged 5–11 Years — United States, November 3–December 19, 2021

Anne M. Hause, PhD[1]; James Baggs, PhD[1]; Paige Marquez, MSPH[1]; Tanya R. Myers, PhD[1]; Julianne Gee, MPH[1]; John R. Su, MD, PhD[1]; Bicheng Zhang, MS[1]; Deborah Thompson, MD[2]; Tom T. Shimabukuro, MD[1]; David K. Shay, MD[1]

On October 29, 2021, the Food and Drug Administration (FDA) amended the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 (BNT162b2) mRNA vaccine to expand its use to children aged 5–11 years, administered as 2 doses (10 µg, 0.2mL each) 3 weeks apart (*1*). As of December 19, 2021, only the Pfizer-BioNTech COVID-19 vaccine is authorized for administration to children aged 5–17 years (*2*,*3*). In preauthorization clinical trials, Pfizer-BioNTech COVID-19 vaccine was administered to 3,109 children aged 5–11 years; most adverse events were mild to moderate, and no serious adverse events related to vaccination were reported (*4*). To further characterize safety of the vaccine in children aged 5–11 years, CDC reviewed adverse events after receipt of Pfizer-BioNTech COVID-19 vaccine reported to the Vaccine Adverse Event Reporting System (VAERS), a passive vaccine safety surveillance system co-managed by CDC and FDA, and adverse events and health impact assessments reported to v-safe, a voluntary smartphone-based safety surveillance system for adverse events after COVID-19 vaccination,* during November 3–December 19, 2021. Approximately 8.7 million doses of Pfizer-BioNTech COVID-19 vaccine were administered to children aged 5–11 years† during this period; VAERS received 4,249 reports of adverse events after vaccination with Pfizer-BioNTech COVID-19 vaccine in this age group, 4,149 (97.6%) of which were not serious. Approximately 42,504 children aged 5–11 years were enrolled in v-safe after vaccination with Pfizer-BioNTech COVID-19 vaccine; after dose 2, a total of 17,180 (57.5%) local and 12,223 systemic (40.9%) reactions (including injection-site pain, fatigue, or headache) were reported. The preliminary safety findings are similar to those from preauthorization clinical trials (*4*,*5*). The Advisory Committee on Immunization Practices (ACIP) recommends the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years for the prevention of COVID-19 (*6*). Parents and guardians of children aged 5–11 years vaccinated with Pfizer-BioNTech COVID-19 vaccine should be advised that local and systemic reactions are expected after vaccination. Vaccination is the most effective way to prevent COVID-19. CDC and FDA will

* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
† https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic (Accessed December 19, 2021).

INSIDE

1761 Interim Estimate of Vaccine Effectiveness of BNT162b2 (Pfizer-BioNTech) Vaccine in Preventing SARS-CoV-2 Infection Among Adolescents Aged 12–17 Years — Arizona, July–December 2021
1766 Characteristics and Clinical Outcomes of Children and Adolescents Aged <18 Years Hospitalized with COVID-19 — Six Hospitals, United States, July–August 2021
1773 Evaluation of a Test to Stay Strategy in Transitional Kindergarten Through Grade 12 Schools — Los Angeles County, California, August 16–October 31, 2021
1778 Evaluation of Test to Stay Strategy on Secondary and Tertiary Transmission of SARS-CoV-2 in K–12 Schools — Lake County, Illinois, August 9–October 29, 2021
1782 Investigation of a SARS-CoV-2 B.1.1.529 (Omicron) Variant Cluster — Nebraska, November–December 2021
1785 QuickStats

Continuing Education examination available at https://www.cdc.gov/mmwr/mmwr_continuingEducation.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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continue to monitor vaccine safety and will provide updates as needed to guide COVID-19 vaccination recommendations.

VAERS is a national passive vaccine safety surveillance system, jointly managed by CDC and FDA, that monitors adverse events after vaccination (*7*). VAERS accepts reports from anyone, including health care providers,[§] vaccine manufacturers, and members of the public. Symptoms, signs, and diagnostic findings in VAERS reports are assigned Medical Dictionary for Regulatory Activities (MedDRA) preferred terms by VAERS staff members.[¶] VAERS reports are classified as serious if any of the following are reported: hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death.[**] Reports of serious adverse events receive follow-up by VAERS staff members to obtain additional information, including medical records. For reports of death, death certificates and autopsy reports are obtained, if available. CDC physicians reviewed all available information for each decedent to form an impression about cause of death. Reports of myocarditis and pericarditis after receipt of COVID-19 vaccine were identified by a search for selected MedDRA preferred terms (*7*); CDC staff members attempted to collect information about clinical course and recovery related to myocarditis and pericarditis from patients and health care providers.

CDC established v-safe,[††] a voluntary smartphone-based active safety surveillance system, specifically to monitor adverse events after COVID-19 vaccination. Parents and guardians can enroll children in v-safe after either the first or second vaccine dose. Text message reminders for online health surveys are sent to parents or guardians to complete for a child.[§§] Health surveys sent in the first week after vaccination included questions about local injection site and systemic reactions (mild, moderate, or severe)[¶¶] and health impacts (i.e., whether the child was unable to perform normal daily activities, missed school, or received care from a medical professional because of new symptoms or conditions). CDC's v-safe call center contacted a parent or guardian when a report indicated that a

[§] Under COVID-19 vaccine EUA requirements, health care providers are required to report certain adverse events after vaccination to VAERS, including death. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html

[¶] Each VAERS report might be assigned more than one MedDRA preferred term. A MedDRA-coded event does not indicate a medically confirmed diagnosis. https://www.meddra.org/how-to-use/basics/hierarchy

[**] Based on the Code of Federal Regulations Title 21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32

[††] https://vsafe.cdc.gov

[§§] Children and adolescents aged ≤15 years must be enrolled by a parent or guardian and cannot self-enroll. Children aged 5–11 years might be enrolled in v-safe if they were vaccinated on or after November 3, 2021. Health check-ins are sent via text messages that link to web-based surveys on days 0–7 after vaccination; then weekly through 6 weeks after vaccination; and then 3, 6, and 12 months after vaccination.

[¶¶] Parents and guardians who participate in v-safe use the following definitions to describe the severity of a child's symptoms: mild (noticeable, but not problematic), moderate (limit normal daily activities), or severe (make daily activities difficult or impossible).

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Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. MMWR Morb Mortal Wkly Rep 2021;70:[inclusive page numbers].

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child received medical care for new or worsening symptoms; completion of a VAERS report, if indicated, was encouraged.

VAERS and v-safe data collected during November 3–December 19, 2021 among children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine were analyzed and described overall and by sex, age group, and race/ethnicity. Among 5,277 VAERS reports received for children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine, 1,028 (19.5%) were excluded from this analysis because vaccination occurred before authorization for use in this age group or date of vaccination was unknown. SAS software (version 9.4; SAS Institute) was used to conduct all analyses. These activities were reviewed by CDC and conducted consistent with applicable federal law and CDC policy.[***]

Review of VAERS Data

During November 3–December 19, 2021, VAERS received and processed 4,249 reports of adverse events (Table 1) for children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine[†††]; the median age was 8 years, and 1,896 (44.6%) reports were for males. Most children (4,143; 97.5%) received Pfizer-BioNTech COVID-19 vaccine alone; seasonal influenza vaccine was the most frequently simultaneously administered vaccine (91 [2.1%] children).

Overall, 4,149 (97.6%) VAERS reports were for nonserious events, and 100 (2.4%) were for serious events. The median age of children with reports of nonserious events was 8 years, and 1,835 (44.2%) of these reports were for males. The most commonly reported nonserious events were related to vaccine administration (some without any adverse event), including no adverse event (1,157; 27.9%), product preparation issue (925; 22.3%), and incorrect dose administered (675; 16.3%), (Table 2). The median age of children with reports of serious events was 9 years, and 61 (61.0%) reports were among males. The most commonly reported conditions and diagnostic findings among the 100 reports of serious events were fever (29; 29.0%), vomiting (21; 21.0%), and increased troponin[§§§] (15; 15.0%). Among 12 serious reports of seizure, one child experienced syncope (not seizure) and another child potentially experienced syncope, two children experienced febrile seizure, one child had a history of seizures, two children had a potentially evolving seizure disorder, and five children experienced new-onset seizures. Among 15 preliminary reports of myocarditis identified during the analytic period, 11 were verified (by provider interview or medical record review) and met the case definition for myocarditis[¶¶¶]; of these 11 children, seven recovered, and four were recovering at time of the report. VAERS received two reports of death during the analytic period; both are under review. These deaths occurred in two females, aged 5 and 6 years, both of whom had complicated medical histories and were in fragile health before vaccination. None of the data suggested a causal association between death and vaccination.

Review of v-safe Data

During November 3–December 19, 2021, v-safe enrolled 42,504 children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine (Table 3); second dose information was available for 29,899 (70.3%) of these children. During the week after receipt of dose 1, local (23,290; 54.8%) and systemic (14,734; 34.7%) reactions were frequently reported; systemic

*** 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

††† Processed VAERS reports are those that have been coded using MedDRA, have been deduplicated, and have undergone standard quality assurance and quality control review.

TABLE 1. Adverse event reports among children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine, by selected demographic characteristics and reported symptoms (N = 4,249) — Vaccine Adverse Event Reporting System, United States, November 3–December 19, 2021

Characteristic	Total, % (N = 4,249)	Nonserious, % (n = 4,149)	Serious, %* (n = 100)
Sex			
Female	45.0	45.1	39.0
Male	44.6	44.2	61.0
Unknown	10.4	10.7	0
Age range, yrs (median)	**5–11 (8)**	**5–11 (8)**	**5–11 (9)**
Ethnicity			
Hispanic or Latino	11.0	10.9	16.0
Non-Hispanic or Latino	40.0	39.7	56.0
Unknown ethnicity	48.9	49.4	28.0
Race			
American Indian or Alaska Native	0.6	0.6	0
Asian	4.0	4.0	7.0
Black	4.1	4.2	2.0
Native Hawaiian or Other Pacific Islander	0.2	0.2	0
White	39.5	39.2	52.0
Multiracial	2.2	2.1	9.0
Other	7.1	7.1	4.0
Unknown race	42.3	42.7	26.0

Abbreviation: VAERS = Vaccine Adverse Event Reporting System.

* VAERS reports are classified as serious if any of the following are reported: hospitalization or prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death.

§§§ Troponins are proteins found in myocytes (heart muscle cells). Troponin levels typically are measured as part of the evaluation of chest pain or other symptoms of possible myocardial damage.

¶¶¶ Acute myocarditis was defined as presence of signs and symptoms (one or more new or worsening of the following: chest pain/pressure/discomfort, dyspnea/shortness of breath/pain with breathing, palpitations, or syncope; or two or more of the following in children aged ≤11 years: irritability, vomiting, poor feeding, tachypnea, or lethargy); and one or more new finding of elevated troponin, electrocardiogram findings consistent with myocarditis, abnormal cardiac function or wall motion on echocardiogram, cardiac magnetic resonance imaging findings consistent with myocarditis, or histopathologic findings consistent with myocarditis; and no other identifiable cause for these findings.

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reactions were more frequently reported during the week after dose 2 (12,223; 40.9%) than dose 1. Reactions were reported most frequently on the day after vaccination for both doses. The most frequently reported reactions after either dose were injection site pain, fatigue, and headache. Fever was more frequently reported after dose 2 (4,001; 13.4%) than dose 1 (3,350; 7.9%).

TABLE 2. Most frequent symptoms, signs, diagnostic results, and conditions by MedDRA preferred term* reported to the Vaccine Adverse Event Reporting System among children aged 5–11 years after receipt of Pfizer-BioNTech COVID-19 vaccine (N = 4,249) — United States, November 3–December 19, 2021

Symptom, sign, diagnostic result, or condition (MedDRA PT)	No. reporting	% Reporting
Nonserious reports (n = 4,149)		
No adverse event†	1,157	27.9
Product preparation issue	925	22.3
Incorrect dose administered	675	16.3
Underdose	324	7.8
Vomiting	316	7.6
Fever	291	7.0
Headache	255	6.2
Syncope	255	6.2
Dizziness	244	5.9
Fatigue	201	4.8
Nausea	192	4.6
Urticaria	186	4.5
Rash	166	4.0
Pallor	151	3.6
Product storage error	146	3.5
Serious reports§ (n = 100)		
Fever	29	29.0
Vomiting	21	21.0
Troponin increased	15	15.0
Chest pain	12	12.0
Echocardiogram normal	12	12.0
Blood test	11	11.0
C-reactive protein increased	11	11.0
SARS-CoV-2 test negative	11	11.0
Appendicitis	10	10.0
Electrocardiogram normal	10	10.0
Headache	10	10.0
Rash	10	10.0
Seizure	10	10.0
Intensive care	9	9.0
Full blood count normal	8	8.0

Abbreviations: MedDRA PT = Medical Dictionary for Regulatory Activities preferred term; VAERS = Vaccine Adverse Event Reporting System.

* Signs and symptoms in VAERS reports are assigned MedDRA PTs by VAERS staff members. Each VAERS report might be assigned more than one MedDRA PT, which can include normal diagnostic findings. A MedDRA PT does not indicate a medically confirmed diagnosis. Reports of myocarditis and seizure were identified using a combination of MedDRA PTs; in some cases, reports of myocarditis (identified by fulfilling criteria of the CDC working case definition of myocarditis) and seizure did not have the MedDRA PT "myocarditis" or "seizure" assigned to them. https://www.meddra.org/how-to-use/basics/hierarchy

† Reports of no adverse event were accompanied by product preparation issue, incorrect dose administered, or underdose.

§ VAERS reports are classified as serious if any of the following are reported: hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death; MedDRA PTs are included with serious reports when they occur in association with the criteria for serious classification (i.e., radiologic or laboratory tests that occur during a hospitalization).

Approximately 5.1% of parents reported that their child was unable to perform normal daily activities on the day after receipt of dose 1, and 7.4% after receipt of dose 2. Approximately 1% of parents reported seeking medical care in the week after vaccination; most medical care was received via a clinic appointment (441; 0.6%). Fourteen (0.02%) children reportedly received care at a hospital; information regarding reason for hospitalization was available for five children and included appendicitis (two), vomiting and dehydration (one), respiratory infection (one), and retropharyngeal cellulitis (one). Parents and guardians of all hospitalized children were contacted; two parents completed VAERS reports, and one revealed hospitalization was reported in error.

Discussion

This report provides preliminary safety findings from VAERS and v-safe data collected during the administration of approximately 8 million doses of Pfizer-BioNTech COVID-19 vaccine to children aged 5–11 years. The findings summarized in this report are similar to the safety data from preauthorization trials for Pfizer-BioNTech COVID-19 vaccine administered to

TABLE 3. Reactions reported for children aged 5–11 years (N = 42,504) who completed at least one v-safe health check-in survey on days 0–7 after receiving Pfizer-BioNTech COVID-19 vaccine — United States, November 3–December 19, 2021

	% of v-safe enrollees reporting reaction or health impact*	
Event	**Dose 1 (N = 42,504)**	**Dose 2 (n = 29,899)**
Any injection site reaction	54.8	57.5
Itching	3.8	3.7
Pain	52.7	55.8
Redness	3.7	4.4
Swelling	3.9	4.9
Any systemic reaction	34.7	40.9
Abdominal pain	5.1	6.4
Myalgia	7.1	10.2
Chills	3.9	6.8
Diarrhea	2.6	2.2
Fatigue	20.1	25.9
Fever	7.9	13.4
Headache	13.9	19.8
Joint pain	2.1	2.9
Nausea	5.0	6.9
Rash	1.2	1.0
Vomiting	2.3	2.7
Any health impact	10.9	15.1
Unable to perform normal daily activities	5.1	7.4
Unable to attend school	7.9	10.9
Needed medical care	1.2	1.1
Telehealth	0.3	0.2
Clinic	0.6	0.6
Emergency visit	0.1	0.1
Hospitalization	0.02	0.02

* Percentage of enrollees who reported a reaction or health impact at least once during days 0–7 post-vaccination.

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children aged 5–11 years (*4*,*5*). Trial participants who received Pfizer-BioNTech COVID-19 vaccine frequently reported local (86.2%) and systemic (66.6%) reactions that were mostly mild (i.e., did not interfere with normal daily activities) or moderate (some interference with normal daily activities); no serious adverse events judged to be related to vaccination were reported (*3*).

Among VAERS reports for children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine, approximately 97% were nonserious. The most common adverse events reported to VAERS in the age group were related to administration error. This age group is the first to receive a smaller dosage of mRNA (10 μg) than that recommended for persons aged ≥12 years (30 μg), and administration errors are not unexpected. Most reports of administration errors often mentioned that no adverse event was associated with receipt of an incorrect dose.

Myocarditis is a rare and serious adverse event that has been associated with mRNA-based COVID-19 vaccines; reporting rates for vaccine-associated myocarditis appears highest among males aged 12–29 years (*8*). To date, myocarditis among children aged 5–11 years appears rare; 11 verified VAERS reports have been received after administration of approximately eight million vaccine doses, and, in an active vaccine safety surveillance system, no chart-confirmed reports of myocarditis were observed during the 1–21 days or 1–42 days after 333,000 vaccine doses were administered to children of the same age (*6*) These cases appear consistent with other reports of myocarditis after mRNA COVID-19 vaccination regarding time to symptom onset and a mild clinical course (*9*). Two deaths after Pfizer-BioNTech COVID-19 vaccine were reported for children with multiple chronic medical conditions; on initial review, no data were found that would suggest a causal association between death and vaccination.

Local (57.5%) and systemic (40.9%) reactions after receipt of dose 2 of Pfizer-BioNTech COVID-19 vaccination among v-safe registrants aged 5–11 years were less frequently reported than reactions reported among children and adolescents aged 12–15 years (local 62.4%; systemic, 63.4%) (*9*). Fourteen v-safe registrants aged 5–11 years were reported to have been hospitalized after vaccination. V-safe does not directly record diagnoses associated with hospitalization; however, parents and guardians can include supplemental text for each health check-in. Whether hospitalization was the result of vaccination could not be determined; however, all parents and guardians who reported a child's hospitalization were contacted and encouraged to complete a VAERS report. Two parents completed a VAERS report on behalf of a child who was reported to v-safe to have been hospitalized.

Summary

What is already known about this topic?

In preauthorization trials for Pfizer-BioNTech (BNT162b2) COVID-19 vaccine, vaccinated children aged 5–11 years reported mild to moderately severe local and systemic reactions; no serious vaccination-related events were noted.

What is added by this report?

After authorization of Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years during October 2021, and administration of approximately 8 million doses, local and systemic reactions after vaccination were commonly reported to VAERS and v-safe for vaccinated children aged 5–11 years. Serious adverse events were rarely reported.

What are the implications for public health practice??

Parents and guardians of children aged 5–11 years should be advised that local and systemic reactions are expected after vaccination with Pfizer-BioNTech COVID-19 vaccine and are more common after the second dose.

The findings in this report are subject to at least four limitations. First, VAERS is a passive surveillance reporting system and is subject to reporting biases and underreporting, especially of nonserious events (*8*). Second, data on race/ethnicity were not provided in >40% of VAERS reports. Third, v-safe is a voluntary program; as a result, v-safe data might not be representative of the vaccinated population. Finally, these data are limited by the short surveillance period and might change as safety monitoring continues and more doses are administered to children aged 5–11 years.

Vaccination is the most effective way to prevent COVID-19 infection. ACIP recommends the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years for the prevention of COVID-19 (*10*). Preliminary safety findings are similar to those described in the clinical trials. Parents and guardians of children aged 5–11 years vaccinated with Pfizer-BioNTech COVID-19 vaccine should be advised that local and systemic reactions are expected after vaccination. CDC and FDA will continue to monitor vaccine safety and will provide updates as needed to guide COVID-19 vaccination recommendations.

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Interim Estimate of Vaccine Effectiveness of BNT162b2 (Pfizer-BioNTech) Vaccine in Preventing SARS-CoV-2 Infection Among Adolescents Aged 12–17 Years — Arizona, July–December 2021

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The BNT162b2 (Pfizer-BioNTech) mRNA COVID-19 vaccine has demonstrated high efficacy in preventing infection with SARS-CoV-2 (the virus that causes COVID-19) in randomized placebo-controlled Phase III trials in persons aged 12–17 years (referred to as adolescents in this report) (*1*); however, data on real-word vaccine effectiveness (VE) among adolescents are limited (*1–3*). As of December 2021, the Pfizer-BioNTech vaccine is approved by the Food and Drug Administration (FDA) for adolescents aged 16–17 years and under FDA emergency use authorization for those aged 12–15 years. In a prospective cohort in Arizona, 243 adolescents aged 12–17 years were tested for SARS-CoV-2 by reverse transcription–polymerase chain reaction (RT-PCR) each week, irrespective of symptoms, and upon onset of COVID-19–like illness during July 25–December 4, 2021; the SARS-CoV-2 B.1.617.2 (Delta) variant was the predominant strain during this study period. During the study, 190 adolescents contributed fully vaccinated person-time (≥14 days after receiving 2 doses of Pfizer-BioNTech vaccine), 30 contributed partially vaccinated person-time (receipt of 1 dose or receipt of 2 doses but with the second dose completed <14 days earlier), and 66 contributed unvaccinated person-time. Using the Cox proportional-hazards model, the estimated VE of full Pfizer-BioNTech vaccination for preventing SARS-CoV-2 infection was 92% (95% CI = 79%–97%), adjusted for sociodemographic characteristics, health information, frequency of social contact, mask use, location, and local virus circulation. These findings from a real-world setting indicate that 2 doses of Pfizer-BioNTech vaccine are highly effective in preventing SARS-CoV-2 infection among Arizona adolescents. CDC recommends COVID-19 vaccination for all eligible persons in the United States, including persons aged 12–17 years.*

The PROTECT† study is a prospective cohort of persons aged 4 months–17 years initiated in Arizona in July 2021. The study seeks to understand the risk for COVID-19 and how well COVID-19 vaccines protect children and adolescents from SARS-CoV-2 infection and illness. PROTECT expanded to Florida, Texas, and Utah in late September 2021, and those sites will be included in future analyses. PROTECT is an ancillary study of the HEROES-RECOVER cohorts,§ which previously reported VE of COVID-19 vaccines among working adults aged 18–85 years using similar methods (*4*). PROTECT participants in Arizona were recruited from families of adults participating in the HEROES study and the general public. Upon enrollment, participants responded to electronic surveys collecting demographic, health and vaccination history, and prior SARS-CoV-2 infection information. Participants submitted self-collected (or parent-/guardian-collected) mid-turbinate nasal swabs weekly, irrespective of COVID-19–like illness symptoms, and collected an additional swab at the onset of any COVID-19–like illness. Self-reported signs and symptoms of COVID-19–like illness (fever, chills, cough, shortness of breath, sore throat, diarrhea, muscle or body aches, change in smell or taste, or loss of appetite or poor feeding) that occurred in the preceding 7 days were self-reported on the weekly nasal swab envelopes. Specimens were shipped on cold packs and tested by RT-PCR assay for SARS-CoV-2 at Marshfield Clinic Laboratory (Marshfield, Wisconsin). Receipt of COVID-19 vaccines was documented by self-report in electronic surveys and direct upload of vaccine card images by participants' parents or guardians. The number of hours and percentage of time participants wore masks in school and in the community were also collected via self-reported electronic surveys upon enrollment and each subsequent month.

The primary outcome measure was time to RT-PCR–confirmed SARS-CoV-2 infection in vaccinated participants compared with that in unvaccinated participants. VE was calculated using the Anderson-Gill extension of the Cox proportional-hazards models, in which unvaccinated person-time included days before receiving the first dose of a COVID-19

* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html

† Pediatric Research Observing Trends and Exposures in COVID-19 Timelines (PROTECT).

§ Arizona Healthcare, Emergency Response and Other Essential Workers Surveillance Study (HEROES) and Research on the Epidemiology of SARS-CoV-2 in Essential Response Personnel (RECOVER) cohorts.

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vaccine, and fully vaccinated person-time included number of days following 14 days after receipt of the second of 2 Pfizer-BioNTech vaccine doses. For participants infected with SARS-CoV-2, the event date for this analysis was the earlier of the collection date of the first specimen to test positive or the symptom onset date. Unadjusted VE was calculated as 100% x (1 – hazard ratio for SARS-CoV-2 infection in vaccinated versus unvaccinated participants). An adjusted model used an inverse probability of treatment weighting approach (*5*) with individual propensities to be vaccinated during each week based on sociodemographic characteristics (age, sex, race/ethnicity, and household size); health information (chronic conditions and daily medication use); frequency of close social contact (school and community); percentage of time wearing masks (school and community); and local virus circulation (daily percentage of all SARS-CoV-2 tests performed in the local county returning a positive result). These predicted propensities were used to calculate stabilized weights, which were incorporated into a Cox proportional-hazards model. Robust SEs were used to account for the clustering of participants within the same household and correlation by stabilized weights. All analyses were conducted using SAS software (version 9.4; SAS Institute) or R software (version 4.1.2; R Foundation for Statistical Computing). This activity was approved by University of Arizona Institutional Review Board on which CDC relied. The study was conducted consistent with applicable federal law and CDC policy.¶

Among 1,478 participants aged 4 months–17 years in the full Arizona PROTECT cohort, 280 (18.9%) were aged 12–17 years; 32 (11.4%) of these participants were excluded based on a documented RT-PCR–positive SARS-CoV-2 test result before enrollment, three were excluded because of failure to complete weekly nasal swabs, one was excluded because vaccination information was incomplete, and one was excluded because the participant had received the mRNA-1273 (Moderna) COVID-19 vaccine, leaving 243 participants (86.8% of participants aged 12–17 years) in the analytic sample.

Approximately one half (51.4%) were male, 65.8% were from Tucson, most were aged 12–15 years (74.5%), White (87.7%), non-Hispanic (74.5%), and had private insurance (85.2%) (Table 1). Participants reported attending in-person school a mean of 28.2 (SE = 1.0) hours per week. They reported wearing a mask in school 73.3% (SE = 2.4) of the time; the SE, in part, reflects the variability in mask mandates across the state (*6*). Participants who received a positive SARS-CoV-2 test result during the study reported a lower percentage of time masked in school (48.6%, SE = 10.0) compared with those who did not receive a positive test result (75.7%, SE = 2.3) (p = 0.031). Participants also reported using masks in the community a mean of 58.5% (SE = 2.6) of the time overall, with participants who received positive SARS-CoV-2 test results reporting a lower mean percentage of community masked time (29.3%; SE = 9.0) compared with those who received negative test results (61.3%; SE = 2.7) (p = 0.003).

During the study period, 66 participants contributed 4,288 unvaccinated person-days, 30 contributed 909 partially vaccinated person-days, and 190 contributed 21,693 fully vaccinated person-days (Table 2). Most (n = 171, 70.3%) vaccinated participants entered the study fully vaccinated. The median number of fully vaccinated person-days during the analysis period was 119 (IQR = 105–133 days).

Twenty-one persons (8.6%) received positive RT-PCR SARS-CoV-2 test results (Table 1). RT-PCR–confirmed infection was more prevalent among residents of areas other than Tucson or Phoenix (p = 0.003). The majority (n = 18, 85.7%) of participants with RT-PCR–confirmed infection reported COVID-19–like illness. The remaining three participants reported being asymptomatic. Two participants with RT-PCR–confirmed infections, both unvaccinated and from the same household, sought outpatient medical care for their illness.

During the 4,288 unvaccinated person-days, 16 RT-PCR–confirmed infections were identified (incidence rate = 3.73 per 1,000 person-days) (Table 2). During the 909 person-days <14 days after receipt of the second vaccine dose, when persons were considered partially vaccinated, no RT-PCR–confirmed infections were identified. Five RT-PCR–confirmed infections occurred during 21,693 fully vaccinated person-days (incidence rate = 0.23 per 1,000 person-days). Estimated unadjusted VE of full vaccination for preventing SARS-CoV-2 infection was 94% (95% CI = 83%–98%). Estimated adjusted VE of full vaccination for preventing SARS-CoV-2 infection was 92% (95% CI = 79%–97%).

Discussion

Analysis of a prospective Arizona cohort of adolescents found adjusted VE for full vaccination with 2 doses of Pfizer-BioNTech vaccine to be 92% against RT-PCR–confirmed SARS-CoV-2 infection, indicating that the Pfizer-BioNTech COVID-19 vaccine is highly effective in real-world conditions among adolescents aged 12–17 years.

These findings are consistent with those from previous Phase III trials (*1*,*7*) and recent observational studies of mRNA VE against severe COVID-19 in adolescents and young adults (*3*,*8*). The scientific rigor of these findings is enhanced by the study's prospective design and the participants' weekly specimen collections. The observation period for this analysis coincided with the period of Delta variant predominance in the

¶45 C.F.R. part 46; 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d), 5 U.S.C. Sect. 552a, 44 U.S.C. Sect. 3501 et seq.

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United States and with return to in-person K–12 instruction in Arizona schools, with potentially higher rates of exposure.

The findings in this report are subject to at least five limitations. First, VE point estimates should be interpreted with caution given the moderately wide CIs, attributable in part to the limited number of unvaccinated person-days relative to fully vaccinated person-days, and a small overall sample size. Second, although several potential confounders were controlled for, including differences in mask use between vaccinated and unvaccinated participants, residual and unmeasured confounding might have occurred. Third, self-collection of specimens and use of nasal rather than nasopharyngeal swabs could reduce sensitivity of virus detection by RT-PCR but might have increased participation, because studies indicate that nasal swabs are more acceptable to participants (*9*); if the difference in sensitivity of virus detection between the two methods disproportionately affected those who received the vaccine, VE would be overestimated. Fourth, if vaccination attenuates viral RNA shedding among children, as has been noted in some studies of adults (*4*), this effect would also result in overestimation of VE by reducing RT-PCR detection among infected but vaccinated participants. Finally, the study

TABLE 1. Demographic and epidemiologic characteristics of adolescents aged 12–17 years in the Arizona PROTECT Pfizer-BioNTech COVID-19 vaccine effectiveness cohort (N = 243) — Arizona, July–December 2021

	Participants	SARS-CoV-2 infection	No SARS-CoV-2 infection		Unvaccinated	Vaccinated 1 dose	
Characteristic	**No. (col. %)**	**No. (row %)**	**No. (row %)**	**p-value***	**No. (row %)**	**No. (row %)**	**p-value***
Total	**243 (100.0)**	**21 (8.6)**	**222 (91.4)**	—	**49 (20.2)**	**194 (79.8)**	—
Gender							
Male	125 (51.4)	12 (9.6)	113 (90.4)	0.191	25 (20.0)	100 (80.0)	>0.999
Female	106 (43.6)	7 (6.6)	99 (93.4)		22 (20.8)	84 (79.2)	
Transgender	2 (0.8)	1 (50.0)	1 (50.0)		0 (0.0)	2 (100.0)	
None of these or did not respond	10 (4.1)	1 (10.0)	9 (90.0)		2 (20.0)	8 (80.0)	
Site							
Phoenix	49 (20.2)	5 (10.2)	44 (89.2)	0.003	10 (20.4)	39 (79.6)	0.594
Tucson	160 (65.8)	8 (5.0)	152 (95.0)		30 (18.8)	130 (81.2)	
Other	34 (14.0)	8 (23.5)	26 (76.5)		9 (26.5)	25 (73.5)	
Age group, yrs							
12–15	181 (74.5)	15 (8.3)	166 (91.7)	0.941	38 (21.0)	143 (79.0)	0.713
16–17	62 (25.5)	6 (9.7)	56 (90.3)		11 (17.7)	51 (82.3)	
Ethnicity (all races)							
Hispanic	64 (25.5)	3 (4.8)	59 (95.2)	0.298	10 (16.1)	54 (83.9)	0.383
Non-Hispanic	179 (74.5)	18 (9.9)	163 (90.1)		39 (22.7)	140 (77.2)	
Race (all ethnicities)							
White	216 (87.7)	20 (9.4)	196 (90.6)	0.484	40 (18.8)	175 (81.2)	0.041
Other races†	27 (12.3)	1 (3.3)	26 (96.7)		9 (36.7)	19 (63.3)	
Household composition							
1 child per household	58 (23.9)	3 (5.2)	55 (94.8)	0.422	10 (17.2)	48 (82.8)	0.654
≥2 children per household	185 (76.1)	18 (9.7)	167 (90.3)		39 (21.1)	146 (78.9)	
Swab adherence§							
>80%	194 (79.8)	19 (9.8)	175 (90.2)	0.264	35 (18.0)	159 (82.0)	0.149
Chronic conditions¶							
≥1	25 (10.3)	4 (16.0)	21 (84.0)	0.247	7 (28.0)	18 (72.0)	0.443
None	218 (89.7)	17 (7.8)	201 (92.2)		42 (19.3)	176 (80.7)	
Insurance							
Private	207 (85.2)	17 (8.2)	190 (91.8)	0.387	39 (18.8)	168 (81.2)	0.409
None or did not respond	18 (7.4)	3 (16.7)	15 (83.3)		5 (27.8)	13 (72.2)	
Public	18 (7.4)	1 (5.6)	17 (94.4)		5 (27.8)	13 (72.2)	
Potential virus exposure and mask use (hours weekly), no. (col. %)							
Hours attending school, mean (SE)	28.2 (1.0)	22.2 (3.8)	28.8 (1.0)	0.178	25.2 (2.4)	29.0 (1.0)	0.308
% time masked, school, mean (SE)	73.3 (2.4)	48.6 (10.0)	75.7 (2.3)	0.031	61.6 (6.1)	76.2 (2.5)	0.216
Hours in community, mean (SE)	10.4 (0.8)	11.9 (2.1)	10.3 (0.9)	0.174	11.6 (1.7)	10.1 (1.0)	0.228
% time masked, community, mean (SE)	58.5 (2.6)	29.3 (9.0)	61.3 (2.7)	0.003	39.5 (6.2)	63.2 (2.8)	0.002

Abbreviations: Col = column; PROTECT = Pediatric Research Observing Trends and Exposures in COVID-19 Timelines.

* P-values comparing the percentage of persons with SARS-CoV-2 infections to those not infected by sociodemographic and health categories and comparing the percentage of vaccinated persons to those not vaccinated by these categories, calculated using Pearson's chi-square test (cells with ≥5 observations) or Fisher's exact test (cells with <5 observations). P-values for continuous variables calculated using the Mann-Whitney test.

† All participants in the "Other races" category were collapsed into a single group because of small numbers.

§ Number and percentage of participants who completed weekly nasal swab throughout the analysis period.

¶ Chronic conditions included asthma or chronic lung disease, cancer, diabetes, heart disease, hypertension, immunosuppression or autoimmune disorder, kidney disease, liver disease, neurologic or neuromuscular disorder, or other chronic conditions.

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might not be generalizable to other populations. The study was restricted to adolescents in Arizona and might not be representative of the racial or ethnic distribution in Arizona nor the United States. In addition, participants reported very few chronic conditions and low rates of obesity; previous studies have indicated that VE has not varied by chronic conditions except for among immunocompromised adults (*10*). The study was also restricted to persons aged 12–17 years; it is not known whether these findings can be generalized to children aged 5–11 years, who are now eligible to receive the Pfizer-BioNTech vaccine under an emergency use authorization.

The VE estimates described in this report for the Pfizer-BioNTech vaccine in real-world conditions during the period of Delta variant predominance corroborate and expand upon the VE estimates from other recent studies in adolescents (*1*,*7*) and reinforce previous findings that current vaccination efforts are resulting in substantial preventive benefits among adolescents aged 12–17 years. CDC recommends COVID-19 vaccination for all eligible persons in the United States, including adolescents aged 12–17 years.

Summary

What is already known about this topic?

The Pfizer-BioNTech COVID-19 vaccine has been shown to be effective in preventing SARS-CoV-2 infection in adolescents in randomized placebo-controlled Phase III trials.

What is added by this report?

A prospective cohort of 243 adolescents aged 12–17 years in Arizona completed weekly SARS-CoV-2 testing by nasal swab for 19 consecutive weeks. Under real-world conditions, vaccine effectiveness of full immunization (completion of the second in a 2-dose series ≥14 days earlier) was 92% against SARS-CoV-2 infections irrespective of symptom status.

What are the implications for public health practice?

In real-world conditions among adolescents aged 12–17 years, the Pfizer-BioNTech vaccine was highly effective in preventing SARS-CoV-2 infection.

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TABLE 2. Contributing participants, total person-days, number of RT-PCR–confirmed SARS-CoV-2 infections by vaccination status, and estimated Pfizer-BioNTech COVID-19 vaccine effectiveness for full vaccination in preventing infection among vaccine-eligible adolescents aged 12–17 years (N = 243) — Arizona, July–December 2021

Pfizer COVID-19 vaccination status	No. of contributing participants*	Total person-days	No. of days, median (IQR)	No. of SARS-CoV-2 infections	VE, % (95% CI)	
					Unadjusted	Adjusted†,§
Unvaccinated	66	4,288	62 (23–98)	16	—	—
Partially vaccinated (≥14 days after dose 1 to day 13 after dose 2)	30	909	21 (20–28)	0	—	—
Fully vaccinated (≥14 days after dose 2)	190	21,693	119 (105–133)	5	94 (83–98)	92 (79–97)

Abbreviations: RT-PCR = reverse transcription–polymerase chain reaction; SMD = standardized mean difference; VE = vaccine effectiveness.

* Contributing participants in vaccination categories did not equal the number of participants in the study because participants could contribute to more than one vaccination category since vaccination status varies by time.

† Adjusted VE is inversely weighted for propensity to be vaccinated; all covariates met balance criteria of SMD<0.2 after weighting except community mask use and local virus circulation (SMD = 0.228 and 0.288, respectively), but community mask use was only found to change VE estimate by ≥5% when added to the model and was therefore included as a covariate in the Cox regression model for VE.

§ Five participants missing community mask use were excluded from analysis; this exclusion did not affect the VE estimate.

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Characteristics and Clinical Outcomes of Children and Adolescents Aged <18 Years Hospitalized with COVID-19 — Six Hospitals, United States, July–August 2021

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During June 2021, the highly transmissible[†] B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, became the predominant circulating strain in the United States. U.S. pediatric COVID-19–related hospitalizations increased during July–August 2021 following emergence of the Delta variant and peaked in September 2021.[§] As of May 12, 2021, CDC recommended COVID-19 vaccinations for persons aged ≥12 years,[¶] and on November 2, 2021, COVID-19 vaccinations were recommended for persons aged 5–11 years.[**] To date, clinical signs and symptoms, illness course, and factors contributing to hospitalizations during the period of Delta predominance have not been well described in pediatric patients. CDC partnered with six children's hospitals to review medical record data for patients aged <18 years with COVID-19–related hospitalizations during July–August 2021.[††] Among 915 patients identified, 713 (77.9%) were hospitalized for COVID-19 (acute COVID-19 as the primary or contributing reason for hospitalization), 177 (19.3%) had incidental positive SARS-CoV-2 test results (asymptomatic or mild infection unrelated to the reason for hospitalization), and 25 (2.7%) had multisystem inflammatory syndrome in children (MIS-C), a rare but serious inflammatory condition associated with COVID-19.[§§] Among the 713 patients hospitalized for COVID-19, 24.7% were aged <1 year, 17.1% were aged 1–4 years, 20.1% were aged 5–11 years, and 38.1% were aged 12–17 years. Approximately two thirds of patients (67.5%) had one or more underlying medical conditions, with obesity being the most common (32.4%); among patients aged 12–17 years, 61.4% had obesity. Among patients hospitalized for COVID-19, 15.8% had a viral coinfection[¶¶] (66.4% of whom had respiratory syncytial virus [RSV] infection). Approximately one third (33.9%) of patients aged <5 years hospitalized for COVID-19 had a viral coinfection. Among 272 vaccine-eligible (aged 12–17 years) patients hospitalized for COVID-19, one (0.4%) was fully vaccinated.[***] Approximately one half (54.0%) of patients hospitalized for COVID-19 received oxygen support, 29.5% were admitted to the intensive care unit (ICU), and 1.5% died; of those requiring respiratory support, 14.5% required invasive mechanical ventilation (IMV). Among pediatric patients with COVID-19–related hospitalizations, many had severe illness and viral coinfections, and few vaccine-eligible patients hospitalized for COVID-19 were vaccinated, highlighting the importance of vaccination for those aged ≥5 years and other prevention strategies to protect children and adolescents from COVID-19, particularly those with underlying medical conditions.

* These authors contributed equally to this report.

† https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html; https://covid.cdc.gov/covid-data-tracker/#variant-proportions (Accessed September 15, 2021).

§ https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions

¶ https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s_cid=mm7020e1_w

** https://www.cdc.gov/mmwr/volumes/70/wr/mm7045e1.htm?s_cid=mm7045e1_w

†† COVID-19 was confirmed with laboratory detection of SARS-CoV-2 by reverse transcription–polymerase chain reaction or antigen test.

§§ Patients with MIS-C as the reason for hospitalization included patients who met the clinical case definition for MIS-C (clinically severe illness requiring hospitalization in a person aged <21 years with fever, laboratory evidence of inflammation, multisystem [≥2] organ involvement and no alternative plausible diagnosis, and evidence of current or recent SARS-CoV-2 infection by reverse transcription polymerase chain reaction, serology or antigen test, or COVID-19 exposure within the 4 weeks preceding symptom onset [https://emergency.cdc.gov/han/2020/han00432.asp]) and were hospitalized for diagnosis and management of MIS-C, based on chart review.

¶¶ Patients were considered to have a viral coinfection if they had ≥1 of the following infections: type A influenza, type B influenza, unspecified influenza, coronavirus 229e, coronavirus hku1, coronavirus nl63, coronavirus 0c43, respiratory syncytial virus, adenovirus, parainfluenza type 1, parainfluenza type 2, parainfluenza type 3, parainfluenza type 4, human metapneumovirus, rhinovirus, enterovirus, or other viral coinfection.

*** Fully vaccinated was defined as having received 2 doses of an mRNA-based COVID-19 vaccine ≥14 days before hospital admission date. Partially vaccinated was defined as having received only 1 dose of an mRNA-based COVID-19 vaccine ≥14 days before hospitalization. All vaccinated patients in this study received the Pfizer-BioNTech (BNT162b2) vaccine.

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Data were collected from six U.S. children's hospitals located in areas with high COVID-19 incidence during July–August 2021 (Arkansas, District of Columbia, Florida, Illinois, Louisiana, and Texas).††† Data from hospitalized patients aged <18 years with COVID-19 or SARS-CoV-2 infection§§§ were abstracted from electronic medical records using REDCap software (version 11.1.8; Vanderbilt University). Patients were categorized¶¶¶ by reason for hospitalization: 1) acute COVID-19, 2) incidental positive SARS-CoV-2 test result, or 3) MIS-C. Patient demographic characteristics, medical history, coinfections, and disease severity, including need for and duration of respiratory support, ICU admission, IMV, extracorporeal membrane oxygenation (ECMO),**** and deaths were abstracted from the medical record. Among patients hospitalized for COVID-19, presence of underlying medical conditions (including obesity),†††† viral coinfection, and illness course were described by age group. Pearson's chi-square and Kruskal-Wallis tests were used to compare categorical and continuous variables, respectively; p-values <0.05 were

††† A convenience sample of six hospitals was selected among members of the Children's Hospital Association. All hospitals were in jurisdictions with a high level of COVID-19 community transmission during July–August 2021; these jurisdictions were not represented by the COVID-NET surveillance system. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html

§§§ COVID-19 diagnosis indicated in medical record or based on positive SARS-CoV-2 test result (antigen or polymerase chain reaction/nucleic acid amplification test, or antibody test among patients with a diagnosis of MIS-C).

¶¶¶ Abstractors selected the category that best fit the overall reason for hospitalization, with adjudication by project leaders, and through audits of 5% of all charts.

**** ECMO is a form of advanced life support used in patients with medically refractory respiratory or cardiac failure.

†††† For children aged ≥2 years, height and weight were used to calculate body mass index (BMI) (kg/m^2). BMI percentiles were calculated using BMI, age, and sex. Children with BMI percentiles ≥95% were considered to have obesity (https://www.cdc.gov/obesity/childhood/defining.html) and those with BMI ≥120% of the 95th percentile were considered to have severe obesity. BMI data extracted from charts was used if height or weight was missing. If BMI was missing or unable to be calculated, a diagnosis of obesity recorded in charts was used and severity of obesity was unable to be assessed. Obesity was not assessed for children aged <2 years.

TABLE 1. Demographic characteristics and COVID-19 vaccination status of hospitalized patients aged <18 years with a positive SARS-CoV-2 test result or diagnosis of COVID-19, by reason for hospitalization — six hospitals,* United States, July–August 2021

	Reason for hospitalization, no. (%)			
	Overall	COVID-19†	Incidental positive SARS-CoV-2 test result	MIS-C§
Characteristic	**N = 915 (100)**	**n = 713 (77.9)**	**n = 177 (19.3)**	**n = 25 (2.7)**
Age, yrs, median (IQR)	8.0 (1.3-14.0)	8.0 (1.0-14.0)	9.0 (2.0-14.0)	8.0 (4.0-13.0)
Age group, yrs				
<1	206 (22.5)	176 (24.7)	29 (16.4)	1 (4.0)
1–4	167 (18.3)	122 (17.1)	36 (20.3)	9 (36.0)
5–11	197 (21.5)	143 (20.1)	47 (26.6)	7 (28.0)
12–17	345 (37.7)	272 (38.1)	65 (36.7)	8 (32.0)
Sex				
Female	437 (47.8)	340 (47.7)	87 (49.2)	10 (40.0)
Male	478 (52.2)	373 (52.3)	90 (50.8)	15 (60.0)
Race/Ethnicity				
White, non-Hispanic	277 (30.3)	210 (29.5)	59 (33.3)	8 (32.0)
Black or African American, non-Hispanic	260 (28.4)	202 (28.3)	48 (27.1)	10 (40.0)
Hispanic	267 (29.2)	211 (29.6)	52 (29.4)	4 (16.0)
Other, Non-Hispanic¶	42 (4.6)	35 (4.9)	6 (3.4)	1 (4.0)
Unknown	69 (7.5)	55 (7.7)	12 (6.8)	2 (8.0)
COVID-19 vaccination status				
Eligible for vaccination (aged 12–17 yrs)**	345 (37.7)	272 (38.1)	65 (36.7)	8 (32.0)
Fully vaccinated	3 (0.9)	1 (0.4)	2 (3.1)	0 (—)
Partially vaccinated	18 (5.2)	12 (4.4)	4 (6.2)	2 (25.0)
Not vaccinated	224 (64.9)	196 (72.1)	22 (33.8)	6 (75.0)
Unknown vaccination status	100 (29.0)	63 (23.2)	37 (56.9)	0 (—)
Ineligible for vaccination (aged <12 yrs)	570 (62.3)	441 (61.9)	112 (63.3)	17 (68.0)

Abbreviation: MIS-C = multisystem inflammatory syndrome in children.

* The six children's hospitals were in Arkansas, District of Columbia, Florida, Illinois, Louisiana, and Texas.

† Patients hospitalized for COVID-19 included patients with acute COVID-19 as the primary reason for hospitalization or with acute COVID-19 as a secondary or contributing reason for hospitalization, based on chart review.

§ Patients with MIS-C as the reason for hospitalization included patients who met the clinical case definition for MIS-C (clinically severe illness requiring hospitalization in a person aged <21 years with fever, laboratory evidence of inflammation, multisystem [≥2] organ involvement and no alternative plausible diagnosis, and evidence of current or recent SARS-CoV-2 infection by reverse transcription polymerase chain reaction, serology or antigen test, or COVID-19 exposure within the 4 weeks preceding symptom onset [https://emergency.cdc.gov/han/2020/han00432.asp]) and were hospitalized for diagnosis and management of MIS-C, based on chart review.

¶ Other race/ethnicity includes Asian, Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, and Other (not specified).

** Fully vaccinated was defined as having received 2 doses of an mRNA-based COVID-19 vaccine ≥14 days before the hospital admission date. Partially vaccinated was defined as having received only 1 dose of an mRNA-based COVID-19 vaccine ≥14 days before hospitalization. All vaccinated patients in this study received the Pfizer-BioNTech (BNT162b2) vaccine.

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considered statistically significant. All analyses were conducted using SAS (version 9.4; SAS Institute) and R (Version 4.0.3; R Foundation for Statistical Computing). This activity was reviewed by CDC and the other participating institutions and was conducted consistent with applicable federal law and CDC policy.[§§§§]

[§§§§] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

Among 915 patients aged <18 years, 713 (77.9%) were hospitalized for COVID-19, 177 (19.3%) had incidental SARS-CoV-2 infections, and 25 (2.7%) had MIS-C (Table 1). Among all 915 patients, 22.5% were aged <1 year, 18.3% were aged 1–4 years, 21.5% were aged 5–11 years, and 37.7% were aged 12–17 years. Among the 713 patients hospitalized for COVID-19, approximately one half (373; 52.3%) were male, 210 (29.5%) were non-Hispanic White persons, 202 (28.3%)

TABLE 2. Hospitalization and illness course among children and adolescents aged <18 years hospitalized for COVID-19,* by age group — six hospitals,† United States, July–August 2021

	Age group, yrs, no. (%)					
Characteristic	Overall (N = 713)	<1 (n = 176)	1–4 (n = 122)	5–11 (n = 143)	12–17 (n = 272)	p-value§
No. of underlying medical conditions						
None	232 (32.5)	124 (70.5)	51 (41.8)	25 (17.5)	32 (11.8)	<0.001
1–2	366 (51.3)	47 (26.7)	46 (37.7)	89 (62.2)	184 (67.6)	
≥3	115 (16.1)	5 (2.8)	25 (20.5)	29 (20.3)	56 (20.6)	
Five most prevalent conditions by system						
Metabolic or endocrine¶	258 (36.2)	2 (1.1)	17 (13.9)	59 (41.3)	180 (66.2)	<0.001
Obesity**	231 (32.4)	—	16 (13.1)	48 (33.6)	167 (61.4)	
Obesity	90 (39.0)	—	14 (87.5)	17 (35.4)	59 (35.3)	<0.001
Severe obesity	131 (56.7)	—	1 (6.3)	29 (60.4)	101 (60.5)	
Obesity, unknown severity	10 (4.3)	—	1 (6.3)	2 (4.2)	7 (4.2)	
Neurologic or developmental††	144 (20.2)	41 (23.3)	33 (27.0)	28 (19.6)	42 (15.4)	0.038
Seizure disorder	57 (8.0)	6 (3.4)	15 (12.3)	14 (9.8)	22 (8.1)	0.033
Respiratory§§	142 (19.9)	7 (4.0)	18 (14.8)	34 (23.8)	83 (30.5)	<0.001
Asthma or RAD	114 (16.0)	2 (1.1)	12 (9.8)	26 (18.2)	74 (27.2)	<0.001
Gastrointestinal or hepatic¶¶	85 (11.9)	12 (6.8)	28 (23.0)	16 (11.2)	29 (10.7)	<0.001
Feeding tube dependent	59 (8.3)	7 (4.0)	23 (18.9)	13 (9.1)	16 (5.9)	<0.001
Psychiatric***	58 (8.1)	0 (—)	0 (—)	13 (9.1)	45 (16.5)	<0.001
Depression	23 (3.2)	0 (—)	0 (—)	1 (0.7)	22 (8.1)	<0.001
Multiple admissions						
Yes	28 (3.9)	4 (2.3)	5 (4.1)	6 (4.2)	13 (4.8)	0.607
No	685 (96.1)	172 (97.7)	117 (95.9)	137 (95.8)	259 (95.2)	
Unknown	14 (2.4)	3 (1.9)	2 (2.0)	2 (1.9)	6 (2.7)	
Hospital length of stay, median days (IQR)	3.0 (1.0–7.0)	3.0 (1.0–6.8)	3.0 (2.0–4.5)	3.0 (1.0–7.0)	4.0 (2.0–8.0)	0.187
Admitted to ICU						
Yes	210 (29.5)	34 (19.3)	31 (25.4)	37 (25.9)	108 (39.7)	<0.001
No	503 (70.5)	142 (80.7)	91 (74.6)	106 (74.1)	164 (60.3)	
Total length of stay in ICU, median days (IQR)	3.0 (1.0–7.0)	3.0 (1.0–6.8)	3.0 (2.0–4.5)	3.0 (1.0–7.0)	4.0 (2.0–8.0)	0.187
Highest level of respiratory support required						
No oxygen support	328 (46.0)	94 (53.4)	57 (46.7)	82 (57.3)	95 (34.9)	<0.001
Oxygen support	385 (54.0)	82 (46.6)	65 (53.3)	61 (42.7)	177 (65.1)	
Nasal cannula	111 (28.8)	22 (26.8)	14 (21.5)	24 (39.3)	51 (28.8)	
Mask	7 (1.8)	0 (—)	2 (3.1)	1 (1.6)	4 (2.3)	
CPAP or BiPAP	69 (17.9)	5 (6.1)	10 (15.4)	11 (18.0)	43 (24.3)	
High-flow nasal cannula	142 (36.9)	43 (52.4)	32 (49.2)	14 (23.0)	53 (29.9)	
IMV	56 (14.5)	12 (14.6)	7 (10.8)	11 (18.0)	26 (14.7)	
Duration on IMV, median days (IQR)	7.0 (4.0–14.0)	6.0 (4.8–12.3)	6.0 (2.0–11.5)	5.5 (1.8–10.3)	9.5 (5.0–21.3)	0.596
ECMO required						
Yes	8 (1.1)	1 (0.6)	1 (0.8)	1 (0.7)	5 (1.8)	0.567
No	705 (98.9)	175 (99.4)	121 (99.2)	142 (99.3)	267 (98.2)	
Duration on ECMO, median days (IQR)	12.0 (5.5–17.8)	1.0 (1.0–1.0)	13.0 (13.0–13.0)	—	15.0 (11.0–26.0)	0.247
Viral coinfection†††	**113 (15.8)**	**57 (32.4)**	**44 (36.1)**	**6 (4.2)**	**6 (2.2)**	**<0.001**
RSV	75 (66.4)	42 (73.7)	26 (59.1)	4 (66.7)	3 (50.0)	<0.001
Discharge status						
Discharged alive	702 (98.5)	174 (98.9)	122 (100.0)	142 (99.3)	264 (97.1)	0.231
Deceased	11 (1.5)	2 (1.1)	0 (—)	1 (0.7)	8 (2.9)	

See table footnotes on the next page.

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TABLE 2. (*Continued*) Hospitalization and illness course among children and adolescents aged <18 years hospitalized for COVID-19,* by age group — six hospitals,† United States, July–August 2021

Abbreviations: BiPAP = bilevel positive airway pressure; BMI = body mass index; CPAP = continuous positive airway pressure; ECMO = extracorporeal membrane oxygenation; ICU = intensive care unit; IMV = invasive mechanical ventilation; RAD = reactive airway disease; RSV = respiratory syncytial virus.

* Patients hospitalized for COVID-19 included patients with acute COVID-19 as the primary reason for hospitalization or with acute COVID-19 as a secondary or contributing reason for hospitalization, based on chart review.

† The six children's hospitals were in Arkansas, District of Columbia, Florida, Illinois, Louisiana, and Texas.

§ Clinical characteristics and outcomes were compared among groups using Pearson's chi-square test for categorical variables and a Kruskal-Wallis test for nonnormally distributed variables.

¶ Metabolic and endocrine conditions included dyslipidemia, obesity, thyroid disorder, type 1 diabetes, type 2 diabetes, and other endocrine disorders.

** For children aged ≥2 years, height and weight were used to calculate BMI (kg/m^2). BMI percentiles were calculated using BMI, age, and sex. Those children with BMI percentiles ≥95th percentile were considered to have obesity and those with BMI ≥120% of the 95th percentile were considered to have severe obesity. BMI data extracted from charts were used if height or weight was missing. If BMI was missing or unable to be calculated, a diagnosis of obesity recorded in charts was used and severity of obesity was unable to be assessed. Obesity was not assessed for children aged <2 years.

†† Neurologic and developmental conditions included attention deficit hyperactivity disorder, autism spectrum disorder, cerebral palsy, cognitive disfunction, muscular dystrophy, neural tube defect or spina bifida, neurologic or neurodevelopmental disorder, neuropathy, plegias or paralysis, preterm birth (for children aged <2 years only), seizure disorder, and wheelchair/walker-dependence or bed-bound status.

§§ Respiratory conditions included active tuberculosis, asthma or reactive airway disease, chronic hypoxemic respiratory failure with oxygen or ventilator dependence, cystic fibrosis, current smoking or e-cigarette use, tracheostomy dependence, and other chronic lung diseases.

¶¶ Gastrointestinal or hepatic conditions included Crohn's disease, feeding tube dependence, liver disease, malnutrition, ulcerative colitis, and other gastrointestinal disorders.

*** Psychiatric conditions included anxiety, borderline personality disorder, depression, substance use disorder, and other psychiatric diagnoses.

††† Patients were considered to have a viral coinfection if they had at least one of the following infections: type A influenza, type B influenza, unspecified influenza, coronavirus 229e, coronavirus hku1, coronavirus nl63, coronavirus 0c43, respiratory syncytial virus, adenovirus, parainfluenza type 1, parainfluenza type 2, parainfluenza type 3, parainfluenza type 4, human metapneumovirus, rhinovirus enterovirus, or other viral coinfection.

were non-Hispanic Black persons or African American persons (Black), and 211 (29.6%) were Hispanic persons.

Among the 713 patients hospitalized for COVID-19, 32.5%, 51.3%, and 16.1% had zero, one or two, and three or more underlying medical conditions, respectively (Table 2). The most common conditions were obesity (32.4%), asthma or reactive airway disease (16.0%), and feeding tube dependence (8.3%). Among patients aged 12–17 years, 61.4% had obesity (60.5% of whom had severe obesity). Among patients aged 5–11 years, 33.6% had obesity (60.4% of whom had severe obesity). Among patients hospitalized for COVID-19, 210 (29.5%) had ICU admissions, eight (1.1%) received ECMO, and 11 (1.5%) died. Of the 385 (54.0%) patients hospitalized for COVID-19 who received oxygen support, high-flow nasal cannula was the most common highest level of support (142; 36.9%); 56 (14.5%) patients received IMV. Across all age groups, the median hospital stay was 3 days, and the median IMV duration was 7 days. Patients aged 12–17 years had the longest median hospitalizations (4 days) and IMV requirement (9.5 days). Viral coinfection was common among patients aged <1 year (32.4%) and 1–4 years (36.1%); overall, approximately two thirds of viral coinfections were with RSV (Table 2).

Among 272 vaccine-eligible patients hospitalized for COVID-19, one (0.4%) was fully vaccinated and 12 (4.4%) were partially vaccinated with an mRNA COVID-19 vaccine at the time of hospitalization (Table 1).

A higher percentage of patients hospitalized for COVID-19 with any underlying condition were admitted to the ICU (34.7%) compared with those without an underlying condition (18.5%) (p<0.001) (Table 3). The duration of hospitalization was longer for patients with obesity (median = 4 days [IQR = 2.0–7.5 days]) than that for those without obesity (median = 2 days [IQR = 1.0–5.0 days]) (p<0.001). A higher proportion of patients with obesity were admitted to the ICU (41.1%) than were those without obesity (23.9%) (p<0.001). A higher proportion of patients with viral coinfection required oxygen support (69.0%) compared with those without viral coinfection (51.2%) (p<0.001).

Discussion

In this study of six U.S. hospitals during July–August, 2021, approximately three quarters of pediatric patients with COVID-19–related hospitalizations were hospitalized for COVID-19. The majority of those hospitalized for COVID-19 were Black or Hispanic and were aged <5 or 12–17 years. Approximately one third of patients aged <1 and 1–4 years had a viral coinfection, approximately one third of patients aged 5–11 years and approximately two thirds of patients aged 12–17 years had obesity. Less than 1% of vaccine-eligible patients were fully vaccinated against COVID-19.

Five of the six hospitals had policies to test all pediatric patients for SARS-CoV-2 upon admission during the study period, allowing for detection of incidental positive SARS-CoV-2 test results. However, the proportion of such patients was smaller in this study compared with that in a previous report (*1*). Patients aged 0–4 and 12–17 years accounted for 79% of COVID-19–related hospitalizations in this study, which is consistent with data from other hospitals and communities (*2*). Among hospitalized children aged <5 years, most were aged <1 year, which might reflect clinical practice differences, because infants might be more likely to be hospitalized with milder disease than older children (*3*). Most patients were

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TABLE 3. Hospitalization and illness course among children and adolescents aged <18 years hospitalized for COVID-19* by presence of underlying medical conditions, obesity, and viral coinfection — six hospitals,† United States, July–August 2021

	No. (%)								
	Underlying medical condition			Obesity§			Viral coinfection		
Characteristic	Yes (n = 481)	No (n = 232)	p-value¶	Yes (n = 231)	No (n = 482)	p-value¶	Yes (n = 113)	No (n = 600)	p-value¶
Multiple admissions									
Yes	23 (4.8)	5 (2.2)	0.137	12 (5.2)	16 (3.3)	0.317	3 (2.7)	25 (4.2)	0.621
No	458 (95.2)	227 (97.8)		219 (94.8)	466 (96.7)		110 (97.3)	575 (95.8)	
Hospital length of stay, median days (IQR)	3.0 (2.0–7.0)	2.0 (1.0–4.0)	<0.001	4.0 (2.0–7.5)	2.0 (1.0–5.0)	<0.001	3.0 (2.0–6.0)	3.0 (1.0–6.0)	0.085
Admitted to ICU									
Yes	167 (34.7)	43 (18.5)	<0.001	95 (41.1)	115 (23.9)	<0.001	36 (31.9)	174 (29.0)	0.618
No	314 (65.3)	189 (81.5)		136 (58.9)	367 (76.1)		77 (68.1)	426 (71.0)	
ICU length of stay, median days (IQR)	4.0 (1.0–8.0)	2.0 (1.0–4.0)	0.023	4.0 (2.0–8.0)	3.0 (1.0–6.5)	0.014	4.0 (1.8–10.3)	3.0 (1.0–7.0)	0.37
Highest level of respiratory support required									
None	199 (41.4)	129 (55.6)	<0.001	61 (26.4)	267 (55.4)	<0.001	35 (31.0)	293 (48.8)	<0.001
Oxygen support	282 (58.6)	103 (44.4)		170 (73.6)	215 (44.6)		78 (69.0)	307 (51.2)	
Nasal cannula	77 (27.3)	34 (33.0)		47 (27.6)	64 (29.8)		10 (12.8)	101 (32.9)	
Mask	6 (2.1)	1 (1.0)		2 (1.2)	5 (2.3)		1 (1.3)	6 (2.0)	
CPAP or BIPAP	62 (22.0)	7 (6.8)		43 (25.3)	26 (12.1)		8 (10.3)	61 (20.0)	
High-flow nasal cannula	91 (32.3)	51 (49.5)		55 (32.4)	87 (40.5)		46 (59.0)	96 (31.3)	
IMV	46 (16.3)	10 (9.7)		23 (13.5)	33 (15.3)		13 (16.7)	43 (14.0)	
IMV duration, median days (IQR)	8.0 (4.0–15.0)	5.5 (1.0–6.8)	0.161	8.0 (5.0–14.5)	6.0 (3.8–13.5)	0.472	6.0 (5.0–13.0)	7.0 (3.0–14.5)	0.804
ECMO required									
Yes	5 (1.0)	3 (1.3)	1.000	5 (2.2)	3 (0.6)	0.147	2 (1.8)	6 (1.0)	0.821
No	476 (99.0)	229 (98.7)		226 (97.8)	479 (99.4)		111 (98.2)	594 (99.0)	
ECMO duration, median days (IQR)	15.0 (11.0–26.0)	1.0 (0.5–7.0)	0.101	15.0 (11.0–26.0)	1.0 (0.5–7.0)	0.101	7.0 (4.0–10.0)	13.0 (8.0–23.3)	0.505
Viral coinfection**	**49 (10.2)**	**64 (27.6)**	**<0.001**	**7 (3.0)**	**106 (22.0)**	**<0.001**	**113 (100.0)**	**0 (—)**	**<0.001**
RSV	31 (63.3)	44 (68.8)	<0.001	2 (28.6)	73 (68.9)	<0.001	75 (66.4)	0 (—)	<0.001
Discharge status									
Discharged alive	472 (98.1)	230 (99.1)	0.517	227 (98.3)	475 (98.5)	0.595	111 (98.2)	591 (98.5)	0.81
Deceased	9 (1.9)	2 (0.9)		4 (1.7)	7 (1.5)		2 (1.8)	9 (1.5)	

Abbreviations: BIPAP = bilevel positive airway pressure; BMI = body mass index; CPAP = continuous positive airway pressure; ECMO = extracorporeal membrane oxygenation; ICU = intensive care unit; IMV = invasive mechanical ventilation; RSV = respiratory syncytial virus.

* Patients hospitalized for COVID-19 included patients with acute COVID-19 as the primary reason for hospitalization or with acute COVID-19 as a secondary or contributing reason for hospitalization, based on chart review.

† The six children's hospitals were in Arkansas, District of Columbia, Florida, Illinois, Louisiana, and Texas.

§ For children aged ≥2 years, height and weight were used to calculate BMI (kg/m^2). BMI percentiles were calculated using BMI, age, and sex. Those children with BMI percentiles ≥95th percentile were considered to have obesity, and those with BMI ≥120% of the 95th percentile were considered to have severe obesity. BMI data extracted from charts were used if height or weight was missing. If BMI was missing or unable to be calculated, a diagnosis of obesity recorded in charts was used and severity of obesity was unable to be assessed. Obesity was not assessed for children aged <2 years.

¶ Clinical characteristics and outcomes were compared among groups using Pearson's chi-square test for categorical variables and a Kruskal-Wallis test for nonnormally distributed variables.

** Patients were considered to have a viral coinfection if they had ≥1 of the following infections: type A influenza, type B influenza, unspecified influenza, coronavirus 229e, coronavirus hku1, coronavirus nl63, coronavirus 0c43, respiratory syncytial virus, adenovirus, parainfluenza type 1, parainfluenza type 2, parainfluenza type 3, parainfluenza type 4, human metapneumovirus, rhinovirus, enterovirus, or other viral coinfection.

Black or Hispanic in this study; an earlier study demonstrated higher hospitalization rates among Black or Hispanic children compared with White children (*1*).

Approximately two thirds of patients hospitalized for COVID-19, including 83% and 88% of patients aged 5–11 and 12–17 years, respectively, had one or more underlying medical conditions. Approximately two thirds of patients hospitalized for COVID-19 aged 12–17 years had obesity. Compared with patients without obesity, those with obesity required higher levels and longer duration of care. These findings are consistent with previous reports (*4*) and highlight the importance of obesity and other medical conditions as risk factors for severe COVID-19 in children and adolescents.

The proportions of patients admitted to ICU and who required IMV are similar to those in prior reports, which predominantly included hospitalized pediatric COVID-19 patients before Delta variant predominance (*2*,*5*). Adolescents were more likely to require ICU admission and oxygen support compared with other age groups and required the longest median duration of IMV. The median duration of IMV overall (7 days) is consistent with previous reports (*6*,*7*). Approximately one half of patients aged 1–4 years required

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Summary

What is already known about this topic?

Pediatric COVID-19–related hospitalization rates increased when the highly transmissible SARS-CoV-2 B.1.617.2 (Delta) variant became the predominant circulating strain.

What is added by this report?

Among children and adolescents with SARS-CoV-2 infection admitted to six hospitals during July–August 2021, 77.9% were hospitalized for acute COVID-19. Among these patients, approximately one third aged <5 years had a viral coinfection (approximately two thirds of which were respiratory syncytial virus) and approximately two thirds of those aged 12–17 years had obesity; only 0.4% of age-eligible patients were fully vaccinated.

What are the implications for public health practice?

COVID-19 vaccination and other prevention strategies are important to protect children from COVID-19, particularly children with obesity and other underlying health conditions.

oxygen support, which might be related to the high proportion with viral coinfection. This study occurred during July–August 2021, the first period during the COVID-19 pandemic with high circulation of RSV[¶¶¶¶] and other respiratory viruses. Compared with prior studies (*2*,*5*), this study found a high proportion of patients had high-flow nasal cannula as the highest level of respiratory support (37%), which might reflect a change in practice to avoid intubation or the high proportion of viral coinfections, including RSV.

On November 2, 2021, CDC recommended COVID-19 vaccinations for children aged 5–11 years (*8*). As of July 31, 2021, 29% of U.S. persons aged 12–17 years were fully vaccinated against COVID-19.[*****] In this study, only 0.4% of vaccine-eligible adolescents hospitalized for COVID-19 were fully vaccinated. Hospitalization rates have been shown to be 10 times higher among unvaccinated adolescents compared with fully vaccinated adolescents (*2*). Similarly, this study demonstrates that unvaccinated children hospitalized for COVID-19 could experience severe disease and reinforces the importance of vaccination of all eligible children to provide individual protection and to protect those who are not yet eligible to be vaccinated.

The findings in this report are subject to at least five limitations. First, the data came from only six hospitals, five of which are in the southern U.S. region. The proportion of adolescents with obesity in the southern United States is higher than in other regions,[†††††] which might explain the high rates of obesity described in this report. Therefore, findings might not be generalizable to other areas. Second, findings might reflect differences in practices by hospitals or changes in practice over time and might not reflect differences in severity of COVID-19 related to the Delta variant. Third, incomplete or missing data in medical records might lead to underreporting and underestimation of details such as COVID-19 vaccination frequencies. Fourth, at the time of hospitalization, persons aged 12–15 years had only been vaccine-eligible for 2–3 months (*9*), possibly contributing to the low vaccination rates observed. Finally, hospitals identified patients for review based on positive polymerase chain reaction and antigen SARS-CoV-2 test results and hospitalization during the study period. Therefore, proportions of patients with MIS-C are likely underestimated.

Among pediatric patients with COVID-19–related hospitalizations, many had severe illness and viral coinfections, and few vaccine-eligible patients hospitalized for COVID-19 were vaccinated. These data highlight the importance of COVID-19 vaccination for those aged ≥5 years and other prevention strategies to protect children and adolescents from COVID-19, particularly those with obesity and other underlying health conditions. Further research and surveillance for viral coinfections with SARS-CoV-2 in pediatric patients can inform public health and capacity planning (*10*).

[¶¶¶¶] https://emergency.cdc.gov/han/2021/han00443.asp; https://www.cdc.gov/surveillance/nrevss/rsv/natl-trend.html

[*****] https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends

[†††††] https://nccd.cdc.gov/dnpao_dtm/rdPage.aspx?rdReport=DNPAO_DTM.ExploreByTopic&islClass=OWS&islTopic=&go=GO

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Evaluation of a Test to Stay Strategy in Transitional Kindergarten Through Grade 12 Schools — Los Angeles County, California, August 16–October 31, 2021

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On December 17, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

On July 12, 2021, the California Department of Public Health updated COVID-19 school guidance, allowing a Test to Stay (TTS) strategy to increase access to in-person learning* (*1*). The TTS strategy enabled unvaccinated students, exposed in school to a person infected with SARS-CoV-2 (the virus that causes COVID-19), to remain in school while under quarantine, if both the infected person and the exposed person wore masks correctly and consistently throughout the exposure. To stay in school during the quarantine period, the exposed student must remain asymptomatic, wear a mask at school, and undergo twice weekly testing for SARS-CoV-2. To date, few studies have evaluated the impact of TTS on transmission (*2*–*4*). This study evaluated a TTS strategy implemented by Los Angeles County Department of Public Health (LAC DPH). During September 20–October 31, 2021, among 78 school districts, one half permitted TTS; in total, 432 (21%) of 2,067 schools adopted TTS. TTS schools did not experience increases in COVID-19 incidence among students after TTS implementation, and in 20 identified outbreaks in TTS schools,† no tertiary transmission was identified. The ratio of student COVID-19 incidence in TTS districts to that in non-TTS districts was similar before and after TTS adoption (rate ratio = 0.5). Non-TTS schools lost an estimated 92,455 in-person school days during September 20–October 31 while students were in quarantine, compared with no lost days among quarantined students in TTS schools. Non-TTS schools cited resource-related reasons for not adopting TTS; 75% of these schools were in LAC's most disadvantaged neighborhoods. Preliminary data from LAC suggest that a school-based TTS strategy does not increase school transmission of SARS-CoV-2, and might greatly reduce loss of in-person school days; however, TTS might have barriers to implementation and require resources that are not available for some schools. Continued efforts to simplify school quarantine strategies might help to ensure that all students have access to safe in-person education. Although vaccination remains the leading public health recommendation to protect against COVID-19 for persons aged ≥5 years, schools might consider TTS as an option for allowing students with a school exposure who are not fully vaccinated to remain in the classroom as an alternative to home quarantine.

LAC has 78 public school districts with 2,067 schools for students in transitional kindergarten through grade 12.§ Schools require indoor masking, physical distancing where feasible, vaccination, isolation of persons with confirmed cases, contact tracing, quarantining of close contacts, and SARS-CoV-2 testing (*5*). School SARS-CoV-2 testing strategies include weekly testing of asymptomatic, unexposed persons and response testing of persons with symptoms or exposures using SARS-CoV-2 nucleic acid amplification tests or antigen tests. LAC DPH is notified of school COVID-19 cases and close contacts of persons who received positive test results via a secure line list or online survey using REDCap (version 10.3.3; Vanderbilt University).

LAC DPH allowed schools to adopt a TTS strategy starting on September 20, 2021. For asymptomatic, unvaccinated students under quarantine orders,¶ TTS was permitted during the quarantine period if the exposure occurred in school and the exposed student and infected person both wore masks correctly and consistently during the exposure. During TTS, contacts could continue in-person academic activities during regular school hours if they remained asymptomatic, wore a mask while at school (indoors, outdoors, and on school buses), received testing twice weekly by a certified testing program or health care provider,** and agreed to quarantine at home

* California Department of Public Health's Test to Stay strategy in k–12 schools is described in section 8 of the COVID-19 Public Health Guidance for K–12 Schools in California, 2021–22 School Year. https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/K-12-Guidance-2021-22-School-Year.aspx

† A school outbreak was defined as three or more epidemiologically linked COVID-19 school-associated cases within 14 days. Outbreaks that occurred after September 20, 2021, were reviewed. Because students participating in TTS were permitted to continue in-person academic activities in school only while under quarantine, outbreak data review was limited to outbreaks that occurred in an academic setting at school (e.g., classroom outbreak). Outbreaks in youth sports settings were excluded.

§ Los Angeles County Public School Districts do not include independent, independent charter, regional occupational programs, or Los Angeles County Special Education. Transitional kindergarten is a public school program serving to bridge preschool and kindergarten.

¶ Fully vaccinated persons with school exposures are exempt from quarantine but are recommended to test 5–7 days after their last exposure date. A person is considered fully vaccinated 2 weeks after receiving 1) the Janssen (Johnson & Johnson) COVID-19 vaccine; 2) the second dose of a Pfizer or Moderna mRNA COVID-19 vaccine; or 3) completing the series of a COVID-19 vaccine that is listed for emergency use by the World Health Organization.

** For school-based TTS, the California Department of Public Health recommends the same testing cadence as in standard quarantine: testing immediately after notification of the exposure and subsequent testing on or after day 5 following the date of last exposure.

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when not at school. Contacts could not participate in extracurricular activities or before- or after-school care during the quarantine period.

School COVID-19 cases were defined as a laboratory-confirmed SARS-CoV-2 infection in a person who was at school anytime during the 14 days before their episode date (symptom onset date or the positive SARS-CoV-2 test result date, whichever was earlier). School cases were verified with test results reported by laboratories or health care providers to the LAC DPH Integrated Reporting and Investigation Surveillance System (IRIS). Cases among students with episode dates during August 16–October 31 and school exposures of student close contacts during August 17–October 31 were used to calculate secondary infection risk (number of quarantined contacts with a COVID-19 diagnosis 1–14 days after exposure divided by the total number of quarantined contacts).[††] COVID-19 student case rates were calculated as the average daily number of student cases during a 7-day period divided by the number of enrolled students.[§§] COVID-19 student rates are presented with 95% CIs; rates with non-overlapping CIs were considered to be significantly different. COVID-19 student rate ratios were calculated by dividing COVID-19 student case rates in TTS schools by those in non-TTS schools.

School district administrators were interviewed during November 3–16, 2021, to determine whether the district adopted TTS and to assess implementation challenges and reasons for not implementing TTS. TTS districts might have permitted TTS only for certain school levels; therefore, schools were subsequently categorized as having adopted versus not adopted TTS. School outbreak data were reviewed for evidence of tertiary transmission within TTS schools. Tertiary transmission was defined as likely SARS-CoV-2 transmission to a student, from a student participating in TTS who received a positive SARS-CoV-2 test result during the TTS period (i.e., a student with a secondary case). Schools were grouped into quartiles of disadvantage based on the California Healthy Places Index (HPI)[¶¶] (*6*). Zip codes falling within the lowest HPI quartile represented the most disadvantaged neighborhoods. Among non-TTS schools, estimation of lost in-person school days assumed 5 missed school days for each 7-day student quarantine.[***] This analysis was restricted to public school districts; Pasadena Unified School District (USD), Long Beach USD, and non-residents of LAC were excluded.[†††] SAS statistical software (version 9.4; SAS Institute) was used for all analyses. This public health surveillance activity was reviewed and approved by LAC DPH.

An estimated 1,292,067 LAC public school students returned to school for the 2021–22 academic year, which commenced on August 16, 2021, for most LAC public schools. During August 16–October 31, an average of 462,189 student and staff member SARS-CoV-2 tests were conducted each week in all schools. During the week of August 16, 0.6% of test results were positive, but this percentage declined to 0.2% by October 31 (Figure 1). Among all schools, 12,919 student COVID-19 cases (1% of the student population) and 57,513 student contacts (4% of the student population) were reported during the 10-week observation period; case numbers peaked at 2,270 during the week of August 16, and the number of contacts peaked at 8,589 during the week of August 23.

During September 20–October 31, among 78 school districts, 39 (50%) permitted TTS; within these districts, 94% of schools (432 of 452) adopted TTS (Table). These TTS schools constitute 21% of LAC public schools. LAC's largest school district, which accounts for one third of public school students, did not adopt TTS. Overall, within the 1,635 non-TTS schools, 4,322 COVID-19 cases occurred among 967,188 enrolled students (4.7 cases per 1,000 students); among 18,729 student close contacts, the secondary infection risk was 1.3%. Non-TTS districts lost an estimated 92,455 in-person school days during September 20–October 31 while students were in quarantine. Within the 432 TTS schools, among 324,879 enrolled students, 812 COVID-19 cases occurred (2.5 cases per 1,000 students); among 7,511 student close contacts, the secondary infection risk was 0.7%. As a result of the TTS protocol, no in-person school days were lost among quarantined students participating in TTS. Among 20 school outbreaks that occurred in TTS schools after TTS implementation, three outbreaks included four TTS students who were secondarily infected; contact tracing confirmed seven contacts of these patients and identified no tertiary transmission.

[††] Contacts who had a positive SARS-CoV-2 test result 1–14 days after exposure reported in IRIS but not identified by schools were also classified as having secondary infections. In order to correct surveillance data reporting ambiguities, contacts with a positive SARS-CoV-2 test result date the same as the quarantine start date were not considered to have secondary infections.

[§§] School district student enrollment was reported by the California Department of Education for the 2020–21 school year.

[¶¶] California HPI classifies California zip codes into quartiles based on a composite score of disadvantages. Indicators that determine the HPI score include economic, education, transportation, social, neighborhood, housing, clean environment, and health care access. Zip codes falling within the lowest HPI quartile in LAC represent the most disadvantaged neighborhoods.

[***] Number of lost school days assumed that the quarantined students were under a 7-day quarantine period, and the student might be released from quarantine after day 7 from the last date of exposure, if the student remained without symptoms and had a negative SARS-CoV-2 viral diagnostic test result from a specimen collected on or after day 5 from the last date of exposure. It is assumed that every 7-day student quarantine resulted in 5 days of missed in-person school days. This represents the lower bound of missed in-person school days because quarantined persons without symptoms and a SARS-CoV-2 viral diagnostic test during quarantine were subject to a 10-day quarantine period.

[†††] The cities of Long Beach and Pasadena have their own health departments, separate from LAC DPH, and were therefore not included in the analysis.

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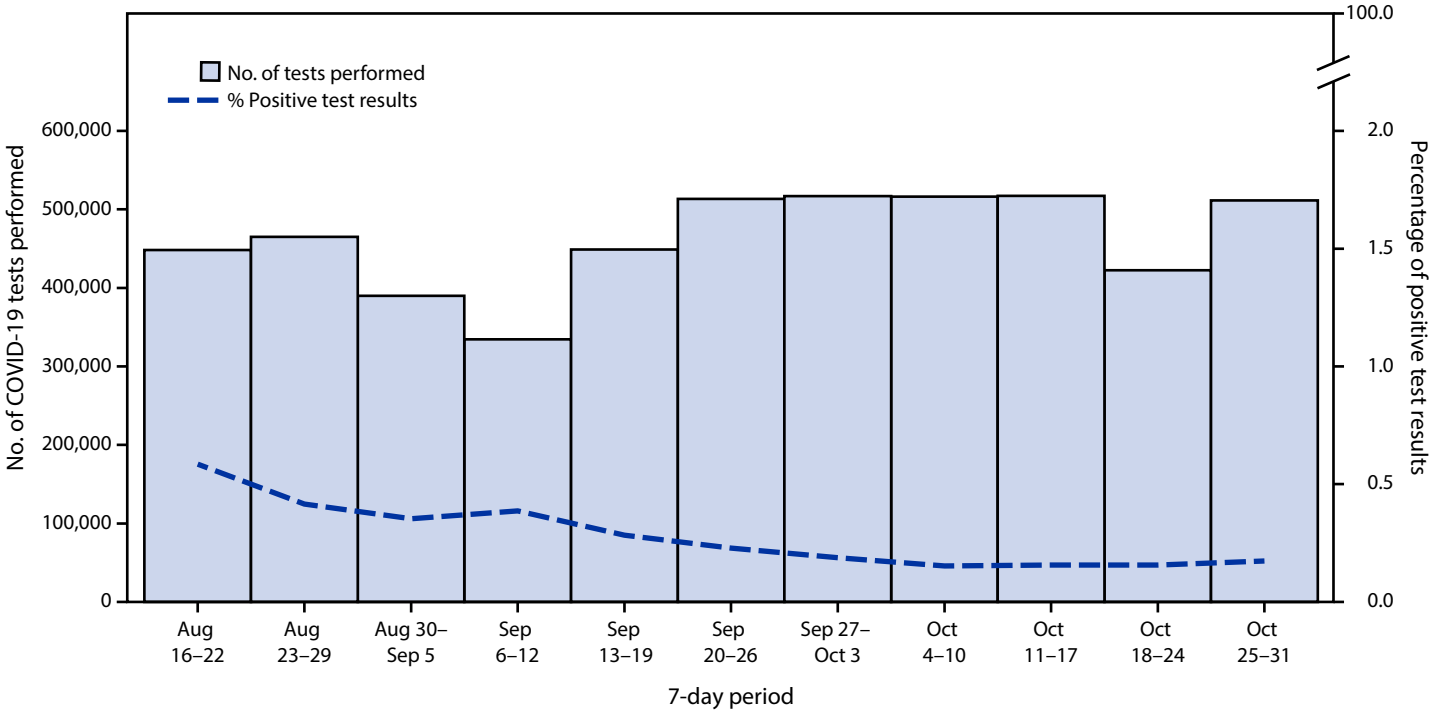
Before TTS adoption (August 16–September 19, 2021), average daily student COVID-19 incidence was lower in TTS districts (10 per 100,000 students; 95% CI = 7–13) than in non-TTS districts (20 per 100,000 students; 95% CI = 18–23) (Figure 2). After TTS adoption, average student daily case rates declined in all districts but remained lower on average in TTS districts (6 per 100,000 students; 95% CI = 3–9) compared with non-TTS districts (11 per 100,000 students; 95% CI = 9–13). The ratio of student COVID-19 incidence in TTS districts to that in non-TTS districts was similar before and after TTS adoption (rate ratio = 0.5). (Figure 2).

FIGURE 1. Number of SARS-CoV-2 tests performed and percentage of positive test results* in transitional kindergarten through grade 12 public school districts — Los Angeles County, California, August 16–October 31, 2021



* Weekly data might have included repeat tests for an individual person.

TABLE. Characteristics of transitional kindergarten through grade 12 public schools, by school Test to Stay status — Los Angeles County, California, September 20–October 31, 2021

Characteristic	Did not implement TTS	Implemented TTS
Schools	**(n = 1,635)**	**(n = 432)**
No. of enrolled students*	967,188†	324,879
Student COVID-19 cases, total	**4,322**	**812**
Elementary school, no. (% of total)	2,403 (56)	341 (42)
Middle school, no. (% of total)	956 (22)	159 (20)
High school, no. (% of total)	963 (22)	312 (38)
Student close contacts of COVID-19 cases,§ total	**18,729**	**7,511**
Elementary school, no. (% of total)	9,177 (49)	2,253 (30)
Middle school, no. (% of total)	4,870 (26)	1,878 (25)
High school, no. (% of total)	4,682 (25)	3,380 (45)
Student secondary infection risk¶	1.3	0.7
Percentage of schools in the most disadvantaged neighborhoods**	74	26

Abbreviations: HPI = Healthy Places Index; LAC = Los Angeles County; TTS = Test to Stay.

* District student enrollment reported by the California Department of Education as of the 2020–21 school year.

† LAC's largest school district, which accounts for one third of public-school students, did not adopt TTS.

§ Student contacts with unknown school level and age were excluded.

¶ Secondary infection risk was defined as the number of quarantined contacts who received a positive SARS-CoV-2 test result 1–14 days after exposure divided by the total number of quarantined contacts. Limited to student school contacts.

** Based on the California HPI, which classifies California zip codes into quartiles based on a composite score of disadvantages. Indicators that determine the HPI score include economic, education, transportation, social, neighborhood, housing, clean environment, and healthcare access. Zip codes falling within the lowest HPI quartile in LAC represent the most disadvantaged neighborhoods. HPI data were missing for 16 non-TTS schools and 22 TTS schools.

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Among the schools that implemented TTS, 107 of 410 (26%) were categorized as most disadvantaged compared with 1,192 of 1,619 (74%) non-TTS schools.[§§§] Challenges cited to TTS implementation were limited staffing and systems to monitor mask use, testing, and lack of family support (Supplementary Table, https://stacks.cdc.gov/view/cdc/112641). Non-TTS districts reported similar resource barriers.

Discussion

Among LAC schools that implemented TTS during September 20–October 31, 2021, COVID-19 incidence did not increase, and tertiary transmission was not identified in school outbreaks after TTS implementation. Non-TTS districts lost substantial in-person school days. Taken together, these findings reinforce the usefulness of TTS for helping to maintain in-person learning in schools.

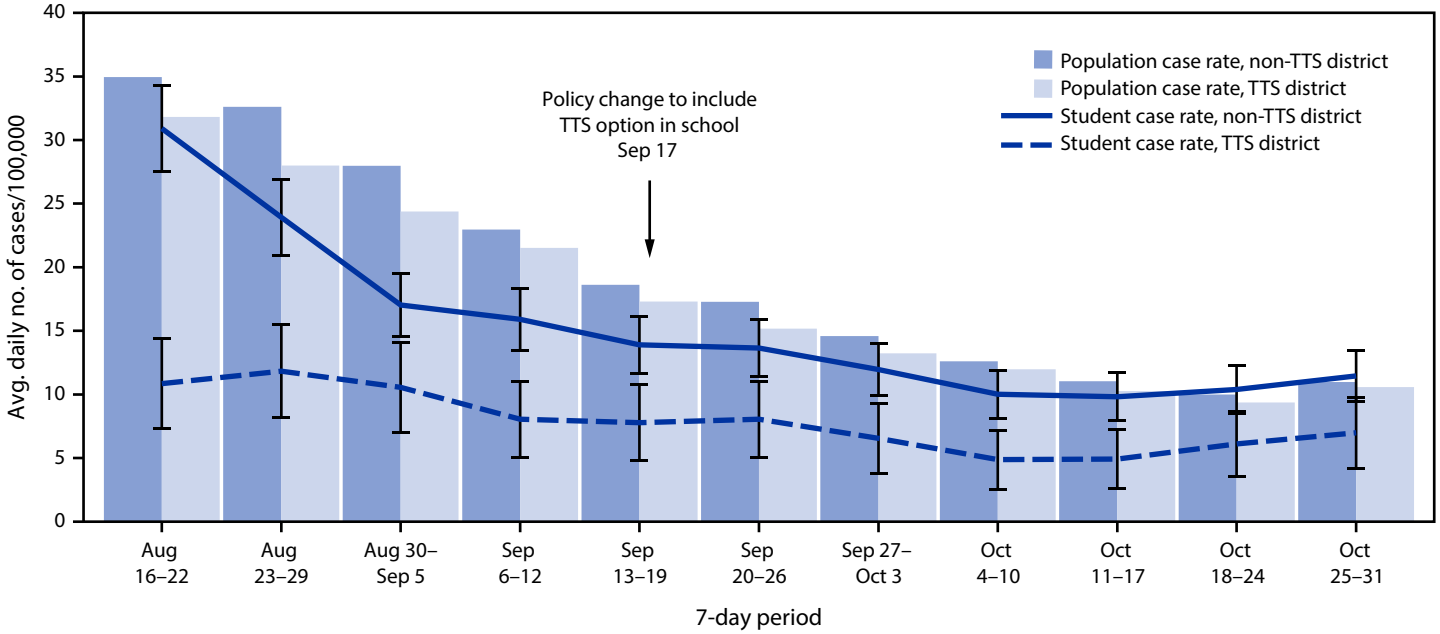
Only one in five public schools in LAC adopted TTS, and non-TTS schools cited resource-related reasons for opting out of TTS. Inability to implement TTS might exacerbate health and educational disparities between TTS and non-TTS schools. Operationalizing TTS requires staffing resources and systems for monitoring eligibility for and compliance to TTS that might not currently be available in schools in disadvantaged communities, including most LAC non-TTS schools. Moreover, because TTS is currently permitted for quarantined students only during regular school hours, families who rely on before- and after-school programs might opt for home quarantine.

The findings in this report are subject to at least three limitations. First, monitoring systems were not established to assess compliance with TTS requirements or designed to evaluate school transmission before and after TTS adoption. Second, this analysis relied on the existing school case reporting system to characterize school transmission after TTS adoption. Because TTS schools were not required to inform LAC DPH about which students participated in TTS, tertiary transmission from a student participating in TTS could not be determined in non-outbreak settings. Finally, rates were unadjusted and did not control for confounders. However, non-TTS schools were disproportionately located in the most disadvantaged neighborhoods, where population case rates tend to be highest (*7*); this might explain the difference in student case rates in TTS and non-TTS schools.

Preliminary data from LAC suggest that a school-based TTS strategy in a large and diverse county did not increase school transmission risk and might greatly reduce loss of in-person school days. Thus, schools might consider TTS as an option for keeping quarantined students in school to continue in-person learning. However, the resources and operational complexities required to implement school-based TTS might present

[§§§] HPI data were missing for 16 (1%) of 1,635 non-TTS schools and 22 (5%) of 432 TTS schools.

FIGURE 2. Student and population COVID-19 case rates,* by school district Test to Stay status — Los Angeles County, California, August 16–October 31, 2021



Abbreviation: TTS = Test to Stay.

* SARS-CoV-2 student case rates were calculated as the average daily number of student cases reported to Los Angeles County Department of Public Health during a 7-day period divided by the number of enrolled students at the school district level. SARS-CoV-2 population case rates were calculated as the average daily number of community cases reported to Los Angeles County Department of Public Health during a 7-day period divided by the population of county residents at the school district level. Standard error bars shown for student case rates.

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Summary

What is already known about this topic?

Los Angeles County Department of Public Health permits Test to Stay (TTS) as a COVID-19 quarantine strategy that allows students with school exposures to remain in school if both infected and exposed persons wore masks.

What is added by this report?

One in five LAC public schools adopted TTS. In TTS schools, student case rates did not increase, and tertiary transmission was not identified. A higher percentage of disadvantaged schools did not implement TTS.

What are the implications for public health practice?

TTS does not appear to increase transmission risk in public schools and might greatly reduce loss of in-person school days. Implementation requires resources that might be currently unavailable for some schools. Vaccination remains the leading recommendation to protect against COVID-19; TTS allows students with a school exposure to remain in the classroom as an alternative to home quarantine.

barriers, particularly for disadvantaged schools. Efforts to better understand barriers and simplify school quarantine strategies might help ensure that all students have access to safe in-person education. Although vaccination remains the leading public health recommendation to protect against COVID-19 for those aged ≥5 years, schools might consider TTS as an option for allowing close contacts who are not fully vaccinated to remain in the classroom as an alternative to home quarantine.

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Evaluation of Test to Stay Strategy on Secondary and Tertiary Transmission of SARS-CoV-2 in K–12 Schools — Lake County, Illinois, August 9–October 29, 2021

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On December 17, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

The COVID-19 pandemic has resulted in school closures and reduction of in-person learning (*1*). In August 2021, the Lake County Health Department (LCHD) in Illinois introduced a Test to Stay (TTS) strategy, whereby unvaccinated students, teachers, and staff members with certain school-related COVID-19 exposures could remain in school and participate in school-related extracurricular activities. Eligibility to participate in TTS required the following conditions to be met: 1) the exposure occurred while both the person with COVID-19 (index patient) and the close contact were masked; 2) the close contact remained asymptomatic, practiced consistent mask wearing, and maintained physical distancing; and 3) the close contact underwent testing for SARS-CoV-2 (the virus that causes COVID-19) on days 1, 3, 5, and 7 after exposure to the index patient. LCHD permitted kindergarten through grade 12 (K–12) schools in Lake County to implement TTS; 90 schools, representing 31 school districts in Lake County, implemented TTS during August 9–October 29, 2021. During the implementation period, 258 COVID-19 cases were reported. Among 1,035 students and staff members enrolled in TTS, the secondary attack risk (number of close contacts who received a positive SARS-CoV-2 test result within 14 days after exposure to an index patient, divided by total number of close contacts) was 1.5% (16 of 1,035). Among the 16 secondary cases identified, all were in students, and none appeared to transmit SARS-CoV-2 to other school-based contacts. However, nine tertiary cases were identified among household contacts of the 16 secondary cases, and four of the nine were fully vaccinated. Assuming a maximum of 8 missed school days for every 10-day quarantine period, up to 8,152 in-person learning days were saved among TTS participants. Implementation of TTS with other concurrent prevention strategies, including masking and physical distancing, limited further spread of SARS-CoV-2 within K–12 schools and allowed students to safely sustain in-person learning. Although vaccination remains the leading public health recommendation to protect against COVID-19 for those aged ≥5 years, schools might consider TTS as an option for allowing close contacts who are not fully vaccinated to remain in the classroom as an alternative to home quarantine.

In fall 2021, LCHD encouraged eligible schools in Lake County, Illinois, to implement TTS. School eligibility criteria included 1) ability to report test results, including index patients and school-based close contacts, to Illinois Department of Public Health (IDPH) and LCHD within 24 hours and 2) school staff members' availability for interviews to provide details regarding school-related exposures. School-based close contacts of persons with COVID-19 were eligible to participate in TTS if both the person with COVID-19 (i.e., index patient) and the contact were masked during the exposure, and the exposure occurred at school or while participating in school-related extracurricular activities. Contacts who met eligibility criteria could participate in TTS if they remained asymptomatic, practiced consistent mask wearing, maintained physical distancing, obtained parental consent, and underwent SARS-CoV-2 testing at school or off campus* on days 1, 3, 5, and 7 after exposure. Asymptomatic TTS participants who received negative SARS-CoV-2 test results and adhered to TTS requirements, including mandatory masking, could ride the school bus and attend in-person learning and school-based extracurricular activities, including sports. TTS participants were required to quarantine at home for 14 days while not attending school or participating in school-based activities. Close contacts were defined as persons who were within 3 feet (0.9 meters) of a COVID-19 patient for ≥15 cumulative minutes over a 24-hour period.† Close contacts who had unmasked exposures within 6 feet (1.8 meters) of a COVID-19 patient were not eligible for TTS and quarantined at home. Persons who were fully vaccinated or who received

* Schools were provided flexibility to recommend that close contacts get off-campus nucleic acid amplification testing or antigen testing through pharmacies, clinics, or community-based testing sites during extended holidays when an interruption in the testing cadence was anticipated or if the school experienced a shortage of testing resources. In addition, some schools might have contracted private laboratories to assist in their testing program.

† Contacts with exposure to COVID-19 outside of school in the 14 days before the school-based exposure were not eligible to participate in TTS. Staff member close contacts were defined as those within 6 ft of a patient with COVID-19 for ≥15 cumulative minutes over a 24-hour period. Before October 18, 2021, a close contact on school transportation was defined by IDPH as being within 6 ft for ≥15 minutes over a 24-hour period. After October 18, 2021, the definition changed to <3 ft for ≥15 minutes over a 24 hour-period and those within 3–6 ft were no longer considered close contacts if both the confirmed patient and the close contact were masked and windows were opened or HEPA air filter was used.

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a COVID-19 diagnosis in the 90 days before exposure were not required to quarantine and were not eligible to participate in TTS.

Schools reported COVID-19 case and close contact information to LCHD via REDCap (version 11.2.6; Vanderbilt University). LCHD staff members called parents of close contacts to identify additional exposures outside of school. Data were supplemented with information from the Salesforce case investigation and contact tracing management system, Illinois' National Electronic Disease Surveillance System (I-NEDSS), and the Illinois state vaccination registry. Among TTS participants, secondary cases were defined as contacts who received a positive SARS-CoV-2 test result by a contact within 14 days after exposure to an index patient. Secondary attack risk of TTS participants was defined as number of close contacts who received a positive SARS-CoV-2 test result within 14 days after exposure divided by total number of close contacts. Estimated in-person learning days saved from TTS was calculated assuming a maximum of 8 missed school days for every 10-day quarantine. All analyses were performed using SAS software (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[§]

During August 9–October 29, 2021, 90 Lake County schools implemented TTS, representing 53.7% (6,267) of staff members and 53.4% (65,384) of public school students in Lake County (*2*). During this period, 258 index COVID-19 patients and 1,664 close contacts were reported. Among 1,068 close contacts eligible for TTS, 1,035 (96.9%) participated (Figure). Among TTS participants, 16 secondary cases were identified, all of whom were in students (Table 1); no secondary cases were identified among staff members. Eleven of the 16 secondary cases occurred among males, and nearly all cases were in non-Hispanic White students. The overall secondary attack risk was 1.5% (16 of 1,035).

The 16 students with secondary cases received their positive test results on days 1 (three students), 2 (two), 3 (two), 4 (two), 5 (four), 6 (one), and 10 (two). Testing after day 7 occurred for those who missed the last day of TTS testing because of school holidays or weekends. Seven of the 16 students with secondary cases were symptomatic on the date of their positive test result, three developed symptoms after receiving a positive test result, and six remained asymptomatic. Based on investigation interviews, the most common likely locations[¶] of COVID-19 exposure among TTS participants were school buses (56.3%), classrooms (32.4%), and school-sanctioned sports (7.4%); among these locations, the secondary attack risks were 1.5%, 0.6%, and 6.5%, respectively (Table 2).

[§] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

[¶] Exposure locations are mutually exclusive. School nurses reported one exposure site per close contact.

TABLE 1. Demographic characteristics of Test to Stay participants by SARS-CoV-2 test results — Lake County, Illinois, August 9–October 29, 2021

Characteristic	Test results of close contacts		
	Positive* (n = 16)	Negative (n = 1,019)	Total (N = 1,035)
Student age, yrs, median (range)	11 (5–16)	10 (3–18)	**10 (3–18)**
Gender, no. (column %)			
Female	5 (31.3)	467 (45.8)	**472 (45.6)**
Male	11 (68.8)	493 (48.4)	**504 (48.7)**
Unknown	0 (—)	59 (5.8)	**59 (5.7)**
Race, no. (column %)			
Black	2 (12.5)	35 (3.4)	**37 (3.6)**
White	14 (87.5)	662 (64.9)	**676 (65.3)**
Asian	0 (—)	71 (7.0)	**71 (6.9)**
American Indian or Alaska Native	0 (—)	7 (0.7)	**7 (0.7)**
Other	0 (—)	136 (13.4)	**136 (13.1)**
Unknown	0 (—)	108 (10.6)	**108 (10.4)**
Ethnicity, no. (column %)			
Hispanic/Latino	1 (6.3)	104 (10.2)	**105 (10.1)**
Not Hispanic/Latino	15 (93.8)	611 (60.0)	**626 (60.5)**
Other	0 (—)	117 (11.5)	**117 (11.3)**
Unknown	0 (—)	187 (18.3)	**187 (18.1)**

* This group represents secondary cases.

Secondary transmission was lowest in elementary schools (1.1%), followed by middle schools (1.3%) and high schools (4.9%).

Assuming a maximum of 8 missed school days for every 10-day quarantine, TTS preserved up to 8,152 in-person learning days for TTS close contacts. None of the 16 secondary cases appeared to transmit SARS-CoV-2 to other school-based contacts. However, nine tertiary cases in five households were identified among household contacts of the 16 secondary cases; four of the nine were fully vaccinated (Figure).

Discussion

Implementation of a TTS strategy with multiple prevention components, including masking and physical distancing, resulted in low secondary transmission of SARS-CoV-2 in K–12 schools in Lake County, Illinois. These findings highlight the usefulness of TTS to limit school-based transmission and sustain in-person learning (*1*,*3*,*4*). Previous research suggests that limited in-person instruction during the pandemic might have had a negative effect on learning and well-being among children (*5*).

Secondary transmission risk to students exposed during school-sanctioned sports was higher than that associated with classroom or school bus exposures. This is consistent with studies showing high transmission among sports participants (*6*,*7*). Also consistent with previous research (*8*), this study found that household contacts of persons exposed at school continue to be at risk for infection; among household contacts of the 16 secondary patients, nine tertiary cases were identified, four in fully vaccinated persons. Schools can help inform parents

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TABLE 2. Grade level and exposure site characteristics of Test to Stay participants by SARS-CoV-2 test results — Lake County, Illinois, August 9–October 29, 2021

Characteristic	Test results of close contacts		
	Positive (n = 16)	Negative (n = 1,019)	Total (N = 1,035)
Grade level/Staff members, no. (row %)			
Teachers/Staff members	0 (—)	2 (100)	**2**
Elementary school students (grades K–5)	7 (1.1)	620 (98.9)	**627**
Middle school students (grades 6–8)	4 (1.3)	299 (98.7)	**303**
High school students (grades 9–12)	5 (4.9)	98 (95.1)	**103**
Location of exposure,* no. (row %)			
Classroom†	2 (0.6)	333 (99.4)	**335**
School bus	9 (1.5)	574 (98.5)	**583**
School-sanctioned sport	5 (6.5)	72 (93.5)	**77**
Extracurricular activity§	0 (—)	6 (100)	**6**
Unknown	0 (—)	34 (100)	**34**

* Exposure locations are mutually exclusive. School nurses reported one exposure site per close contact.
† Classroom exposures include academic classes, indoor recess, physical education class, and staff meetings.
§ Extracurricular activities include drama club and band.

Summary

What is already known about this topic?

COVID-19 transmission within K–12 schools can remain low with implementation of multiple, concurrent prevention strategies.

What is added by this report?

During fall 2021, 90 Lake County, Illinois, schools implemented Test to Stay (TTS), permitting eligible close contacts with masked COVID-19 exposures to remain in school. Secondary transmission among TTS participants was 1.5%; no tertiary transmission was observed among school-based contacts; however, tertiary cases were identified among household contacts. Implementation of TTS preserved up to 8,152 in-person learning days.

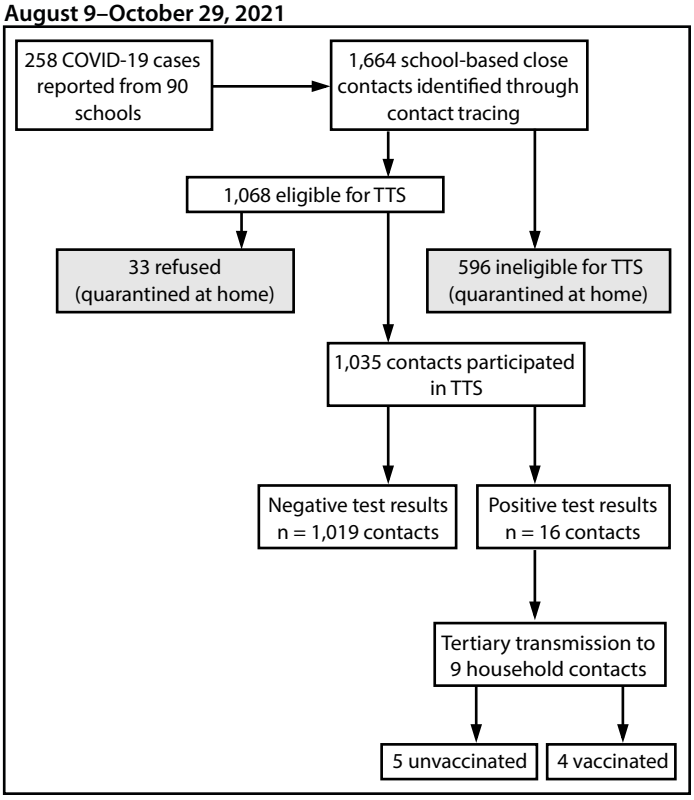
What are the implications for public health practice?

Although vaccination remains the leading recommendation to protect against COVID-19, TTS allows close contacts to remain in the classroom as an alternative to home quarantine.

and guardians about the benefits of COVID-19 prevention strategies, including vaccination.

Although TTS can help limit in-school transmission of SARS-CoV-2, it is a resource-intensive strategy that might be difficult to implement because of increased administrative demands on staff members, requirements for robust contact identification and tracing, and testing availability. Low-resource schools might lack space for physical distancing during lunch, resulting in unmasked exposures within 6 feet, which would disqualify students from TTS eligibility, necessitating home quarantine. Among the 90 TTS schools in this study, 25.6% participated in a subsidized lunch program, compared with 38.1% of schools that did not implement TTS (*9*). Some

FIGURE. Identification of students and staff members who received a positive SARS-CoV-2 test result, school-based close contacts,* and SARS-CoV-2 test results among close contacts — Lake County, Illinois, August 9–October 29, 2021



Abbreviation: TTS = Test to Stay program.
* Ineligibility for TTS includes unmasked exposures within 6 feet of a person with a case of COVID-19 and exposure to a person with a case of COVID-19 outside of school or school-related activities.

schools reported a shortage of testing supplies, requiring TTS participants to access off-site testing, which might have presented a barrier in low-resource school settings. State and local public health and education agencies should strive to ensure that schools in low-resource areas have equitable access to staffing and testing supplies to implement TTS.

The findings in this report are subject to at least seven limitations. First, inequity in school districts' staffing and testing resources might have introduced selection bias because only schools with sufficient resources offered TTS. High-resource schools might have more staffing capacity and physical spacing to apply prevention strategies (e.g., distancing students), which might have resulted in low transmission levels that are not generalizable to low-resource schools. Second, data might not be generalizable to areas with higher COVID-19 incidences and lower vaccination rates; COVID-19 incidence (7-day rolling average number of cases per 100,000 persons) in Lake County ranged from 59.7 to 217.1 over the evaluation period, with 53.5% of the total population vaccinated (*10*). Third, 33% of parents did not respond to LCHD calls or might have chosen not to disclose exposures occurring outside school, resulting in students at high risk being incorrectly enrolled

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in TTS. This would likely have resulted in an overestimation of secondary transmission among TTS participants. Fourth, testing days often deviated from testing cadence because school testing was not conducted on weekends. This deviation might have resulted in a delay of case and close contact identification. Fifth, teachers and staff members had much lower participation rates than did students in this evaluation because of high vaccination rates, low number of exposures meeting close contact definition, and lack of awareness in some schools that adults could participate in TTS. Sixth, households representing three secondary cases were unresponsive to attempted interviews to ascertain tertiary transmission, resulting in incomplete investigations. Finally, this analysis assumes that secondary attack risk represents direct transmission from contacts to cases. Given the unknown exposures and overlapping incubation and infectious periods that occur, distinct generations of transmission might be difficult to ascertain.

Implementation of TTS in coordination with other concurrent prevention strategies, including masking and physical distancing, allowed transmission of SARS-CoV-2 to remain low among K–12 schools in Lake County, Illinois, and saved up to 8,152 in-person learning days. Although vaccination remains the leading public health recommendation to protect against COVID-19 for those aged ≥5 years, schools might consider TTS as an option for allowing close contacts who are not fully vaccinated to remain in the classroom as an alternative to home quarantine.

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MS-DOH-21-1816-A-002021

Investigation of a SARS-CoV-2 B.1.1.529 (Omicron) Variant Cluster — Nebraska, November–December 2021

Lauren Jansen, MD[1,2]; Bryan Tegomoh, MD[1,3]; Kate Lange[4]; Kimberly Showalter[4]; Jon Figliomeni, MHA[1]; Baha Abdalhamid, MD, PhD[5]; Peter C. Iwen, PhD[5]; Joseph Fauver, PhD[6]; Bryan Buss, DVM[1,7]; Matthew Donahue, MD[1]

On December 28, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

The B.1.1.529 (Omicron) variant of SARS-CoV-2 (the virus that causes COVID-19) was first detected in specimens collected on November 11, 2021, in Botswana and on November 14 in South Africa;* the first confirmed case of Omicron in the United States was identified in California on December 1, 2021 (*1*). On November 29, the Nebraska Department of Health and Human Services was notified of six probable cases† of COVID-19 in one household, including one case in a man aged 48 years (the index patient) who had recently returned from Nigeria. Given the patient's travel history, Omicron infection was suspected. Specimens from all six persons in the household tested positive for SARS-CoV-2 by reverse transcription–polymerase chain reaction (RT-PCR) testing on December 1, and the following day genomic sequencing by the Nebraska Public Health Laboratory identified an identical Omicron genotype from each specimen (Figure). Phylogenetic analysis was conducted to determine if this cluster represented an independent introduction of Omicron into the United States, and a detailed epidemiologic investigation was conducted. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.§

The index patient, who was unvaccinated, had a history of domestically acquired symptomatic SARS-CoV-2 infection confirmed by RT-PCR a year prior in November 2020. He reported unmasked close contact¶ with a masked, coughing person on November 20, 2021, during an international conference in Nigeria, which included attendees from multiple African countries. Before his return trip to the United States, he completed required pretravel testing with receipt of a negative antigen test result on November 21. Upon his return on November 23, while still asymptomatic, he had unmasked close contact with five household contacts. One household contact was fully vaccinated** (second Pfizer-BioNTech vaccine dose received in August 2021) and had previous symptomatic COVID-19 (RT-PCR confirmed in November 2020), three were unvaccinated and had previous symptomatic COVID-19 (RT-PCR confirmed in November 2020), and one was unvaccinated and had mild upper respiratory symptoms in November 2020, just before illness onset in the other household members, but received a negative SARS-CoV-2 RT-PCR test result at that time. No household members reported underlying medical conditions or immunocompromising conditions known to increase the risk for severe COVID-19 or diminish response to vaccination.††

On November 24, 2021, the index patient experienced symptoms consistent with COVID-19§§ and initially received a positive SARS-CoV-2 antigen test result from a local medical center on November 26. All six household members (median age = 18.5 years; range = 11–48 years) experienced symptom onset during November 24–26; median interval between earliest possible exposure to the index patient and symptom onset was 73 hours (range = 33–75 hours). The index patient and the four household contacts with previous confirmed infections described the symptoms and severity of their recent COVID-19 infection as being similar to or milder than those during their first infection. The five reinfected patients experienced fewer current symptoms, including loss of taste (none), loss of smell (none), and subjective fever (two), compared with symptoms reported during their first infections (four, four, and four, respectively). The unvaccinated patient without a previous COVID-19 diagnosis experienced cough, joint pain, congestion, fever, and chills. None required hospitalization for either their first or second infections. Twelve close community contacts of the family were identified. Four consented to testing for SARS-CoV-2 (median of 10.5 days postexposure; range = 10–11 days); specimens from these four close contacts tested negative.

Epidemiologic and clinical features of Omicron infection are still being described. Observations from this investigation, which included one patient who experienced reinfection¶¶ after having been fully vaccinated, four patients who experienced reinfection,

* https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html

† https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/

§ 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

¶ https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html#closecontact

** https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#:~:text=A%20person%20is%20considered%20fully,for%20fully%20vaccinated%20people

†† https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

§§ Abdominal pain, diarrhea, fatigue, headache, muscle aches, chest pressure, chills, subjective fever, cough, runny nose, sore throat, and dizziness.

¶¶ https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/#:~:text=The%20following%20should%20be%20enumerated%20as%20a%20new%20case

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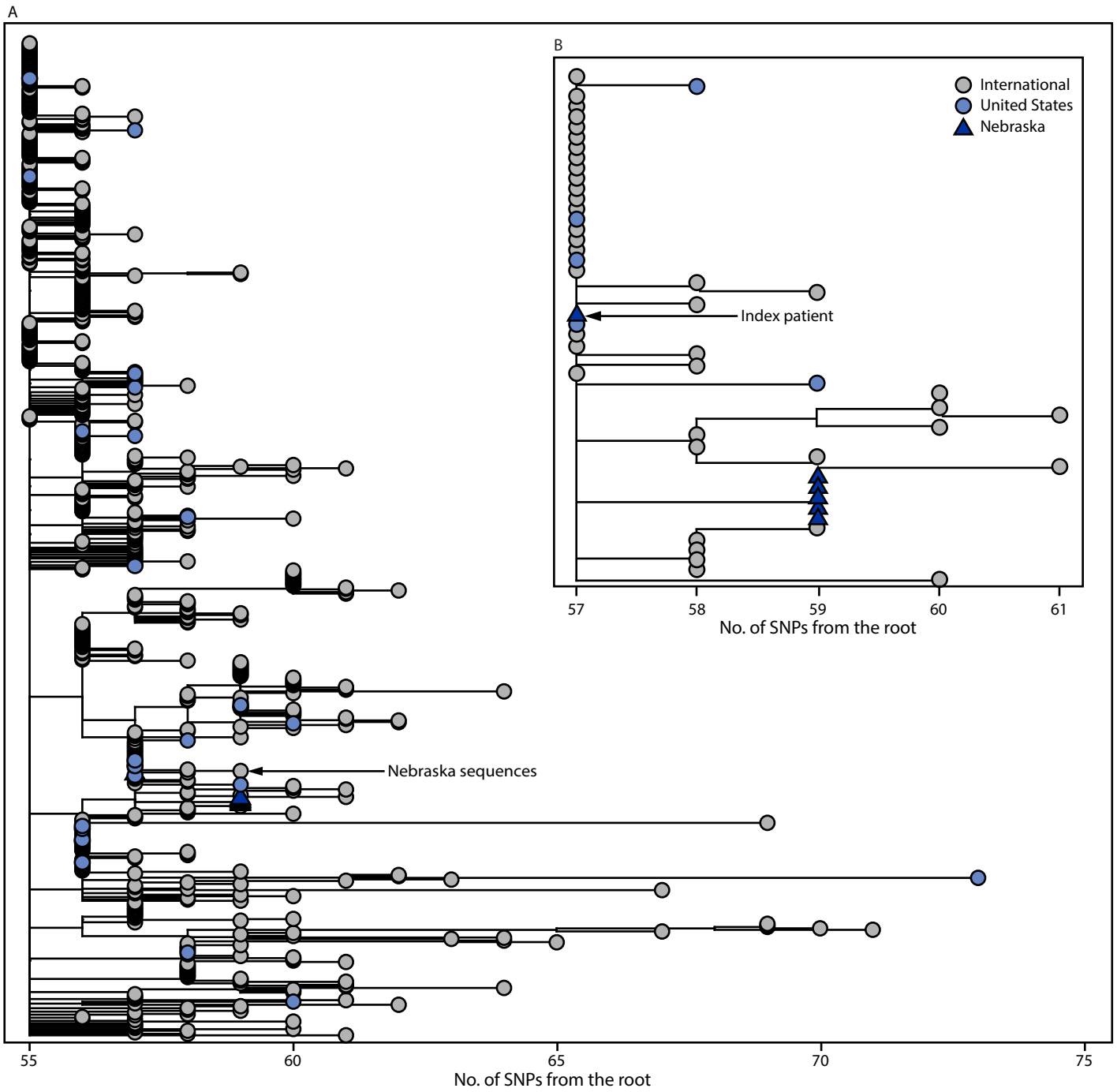
FIGURE. Global phylogeny of B.1.1.529 (Omicron) samples available on Global Initiative on Sharing All Influenza Data* as of December 6, 2021 (650 total genomes) (A) and expanded view of Omicron sequences† (B) — Nebraska, November–December 2021§,¶,,††,§§**



Abbreviation: SNP = single nucleotide polymorphism.

* https://www.gisaid.org

† Branch lengths are shown in number of mutations from the root. The maximum-likelihood phylogenetic trees are rooted with the original SARS-CoV-2 genome Wuhan/Hu-1/2019.

§ Each of the six SARS-CoV-2 genomes generated from this cluster is >94% complete and shares 100% nucleotide identity across the length of the genome, consistent with household transmission.

¶ Genomes from the five secondary cases have SNPs at nucleotide positions T1552C and C23709T that are not yet found in other Omicron genomes sampled.

** The genome from the index patient, NCOV21-42615, has the ambiguous nucleotide "N" at positions 1552 and 23709 and further inspection of the read-level data showed nucleotide variability at both sites. The SNP allele frequency at these sites in the NCOV21-42615 genome is >50%, consistent with epidemiologic findings of household transmission from the index patient to all secondary cases.

†† https://academic.oup.com/bioinformatics/article/34/23/4121/5001388

§§ https://onlinelibrary.wiley.com/doi/full/10.1111/2041-210X.12628

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and one who experienced their first infection, suggest a shorter incubation period and a clinical syndrome similar to or milder than that associated with previously described variants in persons who have been vaccinated or previously infected, and add to existing evidence suggesting an increased potential for reinfection.*** Whereas the median SARS-CoV-2 incubation period has been described as ≥5 days (*2*,*3*), and closer to 4 days for the SARS-CoV-2 B.1.617.2 (Delta) variant,††† the median incubation period§§§ observed in this cluster was approximately 3 days. Although few clinical descriptions of Omicron infections are available, mild illness among vaccinated patients has been reported (*4*). It is unknown whether the mild clinical syndromes or differing symptom descriptions are a result of existing immunity or altered clinical features associated with Omicron infection. The five reinfections, including one after full vaccination, might be explained by waning immunity, the potential for partial immune evasion by Omicron, or both. Conclusions drawn from these observations are limited by small sample size. More data will be needed to fully understand the epidemiology of the Omicron variant.

Travel history of the index patient and phylogenetic analysis of the secondary cases indicate an international introduction of the Omicron variant, consistent with other early cases identified in the United States (*1*). The recent emergence of Omicron, which is now projected to be the dominant variant in the United States,¶¶¶ reinforces the importance of vaccination, in coordination with other prevention strategies (e.g., masking and physical distancing), to protect people from COVID-19, slow transmission, and reduce the likelihood of new variants emerging. In addition, the rapid identification and epidemiologic characterization of this cluster underscore the importance of robust and timely genomic surveillance to detect and respond to emerging SARS-CoV-2 variants of concern.

*** https://www.medrxiv.org/content/10.1101/2021.11.11.21266068v2
††† https://www.medrxiv.org/content/10.1101/2021.07.07.21260122v2
§§§ Incubation period is defined as the interval from earliest possible exposure of household contacts to the index patient until symptom onset.
¶¶¶ https://covid.cdc.gov/covid-data-tracker/#variant-proportions

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Nebraska's genomic surveillance consortium (Nebraska Public Health Laboratory, Creighton University, CHI Health Laboratory [Core Lab] and CHI Health network, the College of Public Health at the University of Nebraska Medical Center); Sharon Clouse, Michele Vana, Public Health Solutions District Health Department; Stacey Bosch, Epidemiology Workforce Branch, CDC.

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[1]Nebraska Department of Health and Human Services; [2]Epidemic Intelligence Service, CDC; [3]CDC Foundation, Atlanta, Georgia; [4]Public Health Solutions District Health Department, Crete, Nebraska; [5]Nebraska Public Health Laboratory, Omaha, Nebraska; [6]College of Public Health, University of Nebraska Medical Center, Omaha, Nebraska; [7]Division of State and Local Readiness, Center for Preparedness and Response, CDC.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Joseph Fauver reports that he is a consultant with Tempus Labs to conduct SARS-CoV-2 genomic surveillance in the National Football League. Peter C. Iwen reports support from the American Rescue Plan Act of 2021 ELC Epi and Lab Capacity for Genomic Sequencing from the U.S. Department of Health and Human Services and the Paycheck Protection Program and Health Care Enhancement Act ELC Epi and Lab Capacity from the U.S. Department of Health and Human Services. No other potential conflicts of interest were disclosed.

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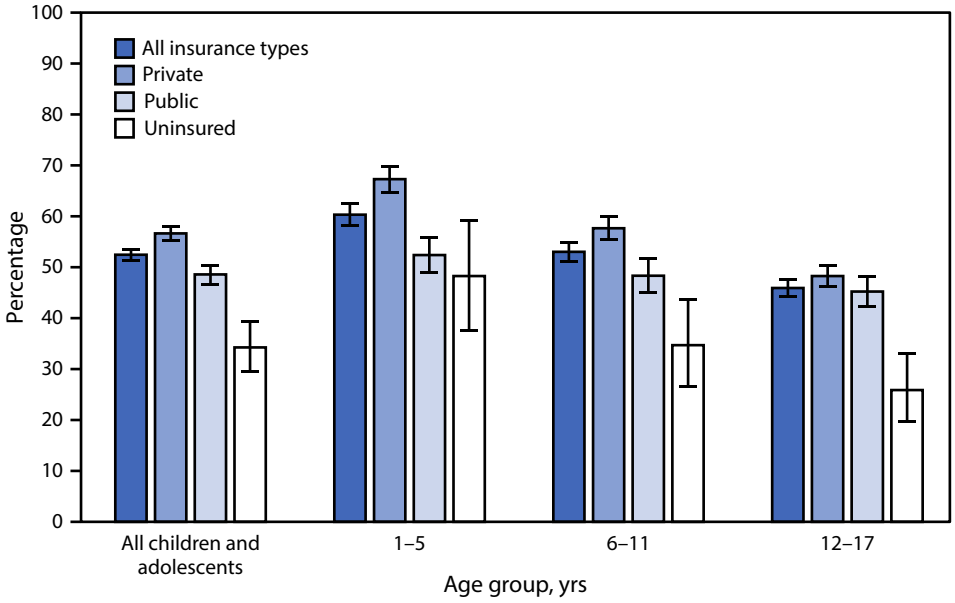
MS-DOH-21-1816-A-002024

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage* of Children and Adolescents Aged 1–17 Years Who Received an Influenza Vaccine Within the Past 12 Months,† by Health Insurance Coverage§ and Age Group — National Health Interview Survey, United States, 2019–2020¶



* With 95% CIs indicated with error bars.

† Based on an affirmative response to the question, "There are two types of flu vaccinations. One is a shot and the other is a spray, mist, or drop in the nose. During the past 12 months, have you had a flu vaccination?" Annual calendar-year estimates of vaccinations are presented, which might differ from seasonal influenza vaccination totals that reflect vaccinations obtained during the influenza season.

§ Health insurance coverage is based on the status at the time of interview. Private insurance includes plans obtained through an employer, purchased directly, and received through local and community programs. Public insurance includes persons without private insurance who reported Medicaid, Children's Health Insurance Program, or other state-sponsored health plans. In addition to those without coverage, uninsured includes a very small percentage of children and adolescents who only have Indian Health Service coverage or a private plan that paid for only one type of service.

¶ Estimates are based on household interviews of a sample of the civilian, noninstitutionalized U.S. population.

Throughout calendar years 2019–2020, 52.4% of children and adolescents aged 1–17 years received an influenza vaccine within the previous 12 months. The percentage was highest in children and adolescents with private insurance (56.6%), followed by those with public insurance (48.6%), and lowest in the uninsured (34.2%). This pattern was seen in each age group. The percentage of children and adolescents who received an influenza vaccine decreased with increasing age from 60.3% in children aged 1–5 years, to 53.0% in those aged 6–11 years, to 45.9% in adolescents aged 12–17 years. The decrease with age group was seen for each insurance type. Privately insured children aged 1–5 years had the highest rate of influenza vaccination, and uninsured adolescents aged 12–17 years had the lowest rate.

Source: National Center for Health Statistics, National Health Interview Survey, 2019–2020. https://www.cdc.gov/nchs/nhis.htm

Reported by: Cynthia Reuben, MA, creuben@cdc.gov, 301-458-4458; Nazik Elgaddal, MS.

For more information on this topic, CDC recommends the following link: https://www.cdc.gov/flu/prevent/vaccinations.htm

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The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit *MMWR* at *https://www.cdc.gov/mmwr/index.html*.

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From: ASPRStakeHolderNoReply (OS/ASPR) <ASPRStakeHolderNoReply@hhs.gov>
Sent: Wednesday, December 29, 2021 3:22 PM
To: COVID19-Therapeutics (OS/ASPR) <COVID19.Therapeutics@hhs.gov>
Cc: ASPR Stake Holder (OS/ASPR) <ASPRStakeholder@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>
Subject: UPDATE – HHS Allocation of bam/ete and REGEN-COV therapeutics

Dear State and Territorial Health Officials,

The U.S. Department of Health and Human Services (HHS) continues to assess the COVID-19 environment to further inform the allocation and distribution of COVID-19 therapeutics.

Based on recent data and assessment, HHS will pause allocations of bamlanivimab/etesevimab and REGEN-COV COVID-19 therapeutics to states or territories within regions of the country that have greater than 80% prevalence of the Omicron variant based on CDC NOWCAST data. These two products are not expected to be effective in patients infected with the Omicron variant, and other therapeutic options are available. The purpose of this pause is to ensure effective product is available in most sites. In regions that have less than 80% prevalence of the Omicron variant, states and territories will continue to receive allocations of the two products to use as clinically appropriate.

If monoclonal antibody treatment sites are able to utilize testing to distinguish between variants (i.e., infections caused by Omicron vs. Delta) and can subsequently treat those individuals within the appropriate treatment window, even in regions that have greater than 80% Omicron variant, states and territories will be able to continue requesting bam/ete and REGEN-COV provided by HHS. Sites that have the test and treat capability and wish to continue receiving bam/ete and REGEN-COV products should submit requests through their state or territorial health department. Health departments can then make the requests directly through their ASPR Regional Emergency Coordinator.

We encourage you to review the updated Food and Drug Administration (FDA) Health Care Provider Fact Sheets for bam/ete and REGEN-COV as they contain specific information regarding expected activity against the Omicron variant. Additionally, health departments and healthcare providers should continue to assess local data and review current National Institutes of Health (NIH) guidelines to help inform treatment decisions.

Thank you for your continued focus and efforts throughout the pandemic. Please contact your ASPR Regional Emergency Coordinator or email us at COVID19Therapeutics@HHS.gov with questions regarding the allocation of bam/ete and REGEN-COV.

Regards,
The Federal COVID-19 Response Team

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Jan. 11 (incl. CDC Partner Alerts, HHS Update, COCA Call, and more)
Date:	Tuesday, January 11, 2022 4:19:27 PM
Attachments:	image001.png image002.png N95 effectiveness as source control .pdf PARTNER ALERT CDC Expands Booster Shot Eligibility.msg COVID-19 Partner Updates January 10 2022.msg HHS Therapeutics Projected Allocations_7 Jan 2022.pdf HHS Update COVID-19 allocation projections for January .pdf Lindsley-2021-A comparison of performance metr.pdf Lindsley-2021-Efficacy of face masks, neck gai.pdf

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Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Partner Alert: N95 Effectiveness as Source Control [Attachments]
  - Today, **Tuesday, January 11**, CDC issued a partner update (attached) in response to numerous questions about N95 mask effectiveness as source control. The update shared two peer reviewed publications from National Institute for Occupational Safety and Health (NIOSH) researchers (both attached) on N95 mask effectiveness, including findings that a N95 respirator was 99% effective at blocking cough aerosols.
- HHS Update: COVID-19 Allocation Projections for January [Attachments]
  - On **Friday, January 7**, the U.S. Department of Health and Human Services (HHS) issued an update with a projected calendar of allocation amounts and cadence of COVID-19 therapeutics for the remainder of January (attached). Questions may be directed to us COVID19Therapetuics@hhs.gov.
- Partner Alert: CDC Expands Booster Shot Eligibility [Attachment, Link]
  - On **Saturday, January 6**, CDC issued a partner alert (attached) adjusting its recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months. CDC has extended this recommendation to recipients of a Moderna primary series. This means that people 12 years of age and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.

- CDC COCA Call: What Clinicians Need to Know About the New Oral Antiviral Medications for COVID-19 [Links]
    - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **tomorrow, Wednesday, January 12 at 2:00 pm EST** to discuss the recent emergency use authorizations (EUAs) for new oral antiviral medications intended to decrease hospitalizations, as well as prevent severe COVID-19 and death Call information is below:
        - Weblink: https://www.zoomgov.com/j/1612974214?pwd=VitYMEorako1YWhCaXpnaWdsc2Ixdz09
          Telephone: (660) 254-5252 or (646) 828-7666 or (669) 216-1590 or (551) 285-1373
          Webinar ID: 161 297 4214
          Passcode: 180866
          Post-Event Recording:
          https://emergency.cdc.gov/coca/calls/2021/callinfo_011222.asp
- Reminder: CDC Preventive Medicine Grand Rounds: "The Public Health System of the Future – Moving Ahead in Partnership with Health Care & Other Sectors" [Link]
    - CDC will host its monthly Preventive Medicine Grand Rounds **tomorrow, Wednesday, January 12** at **1:30 pm EST**. The session will focus on the public health system of the future and the speaker is John Auerbach, Director of Intergovernmental and Strategic Affairs for CDC. Continuing education (CE) is available at no cost. Registration information is available here.

Standing Updates

- CDC Partner Update – January 10 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – January 10 [Link]
    - Please click here for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am ET**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]

- CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Monday, January 10, 2022 4:53 PM EST
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>
Subject: COVID-19 Partner Updates: January 10, 2022

Good afternoon Partners,
Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC at eocevent424@cdc.gov. Thank you for your partnership.

January 10, 2022

Morbidity and Mortality Weekly Report (MMWRs)

- Effectiveness of BNT162b2 (Pfizer-BioNTech) mRNA Vaccination Against Multisystem Inflammatory Syndrome in Children Among Persons Aged 12–18 Years — United States, July–December 2021. Link here.
- Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 years — United States, March 1, 2020–June 28, 2021. Link here.
- Risk Factors for Severe COVID-19 Outcomes Among Persons Aged ≥18 Years Who Completed a Primary COVID-19 Vaccination Series — 465 Health Care Facilities, United States, December 2020–October 2021. Link here.
- Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021. Link here.

CDC Resources

New & Updated

- CDC Recommends Moderna Booster at 5 Months: On January 4th, CDC made this recommendation for recipients of a Pfizer-BioNTech primary series. After FDA action on January 7th, we're extending this recommendation to recipients of a Moderna primary series. This means that people who initially received an mRNA vaccine series——two doses of Moderna or Pfizer-BioNTech —can now receive an mRNA booster shot 5 months after completing their initial series.
- Guidance for COVID-19 Prevention in K-12 Schools was recently updated to reflect new recommendations for isolation for people with COVID-19 and recommendations for people who have come into close contact with a person with COVID-19.
- CDC Expands Booster Shot Eligibility and Strengthens Recommendations for 12-17 Year Olds: CDC now recommends that adolescents age 12 to 17 years old should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccination series.
- CDC Recommends Pfizer Booster at 5 Months, Additional Primary Dose for Certain Immunocompromised Children: On January 4th, CDC updated its recommendation for when many people can receive a booster shot, shortening the interval from 6 months to 5 months for people who received the Pfizer-BioNTech COVID-19 Vaccine.
- Stay Up to Date with Your Vaccines: To align with standard language CDC uses about other vaccinations, CDC is now using the phrase "up to date" when talking about COVID-19 vaccination. CDC recommends that individuals stay "up to date" by receiving any additional doses they are eligible for, according to CDC's recommendations, to ensure they have optimal protection against COVID-19. The technical definition of "fully vaccinated"—two doses of an mRNA vaccine or one dose of the J&J vaccine—has not changed.
- What We Know About Quarantine and Isolation provides information on why CDC shortened quarantine and isolation guidance for the general population.

School and Work

- Guidance for COVID-19 Prevention in K-12 Schools
- Overview of COVID-19 Isolation for K-12 Schools
- Overview of COVID-19 Quarantine for K-12 Schools
- What you Should Know About COVID-19 Testing in Schools
- Responding to COVID-19 Cases in K-12 Schools: Resources for School Administrators
- Schools, Child Care, and Colleges
- Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2
- Strategies to Mitigate Healthcare Personnel Staffing Shortages
- School Learning Modalities (HHS Protect Public Data Hub)

Community

- Communication Resources for Travelers
- CDC COVID-19 Travel
- 12 COVID-19 Vaccination Strategies for Your Community
- Find a COVID-19 vaccine near you: Vaccines.gov
  - Individuals in the U.S. can utilize a text messaging service to locate vaccine locations, available in both English and Spanish. Individuals can text their ZIP code to 438829 (GETVAX) and 822862 (VACUNA) to find three locations nearby that have vaccines available.

Science and Data

COVID-19 Variants

- Science Brief: Omicron (B.1.1.529) Variant provides an overview of the current scientific information regarding the Omicron (B.1.1.529) variant. New data continue to emerge, and recommendations will be updated periodically, as needed.
- Omicron Variant: What You Need to Know provides information on what is currently known about the Omicron (B.1.1.529) variant.
- What You Need to Know About Variants

COVID-19 Testing Guidance

- Testing Strategies for SARS-CoV-2 describes and compares different types of testing strategies for SARS-CoV-2.
- Self-Testing provides information on when, why, and how to use a self-test for COVID-19.

Influenza (flu) Guidance

- Increasing Seasonal Influenza A (H3N2) Activity, Especially Among Young Adults and in College and University Settings, During SARS-CoV-2 Co-Circulation
- FAQ: CDC Distribution of COVID-19 Assays
- CDC Digital Media Toolkit: 2021-22 Flu Season

COVID-19 Vaccines

- CDC Endorses ACIP's Updated COVID-19 Vaccine Recommendations
- CDC Expands COVID-19 Booster Recommendations to 16-and-17-year-olds
- COVID-19 Vaccine Booster Shots
- COVID-19 Vaccines for Children and Teens
- COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19: CDC strongly recommends COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.
- Science Brief: Evidence Used to Update the List of Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19
- Quick Conversation Guide on COVID-19 Vaccines for Children
- Resources to Promote the COVID-19 Vaccine for Children & Teens
- Using the COVID-Vac Tool to Assess Your COVID-19 Vaccination Clinic Staffing and Operations Needs

References to non-CDC sites are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites. URL addresses listed were current as of the date of publication.

Kind regards,
Shyonna Johnson, MPH (She/Her)
STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
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CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

DRAFT – PRE-DECISIONAL & DELIBERATIVE

Therapeutic Allocation

	Drug Class	Allocation Cadence	Sweep Schedule	Allocation Jan 3	Planned Allocation Jan 10	Planned Allocation Jan 17	Planned Allocation Jan 24	Planned Allocation Jan 31
Paxlovid *Pfizer*	Oral antiviral	Bi-Weekly	N/A	0	100,000	0	100,000	0
Molnupirivir *Merck*	Oral antiviral	Bi-Weekly	N/A	0	400,000	0	400,000	0
Evusheld *AstraZeneca*	Monoclonal for prevention	Weekly	N/A	50,000	75,000	75,000	75,000	75,000
Sotrovimab *GSK/Vir*	Monoclonal for treatment	Weekly	N/A	50,000	52,250	52,250	52,250	52,250
Bamlanivimab/ Etesevimab *Lilly*	Monoclonal; omicron resistance	Weekly	Weekly; Saturday	45,000	**45,000*	**45,000*	**45,000*	**45,000*
REGEN-COV *Regeneron*	Monoclonal, omicron resistance	Weekly	Weekly; Saturday	55,000	**55,000*	**55,000*	**55,000*	**55,000*
Remdesivir *Gilead*	IV antiviral	N/A; Commercial Market	N/A	N/A	N/A	N/A	N/A	N/A

** With the rise of the omicron variant, clinically appropriate use should be considered for bam/ete and REGEN-COV. Allocations of these products are subject to change based on omicron prevalence data.*

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From: ASPR Stake Holder (OS/ASPR) <ASPRStakeholder@hhs.gov>
Sent: Friday, January 7, 2022 5:41:02 PM
Subject: HHS Update: COVID-19 allocation projections for January

Dear State and Territorial Health Officials,

Thank you for your continued partnership in this all-of-America approach to fighting the COVID-19 pandemic. It remains our goal to facilitate a fair and equitable process in the allocation of COVID-19 therapeutics, and we certainly couldn't do this without you. We know that providing a longer look ahead for expected allocation amounts will help further support your jurisdictional planning. As such, attached is a projected calendar of allocation amounts and cadence for the remainder of January. Of course, the COVID-19 environment is very dynamic; so, these projections could change based on daily analysis of related data.

Additionally, we wanted to provide you with an update regarding Gilead's product - VEKLURY(tm) (remdesivir), which is not allocated by the federal government but is available commercially. Following the recent statement from the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel regarding therapies for the COVID-19 Omicron variant, CMS created HCPCS code J0248 for the VEKLURY(tm) (remdesivir) antiviral medication when administered in an outpatient setting. This code is available for use by all payers and is effective for dates of service on or after December 23, 2021:

* Long descriptor: Injection, remdesivir, 1 mg
* Short descriptor: Inj, remdesivir, 1 mg

Medicare Administrative Contractors (MACs) determine Medicare coverage when there is no national coverage determination, including in cases when providers use FDA-approved drugs for indications other than what is on the approved label. The MACs consider the major drug compendia, authoritative medical literature and accepted standards of medical practice to determine medical necessity when considering coverage. Therefore, the MACs will determine Medicare coverage for HCPCS code J0248 for VEKLURY(tm) (remdesivir) administered in an outpatient setting.

Thank you, again, and please contact us at COVID19Therapetuics@hhs.gov with any questions.

Regards,
HHS - Coordination Operations and Response Element (H-CORE)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

CSTE

Aerosol Science and Technology

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A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols

William G. Lindsley, Francoise M. Blachere, Donald H. Beezhold, Brandon F. Law, Raymond C. Derk, Justin M. Hettick, Karen Woodfork, William T. Goldsmith, James R. Harris, Matthew G. Duling, Brenda Boutin, Timothy Nurkiewicz, Theresa Boots, Jayme Coyle & John D. Noti

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AEROSOL SCIENCE AND TECHNOLOGY
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A comparison of performance metrics for cloth masks as source control devices for simulated cough and exhalation aerosols

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ABSTRACT

Universal mask wearing is recommended to help control the spread of COVID-19. Masks reduce the expulsion of aerosols of respiratory fluids into the environment (called source control) and offer some protection to the wearer. Masks are often characterized using filtration efficiency, airflow resistance, and manikin or human fit factors, which are standard metrics used for personal protective devices. However, none of these metrics are direct measurements of how effectively a mask blocks coughed and exhaled aerosols. We studied the source control performance of 15 cloth masks (face masks, neck gaiters, and bandanas), two medical masks, and two N95 filtering facepiece respirators by measuring their ability to block aerosols $\leq$7 µm expelled during simulated coughing and exhalation (called source control collection efficiency). These measurements were compared with filtration efficiencies, airflow resistances, and fit factors measured on manikin headforms and humans. Collection efficiencies for the cloth masks ranged from 17% to 71% for coughing and 35% to 66% for exhalation. Filtration efficiencies for the cloth masks ranged from 1.4% to 98%, while the fit factors were 1.3 to 7.4 on headforms and 1.0 to 4.0 on human subjects. The Spearman's rank correlation coefficients between the source control collection efficiencies and the standard metrics ranged from 0.03 to 0.68 and were significant in all but two cases. However, none of the standard metrics were strongly correlated with source control performance. A better understanding of the relationships between source control collection efficiency, filtration efficiency, airflow resistance, and fit factor is needed.

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Yannis Drossinos

Introduction

Humans infected with SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), can produce droplets and aerosols of respiratory fluids containing the virus when they cough, breathe, talk, sing and sneeze (Anderson et al. 2020; CDC 2020b; Hamner et al. 2020; Ma et al. 2020; Morawska and Milton 2020). To reduce the transmission of SARS-CoV-2, public health agencies have recommended that the general public wear cloth masks (CDC 2020c, 2020d, 2021; Edelstein and Ramakrishnan 2020; WHO 2020). The primary purpose of masks (which in this article includes face masks, neck gaiters, bandanas and other face coverings) is to block the expulsion of infectious droplets and aerosols from the wearer into the environment (called source control) and thereby reduce the exposure of other people to the virus (CDC 2020a). Laboratory studies using manikins and human subjects have shown that cloth face masks can partially block respiratory aerosols produced during coughing, breathing and talking (Asadi et al. 2020; Davies et al. 2013; Lindsley et al. 2021; Pan et al.

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2021). Wearing medical face masks (i.e., "surgical masks" as defined by the U.S. Food and Drug Administration [FDA 2004]) reduces the dispersion of potentially infectious aerosols from patients with respiratory infections (Leung et al. 2020; Milton et al. 2013). Masks may also provide some personal protection to the wearer by reducing their exposure to infectious droplets and aerosols produced by others, although they are not as effective as a respiratory protective device such as a NIOSH-approved N95 filtering facepiece respirator (N95 respirator) (CDC 2020a; Lawrence et al. 2006; Oberg and Brosseau 2008; Pan et al. 2021). Several community level studies have shown that universal masking helps reduce the spread of COVID-19 (CDC 2020a). For example, a comparison of counties in the US state of Kansas found that mask mandates were associated with lower incidence rates of COVID-19 (Van Dyke et al. 2020). A study of 10 US states found that statewide mask mandates were associated with a decline in weekly COVID-19–associated hospitalization growth compared to states without such mandates (Joo et al. 2021).

In response to the need for source control devices for the general public, manufacturers worldwide have produced a broad array of masks. Unfortunately, because of the many different designs and construction materials, it is not possible to predict how well a particular mask will perform as a source control device without testing, which is rarely done for non-medical masks not intended for occupational use. Although general guidelines have been developed (CDC 2020d), it is very difficult for public health organizations, governments, medical facilities, and the general public to know which of the available devices are most effective.

Test methods and performance standards do exist for regulated medical face masks and respiratory protective devices (Rengasamy et al. 2017). In the United States, respiratory protective devices, which are devices such as N95 filtering facepiece respirators that are intended to protect the wearer from airborne particles, must be approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 Code of Federal Regulations (CFR) Part 84 (NIOSH 1995). The approval process includes testing the filtration efficiency for the most-penetrating aerosol particle size and measuring the airflow resistance of the device (NIOSH 2019). Medical face masks that are not intended to be used as respiratory protective devices are cleared by the Food and Drug Administration (FDA), which reviews manufacturer-supplied information on filtration efficiency, airflow resistance, resistance to fluid penetration and flammability (FDA 2004). The FDA recommends that manufacturers use the ASTM standards F2299 for measuring particle filtration efficiency through the mask material using latex microspheres (ASTM 2003), and the F2101 Standard test method of evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of *Staphylococcus aureus* (ASTM 2019). Bacterial filtration efficiency can also be measured with the modified Greene and Vesley method using human test subjects (Greene and Vesley 1962; Quesnel 1975).

In addition to filtration performance, how well a respiratory protective device protects the wearer depends upon how well the device fits the face and whether the seal between the face and the device has gaps or leaks (Lawrence et al. 2006). ASTM Standard F3407-20 outlines procedures for testing respirators using a bivariate panel of human test subjects with different facial dimensions (ASTM 2020). The NIOSH approval test for respirators measures the filtration properties but does not include tests of how well the device fits faces of different shapes, although this has been proposed. Consequently, in the United States, when a worker is required to wear a respirator, the Occupational Safety and Health Administration (OSHA) requires that a respirator fit test be performed annually for each worker to determine how well the respirator protects the worker (OSHA 2020). Quantitative fit tests measure the aerosol particle concentration inside and outside the respirator during a series of exercises, and this information is used to calculate the fit factor (outside concentration/inside concentration) (Janssen and McKay 2017). The minimum acceptable fit factor for a respirator depends upon the exposure level and potential health consequences of the hazards to which the worker may be exposed (OSHA 2020).

The existing test methods for respirators and medical face masks provide a possible basis for developing standards for non-medical masks used as source control devices. The American Association of Textile Chemists and Colorists (AATCC) published guidelines for cloth face coverings that include the use of ASTM F2299 and other national and international performance standards (AATCC 2020). Leith, L'Orange, and Volckens (2021) proposed an estimated mask protection factor that is calculated based on tests of filtration efficiency and fit and on estimates of the average time spent speaking, inhaling, and exhaling. ASTM International has released a standard for testing barrier face coverings that includes tests of filtration efficiency and airflow resistance, and an assessment of leakage, which are standard metrics that are commonly used to test personal protective devices (ASTM 2021). The use of these standard performance metrics has many advantages, most notably that the equipment and procedures needed to conduct the tests are widely available. However, none of these metrics are

Table 1. Performance metrics used in this study. Outward mask airflow is in the direction of exhalation. Inward airflow is in the direction of inhalation.

Performance metric	**Parameter measured**	Mask airflow direction	Measurement instrument	**Measurement method**	Particle size	**Instrument airflow rate (liters/minute)**
Cough aerosol collection efficiency	Aerosol mass escaping beyond mask into collection chamber	Outward	Andersen impactor	Fluorescence of aerosol on impactor stages	0.1 to 7 μm	28.3
Exhaled aerosol collection efficiency	Aerosol mass escaping beyond mask into collection chamber	Cyclical	Andersen impactor	Fluorescence of aerosol on impactor stages	0.1 to 7 μm	28.3
Filtration efficiency	Aerosol mass concentration upstream & downstream of mask	Inward	TSI 8130 A	Photometer	75 nm count median diameter (GSD 1.86)	85
Airflow resistance	Pressure required for 85 lpm flow	Inward	TSI 8130 A	Manometer	n/a	85
Manikin fit factor	Aerosol particle count inside & outside mask	Cyclical	TSI PortaCount	Size classifier & condensation particle counter	55 nm (N95 mode)	0.35
Human fit factor	Aerosol particle count inside & outside mask	Cyclical	TSI PortaCount	Size classifier & condensation particle counter	55 nm (N95 mode) 0.02–1.0 μm (Class 100 mode)	0.35

direct measurements of the ability of a mask to block aerosols expelled during coughing and exhalation. To assist in the further development of these types of standards and guidelines, the relationship between the efficacy of masks as source control devices and their performance using standard metrics needs to be better understood. For example, it is possible to measure the filtration efficiency of the mask material, but it is not clear how that filtration efficiency translates to source control efficacy or what minimum performance level should be required.

The purpose of this study was to compare the performance of a variety of N95 respirators, medical masks, and cloth masks as source control devices with their filtration efficiencies, airflow resistances, fit factors measured using manikin headforms, and fit factors measured on humans. The results of these experiments will assist in the development of appropriate test methods and standardized performance metrics to evaluate the efficacy of cloth masks as source control devices for respiratory aerosols.

Materials and methods

Experimental design

A source control measurement system was used to assess the efficacy of N95 respirators, medical masks, and cloth masks as source control devices. The source control performance was determined by measuring the source control collection efficiency of the mask, which is the fraction of the mass of the coughed or exhaled test aerosol particles that were blocked by the mask from reaching the collection chamber. The filtration efficiencies and airflow resistance of the construction materials were measured using a modified version of the test method used for respirator approvals. Fit tests were performed both on a manikin headform with pliable skin and with human test subjects. The source control collection efficiencies were then compared with the fit factors, filtration efficiencies and airflow resistances measured on the same devices. A summary of the performance metrics used in the study is shown in Table 1.

Respiratory aerosol source control measurement system

The efficacy of respirators, medical masks, and cloth masks as source control devices for aerosols produced during coughing and exhalation was determined using a respiratory aerosol source control measurement system described previously (Lindsley et al. 2021). The system includes a coughing and breathing aerosol simulator, a manikin headform, an 136 L aerosol collection chamber, and a cascade impactor (Figure 1). The manikin headform used in the study has pliable skin that mimics the elastic properties of human skin in order to create a realistic simulation of how each source control device would fit a human face (Bergman et al. 2014).

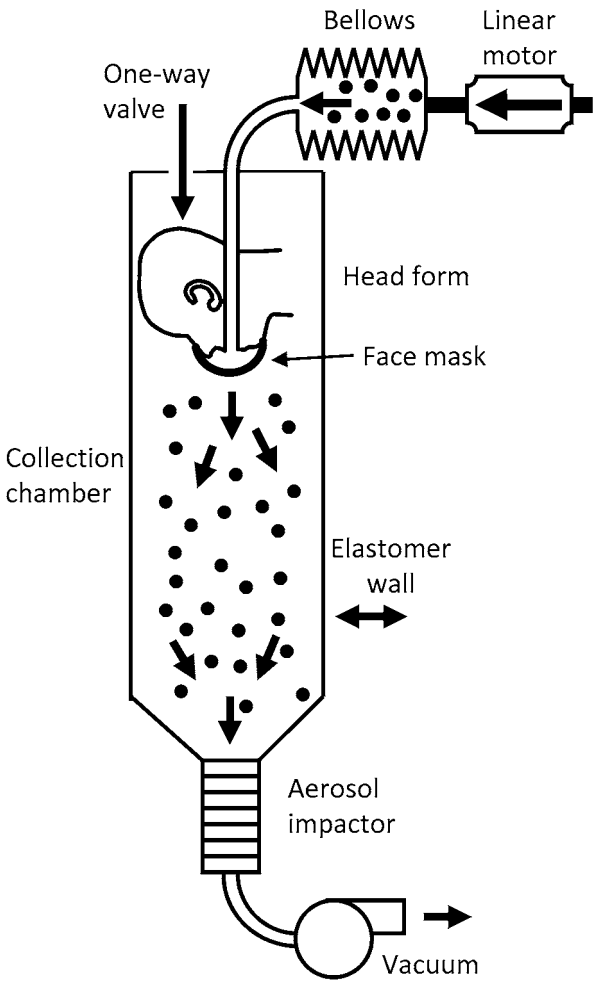

Figure 1. Source control measurement system. The system consists of an aerosol generation system, a bellows and linear motor to produce the simulated coughing and breathing, a pliable skin headform on which the source control device is placed, a 136 liter collection chamber into which the aerosol is coughed or exhaled, and a cascade impactor to separate the aerosol particles by size and collect them. The system is oriented vertically as shown to minimize the loss of aerosol particles due to settling before collection. The system is described in more detail in Lindsley et al. (2021).

The test aerosol was produced using a solution of 14% potassium chloride (KCl) and 0.4% sodium fluorescein in a single-jet Collison nebulizer (BGI, Butler, NJ, USA) at 103 kPa (15 lbs./in^2). The aerosol passed through a diffusion drier (Model 3062, TSI, Shoreview, MN, USA), mixed with dry filtered air flowing at 10 L/min for the cough tests and 15 L/min for the breathing tests, and neutralized using a bipolar ionizer (Model HPX-1, Electrostatics). An elastomeric bellows driven by a computer-controlled linear motor produced the coughing or breathing airflow.

For cough tests, the test aerosol was loaded into the elastomeric bellows and then coughed out using a single cough with a volume of 4.2 L and a peak flow rate of 11 L/s (Lindsley et al. 2013). An Andersen cascade impactor (Model TE-10-830, Tisch Environmental) collected all aerosol particles that traveled through or around the device for 20 min after each cough. For breathing tests, the system used a ventilation rate of 15 L/min with a breathing rate of 12 breathes/min and a tidal volume of 1.25 liters, which corresponds to the ISO standard for a female performing light work (ISO 2015). The test aerosol was only generated for the first 30 s of breathing to avoid overloading the impactor. The breathing continued for 20 min total. The impactor collected the aerosol particles in the chamber during the 20-minute breathing period followed by an additional five minutes of collection after the breathing had stopped.

The impactor operated at a flow rate of 28.3 liters/minute and had six collection stages and a filter that separated the aerosol particles into seven size fractions based on the aerodynamic diameter of the particles: <0.6 µm; 0.6–1.1 µm; 1.1–2.1 µm; 2.1–3.3 µm; 3.3–4.7 µm; 4.7–7.0 µm; and >7 µm. The impactor collection plates were coated with a solution of glycerol and Brij 35 to prevent particles from bouncing off the plates during collection (Mitchell 2003). Because the amount of aerosol in the largest size fraction was small (<0.7% of total aerosol mass) and because of possible losses due to settling of the large aerosol particles, data for the largest size fraction were not included in the analysis. After aerosol collection was completed, the aerosol particles were eluted from the impactor plates using a 0.1 M Tris solution and the fluorescence of the solution was read using a spectrofluorometer (SpectraMax M4, Molecular Devices).

To control for variations in the amount of aerosol in each experiment, a sample of each test aerosol was collected from the bellows prior to coughing or breathing using a 47 mm 5 µm PVC filter. The aerosol was eluted from the filter using 0.1 M Tris. An adjustment factor for the experiment (A) was calculated as:

$$A = \frac{Mass\ of\ aerosol\ on\ filter}{Mean\ (mass\ of\ aerosol\ on\ filter\ for\ all\ control\ experiments)} \quad (1)$$

The adjusted mass of aerosol on each impactor stage for the experiment was then calculated as:

$$M_{stage,\ adjusted} = \frac{M_{stage,\ unadjusted}}{A} \quad (2)$$

The adjusted masses were used for all subsequent calculations. The adjusted aerosol masses collected by the cascade impactor during the experiments are

Table 2. Source control devices used in experiments.

Type	Manufacturer	Product	Fastener	Material
Medical masks & respirators	3M	Model 1860 N95 respirator and surgical mask (TC-84A-0006)	Two elastic straps around head	Polypropylene and polyethylene composition
	BYD	N95 filtering facepiece respirator (TC-84A-9221)	Two elastic straps around head	IL and OL: Polypropylene spun-bound nonwoven fabric. ML: Polypropylene melt-blown nonwoven + hot air cotton
	3M	Model 1818 surgical mask	Two ties behind head	Poly(ethylene terephthalate) and polypropylene
	Excellent Artisan	Procedure mask	Ear loops	3-ply, Nonwoven. Fabric composition unknown
Reusable cloth face masks	Hanes	Defender 3-ply mask	Ear loops	100% cotton
	EnerPlex	3-ply mask	Ear loops	IL and ML: 65% polyester, 35% cotton. OL: 100% polyester
	Craft & Soul	2-ply mask	Ear loops	65% polyester, 35% cotton
	Lefty	2-ply face mask	Ear loops	92% polyester, 8% spandex
	Badger	4-ply mask	Ear loops	IL : 100% cotton. MLs: melt blown filters. OL: air mesh polyester
	Debrief Me	3-ply mask with PM 2.5 filter	Ear loops	IL 100% cotton, ML and OL: polyester blend
	Fabrique Innovations	Mask	Ear loops	100% cotton
	Besungo	Mask with PM 2.5 filter & exhalation valves	Ear loops and Velcro neck strap	Nylon
	Inspire	2-ply mask with PM 2.5 filter	Ear loops	Polyester/cotton blend
Neck gaiters	FKGIONG	Neck gaiter	Encircles head	95% polyester, 5% spandex
	AXBXCX	Neck gaiter	Encircles head	Polyester
	Retro Brand	Neck gaiter	Encircles head	100% polyester
	Givon	Neck gaiter	Encircles head	100% polyester fleece
Bandanas	L & M	Bandana	Ties behind head	100% cotton
	Underwear	Bandana/gaiter	Ear loops	Polyester blend

In this article, the reusable cloth face masks, neck gaiters and bandanas are referred to collectively as "cloth masks". IL is inner layer, ML is middle layer, and OL is outer layer. Photographs are shown in Figures S3–S5 (SI).

shown in Tables S1 and S2 in the supplemental information (SI).

The source control performance, or source control collection efficiency, of a face covering is defined as the fraction of the mass of the respiratory aerosol that is blocked from entering the environment around the wearer. For example, if 80% of the mass of the aerosol from a cough is blocked by a face mask and 20% of the aerosol mass is able to flow through or around the mask into the air around the wearer, then the mask is said to have a collection efficiency of 80%. The performance of each source control device was evaluated by calculating the collection efficiency as:

$$Collection\ efficiency = 1 - \frac{M_{mask}}{M_{control}} \qquad (3)$$

where:

M_{mask} = adjusted total mass of the aerosol particles that passed through or around the source control device and was collected by the impactor.

$M_{control}$ = adjusted total mass of the aerosol particles collected by the impactor while not wearing a source control device.

Note that the collection efficiency is based on the mass of the aerosol rather than a measure such as particle counts. Also, the aerosol is flowing from the inside of the mask toward the outside; that is, in our test system the aerosol flows in the same direction as it would flow during a cough or exhalation by a person wearing the mask.

Respirators, medical masks, and cloth masks

In our study, the term "cloth mask" refers to a cloth face mask, neck gaiter or bandana constructed from textiles or fabrics (both natural and synthetic) that is not a surgical mask or N95 respirator and is not intended for use as personal protective equipment. The term "medical masks" in this article refers to non-woven disposable masks that are held on the face with elastic ear loops. These masks are loose-fitting and are not expected to provide the wearer with as reliable a level of protection against airborne or aerosolized particles as N95 respirators regulated by NIOSH. Commercial manufacturers often refer to

masks held on by ear loops as procedure masks and masks that tie behind the head as surgical masks. However, the U.S. Food and Drug Administration uses the term "surgical mask" to describe commercially produced masks regulated by the under 21 CFR 878.4040 for performing medical procedures (FDA 2004). The FDA definition applies to all masks that cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials, and includes masks that are labeled as surgical, laser, isolation, dental or medical procedure masks with or without a face shield.

Nineteen commercially available N95 respirators, medical masks, and cloth masks were selected to provide a broad cross-section of the different types of source control devices that are available (Table 2). For the source control tests, each device was placed on the headform as it would normally be worn by a person. Three of the neck gaiters were tested both as a single layer of fabric and folded over to provide two layers of fabric. Before the source control test, the manikin fit factor (Janssen and McKay 2017) was measured by performing a respirator fit test (Bergman et al. 2015) for each device using a PortaCount® Pro + respirator fit tester (Model 8038, TSI, Shoreview, MN) in N95 mode with the system breathing at 36 L/min but not producing an aerosol. Each device was used for two consecutive tests. Photographs of the source control devices on the headform are shown in the SI (SI; Figures S1–S3).

Filtration efficiency and airflow resistance measurements

The filtration efficiency of the face covering is the fraction of the test aerosol that is collected as the aerosol passes through the mask material. For example, if 70% of the test aerosol is collected by the mask material and 30% of the aerosol passes through it, then the filtration efficiency is 70%. Note that the filtration efficiency tests are performed by fastening the mask to a holder so that all the aerosol flows through the mask material, and none can escape through face seal leaks. Thus, the filtration efficiency is a property of the mask material.

The filtration efficiency and airflow resistance of the construction materials were measured using automated filter testers (Models 8130 and 8130 A, TSI). Material samples were secured to a test plate using beeswax as shown in Figure S4 in the SI. Measurements were made using a modified version of the NIOSH standard testing procedure (STP) (NIOSH 2019). Under the modified STP, samples were tested at ambient temperature and humidity but were not subjected to conditioning at 38°C and 85% relative humidity for 25 h, and sample testing was limited to 10 min. The device to be tested was oriented in the filter tester so that the air and aerosol flowed from the exterior of the device toward the interior (that is, as if the wearer were inhaling, which is the same direction as when testing a respirator as a personal protective device). The challenge aerosol was generated using a 2% sodium chloride (NaCl) solution in distilled water, conditioned to 25 °C and 30% relative humidity and neutralized to the Boltzmann equilibrium state. The challenge aerosol had a count median diameter of 75 nm ± 20 nm, a mass mean diameter of 260 nm and a geometric standard deviation (GSD) $\leq$ 1.86 (TSI 8130 A specifications). The automated filter tester compares particle mass concentration readings from upstream and downstream light-scattering laser photometers to calculate the material filtration efficiency. An electronic pressure transducer measures the pressure difference across the material sample to indicate airflow resistance. Tests were performed with an airflow of 85 L/minute.

Fit tests on human subjects

A convenience sample of eleven subjects (six males and five females) participated in fit testing. Subjects complied with CDC/NIOSH guidelines for facial hair styles intended for workers who wear tight-fitting respirators (CDC 2017). Fit testing was performed with a PortaCount® fit tester (model 8038, TSI) using OSHA's modified ambient aerosol condensation nuclei counter (CNC) protocol for filtering facepiece respirators (OSHA 2019). Because only fit factors were measured and no identifiable private information was collected, the West Virginia University Office of Human Research Protections determined that Institutional Review Board approval was not required. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy (see e.g., 45 C.F.R. part 46; 21 C.F.R. part 56; 42 U.S.C. §241(d), 5 U.S.C. §552a, 44 U.S.C. §3501 et seq.). All measurements were performed in a room with volume of 43.4 m^3 (1531 ft^3) at 19 °C (67 °F).

An NaCl aerosol generator (Model 8026, TI) was used to supplement the naturally occurring particles in the air. The particle generator was placed 10 feet away from all sampling apparatus and fit testing equipment. The generator was turned on ten minutes prior to testing to seed aerosols and turned off while

a triplicate series of fit tests were performed (around 7 min). As the aerosol concentration in the room had started to slightly decline at this point, the generator was turned on between tests (around 7 min) and then turned off during subsequent tests. This process was repeated until testing for the day was completed.

To verify that suitable aerosol concentrations were present during testing, particle concentrations were measured with a condensation particle counter (CPC Model 3775, TSI) for 25 min beginning at 2 min prior to the nebulizer being initially turned on. Particle size distributions were measured for 20 min with a scanning mobility particle sizer (SMPS Model 3938, TSI) and an electrical low-pressure impactor (ELPI+, Dakati). Information on the aerosol particle size distribution and concentration are shown in the SI (Figures S5 and S6).

Each source control device was tested by three subjects; for each subject three replicate measurements were made using each of the two protocols described below. One individual administered all fit tests. Subjects were instructed in the proper donning of medical masks and respirators, and they were asked to don cloth masks in the manner that they ordinarily don similar coverings for public use. If a cloth mask was too large, it was modified using materials that would be accessible to most lay individuals: tape was used to shorten mask ear loops or head straps, and a binder clip was used to decrease the circumference of neck gaiters. These adjustments were made so that the covering was held flush to the face, but the materials were not under tension.

Two particle measurement protocols were performed on all source control devices: the PortaCount® N95 Companion protocol (referred to here as N95 mode), which counts negatively charged particles 40–70 nm (mean 55 nm) in diameter; and the PortaCount® standard protocol (referred to here as Class 100 mode), which counts all particles from 0.02–1.0 µm (TSI 2010). The "Class 100 mode" is also called "N99 mode". For both modes, the fit factor (FF) was calculated by the PortaCount® software as (Janssen and McKay 2017; TSI 2015):

$$FF = \frac{C_B + C_A}{2C_R} \quad (4)$$

where:

C_B = ambient particle concentration measured before the particle concentration is measured inside the respirator.

C_A = ambient particle concentration measured after the particle concentration is measured inside the respirator.

C_R = particle concentration measured inside the respirator.

Note that the TSI PortaCount instrument used in our experiments measures the aerosol concentration based on the number of aerosol particles rather than the particle mass.

Data analysis

The source control results were compared with the filtration efficiencies, airflow resistances, and fit factor measurements by calculating the Spearman's rank correlation coefficients (ρ) between the metrics. Fit factors were transformed into fit efficiencies (= 1-1/fit factor) to allow for a direct comparison with the other parameters. For example, a fit factor of 5 corresponds to a fit efficiency of 80%, indicating that the mask blocked 80% of the ambient aerosol from being inhaled by the wearer. Because the replicate numbers were different for the different performance metrics, the correlations were calculated based on the mean results for each device. When analyzing the human fit factor results, we did not attempt to account for differences among test subjects. The p-value was calculated based on ρ and the number of types of devices that were tested (22 for all source control devices and 18 for the cloth masks alone, with the 1-layer and 2-layer gaiter tests counted separately). Correlations were considered significant if $p \leq 0.05$.

Results

Efficacy of N95 respirators, medical masks, and cloth masks as source control devices for respiratory aerosols

Twenty-six cough experiments were performed without a source control device to measure the cough aerosol output from the source control measurement system. The cough aerosol had a geometric mean aerodynamic diameter of 1.3 µm with a GSD of 2.3 and a mean mass of 525 µg (standard deviation [SD] 65; Figure 2 and SI Figure S7). Thirty-five breathing aerosol experiments were performed without a source control device to measure the exhaled aerosol output. The exhaled aerosol had a geometric mean aerodynamic diameter of 1.3 µm with a GSD of 2.3 and a mean mass of 495 µg (SD 68; Figure 2 and SI Figure S8). The experiments without source control devices were used as control experiments when evaluating performance of the devices.

The collection efficiencies of the 19 source control devices are shown in Figure 3 and Table 3. The mean

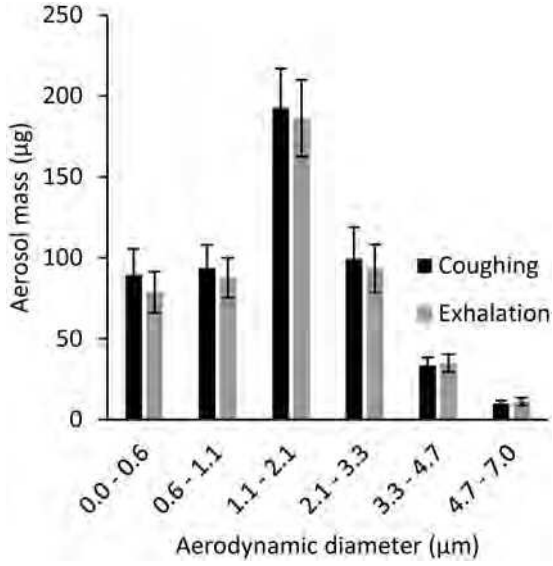

Figure 2. Mass of aerosol expelled by the source control measurement system during coughs and exhalations. The size bins correspond to the stages of the Andersen impactor. The size distribution is shown in units of µg/µm in Figures S7 and S8 in the SI.

collection efficiencies of the N95 respirators and the surgical mask ranged from 83% to 99% for aerosol particles during coughing and exhalation. For the procedure and cloth masks, the mean collection efficiencies ranged from 35% to 71% for coughing (except for the bandana at 17%) and 35% to 66% for exhalation. The collection efficiencies for the coughing and breathing source control experiments were correlated, with a Spearman's correlation coefficient (ρ) of 0.76 ($p < 0.001$; Table 4) when considering all the devices and 0.67 ($p = 0.003$; Table 4) when considering only the cloth face masks, gaiters and bandanas. The amounts of aerosol collected on each stage of the impactor are shown in Tables S1 and S2 in the SI.

Filtration efficiencies and inhalation airflow resistance

The mean material filtration efficiencies were >99% for the respirators, 80% to 93% for the medical masks, and 1.4% to 36% for the cloth face masks, neck gaiters, and bandanas, except for the Besungo sports mask at 98% (Figure 4 and Table 3). The inhalation

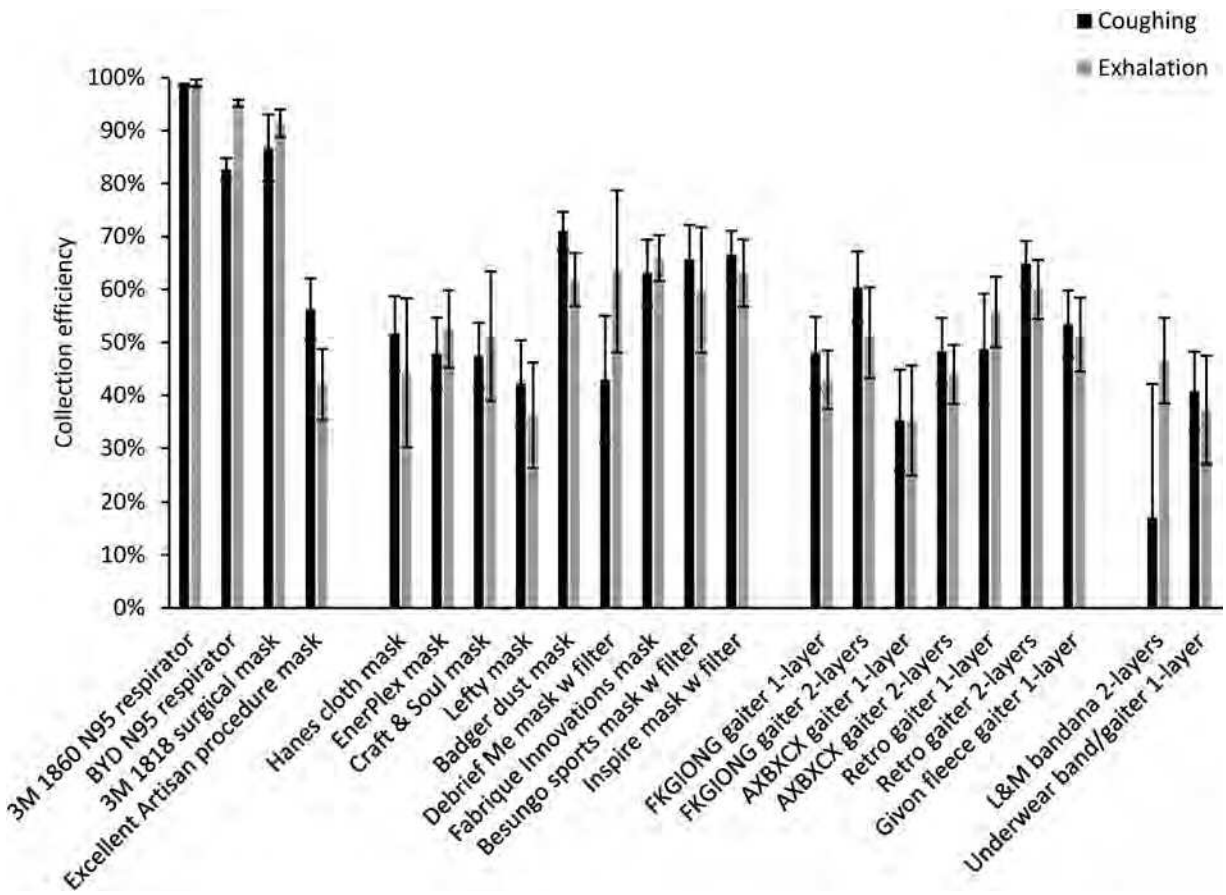

Figure 3. Source control collection efficiencies of N95 respirators, medical masks, cloth face masks, neck gaiters and bandanas during coughing and exhalation aerosol tests with the respiratory aerosol source control measurement system. Each bar is the mean of 4 or 6 experiments. Error bars show the standard deviation.

Table 3. Results for all performance metrics for source control devices.

Face covering	COUGHING				EXHALATION				Filtration Efficiency (%)		Inhalation airflow resistance (Pa)		Human fit factor			
	Collection efficiency (%)		Manikin fit factor		Collection efficiency (%)		Manikin fit factor						N95 mode		Class 100 mode	
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
3M 1860 N95 respirator	98.6%	0.3%	198.0	3.5	99.0%	0.7%	132.5	78.5	99.1%	0.1%	72.2	8.1	163.8	56.2	45.3	10.9
BYD N95 respirator	82.7%	2.1%	25.0	11.3	95.2%	0.6%	113.5	122.3	99.1%	0.1%	150.8	14.5	147.9	33.5	54.9	7.8
3M 1818 surgical mask	86.8%	6.3%	26.1	26.7	91.4%	2.6%	27.5	12.0	92.7%	0.6%	48.0	7.8	78.6	92.0	9.6	5.8
Excellent Artisan procedure mask	56.3%	5.8%	7.4	3.4	42.0%	6.7%	6.1	5.5	79.7%	3.6%	108.0	34.3	3.3	0.7	1.7	0.5
Hanes cloth mask	51.7%	7.1%	1.3	0.1	44.3%	14.0%	2.3	1.1	18.8%	2.7%	64.1	9.5	1.7	0.5	1.0	0
EnerPlex mask	48.0%	6.7%	5.1	1.3	52.6%	7.3%	2.5	0.4	19.9%	3.9%	23.8	10.7	2.1	1.2	1.8	0.7
Craft & Soul mask	47.4%	6.2%	2.5	1.2	51.2%	12.2%	2.3	1.0	9.7%	3.9%	11.4	8.2	2.0	0.5	1.3	0.5
Lefty mask	42.3%	8.1%	2.4	0.7	36.3%	9.9%	1.9	n/a	20.2%	0.8%	96.3	5.9	1.8	0.7	1.6	0.5
Badger dust mask	71.1%	3.5%	5.0	0.1	61.8%	5.0%	3.2	0.6	36.0%	9.9%	92.1	1.0	2.8	1.6	1.7	0.5
Debrief Me mask w filter	43.0%	12.0%	4.6	1.8	63.4%	15.3%	3.0	1.5	30.8%	1.5%	154.1	34.9	2.9	0.9	2.1	0.8
Fabrique Innovations mask	63.2%	6.2%	2.1	n/a	65.9%	4.4%	2.2	0.4	14.8%	n/a	61.7	n/a	1.4	0.7	1.1	0.3
Besungo sports mask w filter	65.7%	6.5%	4.8	n/a	59.9%	11.9%	3.2	0.3	97.8%	0.3%	142.7	22.9	2.7	1.7	1.9	1.4
Inspire mask w filter	66.5%	4.5%	4.3	3.0	63.1%	6.4%	2.7	0.5	27.1%	5.1%	149.8	85.4	4.0	1.4	2.4	0.5
FKGIONG gaiter 1-layer	48.1%	6.7%	1.7	0.5	42.9%	5.5%	1.5	0.2	3.3%	4.3%	13.1	8.0	1.1	0.3	1.0	0
FKGIONG gaiter 2-layers	60.5%	6.7%	1.9	0.4	51.8%	8.6%	1.7	n/a	7.9%	0.5%	23.8	8.4	1.0	0	1.4	0.5
AXBXCX gaiter 1-layer	35.4%	9.5%	1.7	0.1	35.3%	10.3%	1.4	0.1	2.7%	1.1%	14.4	5.7	1.3	0.7	1.0	0
AXBXCX gaiter 2-layers	48.3%	6.3%	1.8	0.1	43.9%	5.6%	1.9	0.5	3.6%	0.3%	29.4	4.5	1.3	0.5	1.3	0.5
Retro gaiter 1-layer	48.7%	10.5%	2.6	n/a	55.8%	6.6%	2.5	0.6	2.2%	n/a	40.2	n/a	1.6	0.7	1.3	0.5
Retro gaiter 2-layers	64.9%	4.2%	2.3	0.4	60.0%	5.5%	2.1	0.4	8.6%	n/a	69.5	n/a	1.7	1.0	1.7	0.5
Givon fleece gaiter 1-layer	53.5%	6.3%	2.1	0.5	51.4%	7.0%	2.3	0.8	8.4%	0.8%	19.3	7.4	1.0	0	1.3	0.5
L&M Bandana 2-layers	17.1%	25.0%	1.3	0.2	46.5%	8.1%	1.6	0.1	1.4%	0.4%	5.2	8.2	1.1	0.3	1.0	0
Underwear Bandana/gaiter 1-layer	40.8%	7.5%	6.9	7.3	37.3%	10.2%	1.4	0.1	3.5%	1.1%	19.3	8.2	1.1	0.7	1.0	0

Manikin fit factors were measured with the fit tester in N95 mode only (as described in the Discussion). Human fit factors were measured using both the N95 mode and Class 100 mode.

Table 4. Correlations between different performance metrics for all source control devices.

		All source control devices		Cloth face masks, gaiters, and bandanas only	
Correlation parameter #1	Correlation parameter #2	ρ	*p*-value	ρ	*p*-value
Cough aerosol collection efficiency	Exhaled aerosol collection efficiency	0.76	<0.001	0.67	0.003
	Filtration efficiency of material	0.69	0.001	0.51	0.032
	Airflow resistance of material	0.55	0.009	0.54	0.020
	Human subject fit (N95 mode)	0.57	0.005	0.30	0.208
	Human subject fit (Class 100 mode)	0.68	<0.001	0.48	0.035
	Manikin fit before coughing	0.39	0.076	0.03	0.890
Exhaled aerosol collection efficiency	Filtration efficiency of material	0.60	0.004	0.54	0.023
	Airflow resistance of material	0.51	0.016	0.58	0.012
	Human subject fit (N95 mode)	0.60	0.003	0.51	0.024
	Human subject fit (Class 100 mode)	0.71	<0.001	0.63	0.003
	Manikin fit before breathing	0.72	<0.001	0.68	0.002
Manikin fit before coughing	Manikin fit before breathing	0.61	0.003	0.38	0.112
Filtration efficiency of material	Airflow resistance of material	0.78	<0.001	0.78	<0.001

Each Spearman's rank coefficient (ρ) was calculated based on data from 22 experiments for all source control devices and 18 experiments for cloth masks (cloth face masks, gaiters, and bandanas). A correlogram of the ρ values in shown in Figure S9 in the SI.

airflow resistances were from 5.2 to 154 Pa (Table 3). When comparing the data for all devices, the filtration efficiencies were correlated with cough aerosol collection efficiency ($\rho = 0.69$, $p = 0.001$) and exhaled aerosol collection efficiency ($\rho = 0.60$, $p = 0.004$; Table 4). For the group of cloth masks, the correlations were not as strong; the cough aerosol collection efficiency and filtration efficiency had an ρ of 0.51 ($p = 0.032$) while the exhaled aerosol collection efficiency and filtration efficiency had an ρ of 0.54 ($p = 0.023$; Table 4). The airflow resistance did not correlate as well as the filtration efficiency when all devices were considered ($\rho = 0.55$ and $p = 0.009$ for coughing; $\rho = 0.51$ and $p = 0.016$ for exhalation). However, when examining the cloth masks alone, the airflow resistance was slightly better correlated than filtration efficiency ($\rho = 0.54$ and $p = 0.020$ for coughing; $\rho = 0.58$ and $p = 0.012$ for exhalation).

Human fit tests

The fit factors measured on the human test subjects are shown in Table 3 and Figure 5. The mean fit factors for the two N95 respirators were 148 and 164

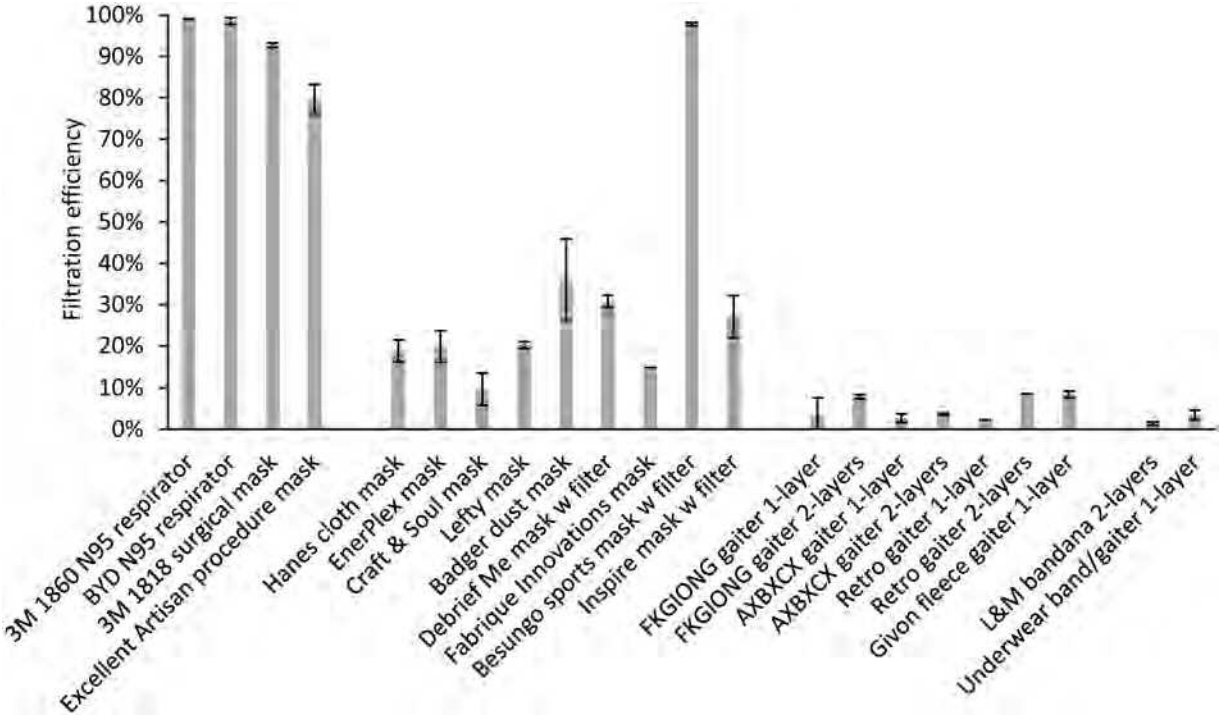

Figure 4. Filtration efficiencies for the source control devices used in the study. Three samples of each device were tested, except for the 3 M 1860 N95 respirator and Hanes cloth mask (10 samples each) and the Fabrique Innovations mask, Retro gaiter 1-layer, and Retro gaiter 2-layers (one sample each). Error bars show the standard deviation.

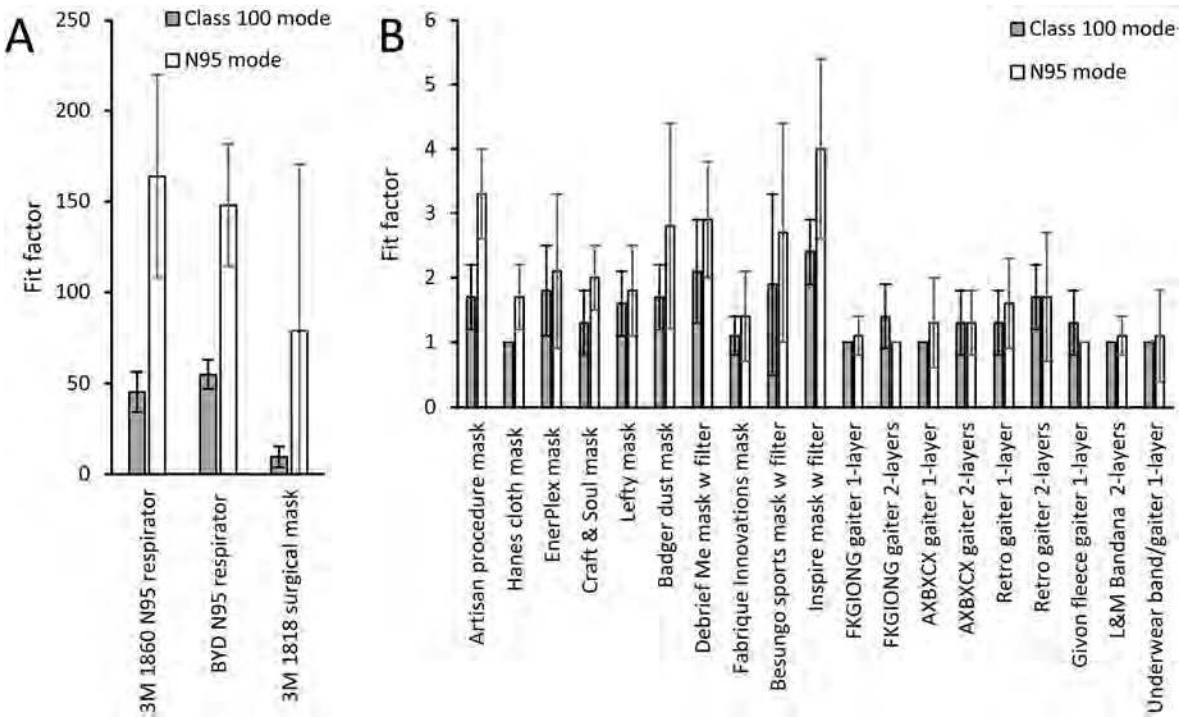

Figure 5. Fit factors measured with human subjects for (a) N95 respirators and surgical mask and (b) procedure mask, cloth face masks, gaiters and bandanas. The plot shows the means and standard deviations. Results for all human fit tests are given in Table S3 in the SI.

when using the N95 mode on the fit tester and 55 and 45 with the Class 100 mode. The surgical mask provided a mean N95 mode fit factor of 79 and a much lower mean fit factor of 9.6 in Class 100 mode. The mean N95 mode fit factor of the reusable cloth face masks ranged from 1.4 to 4.0, and the all sizes

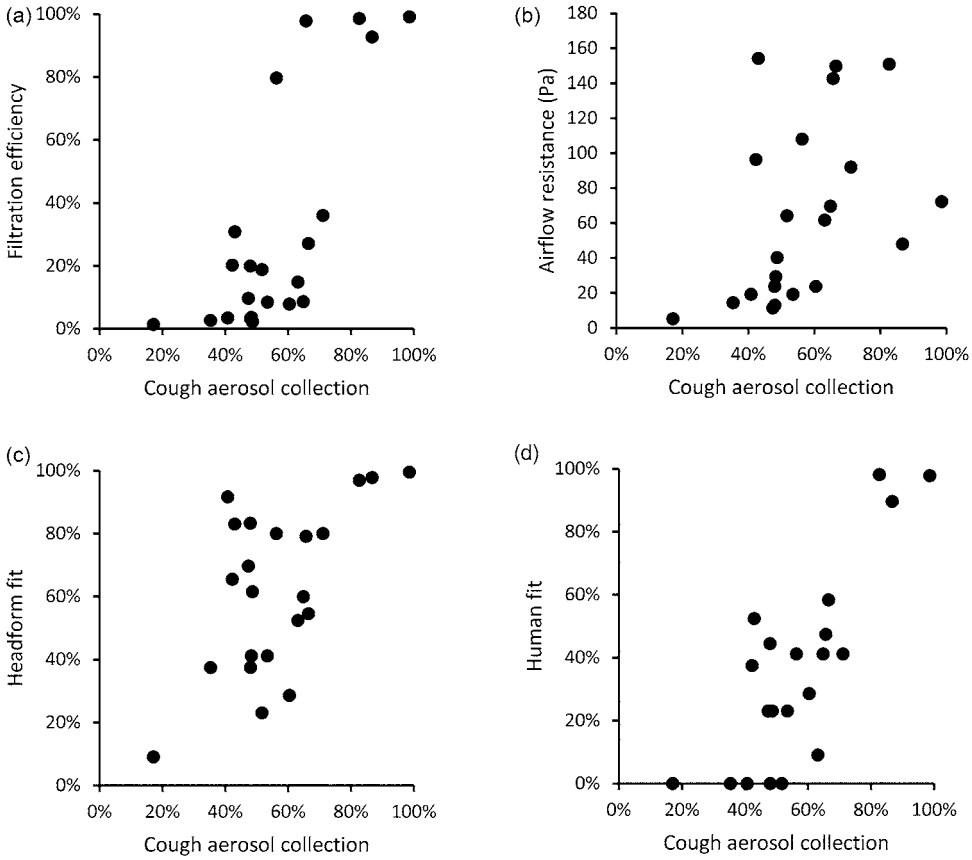

Figure 6. Comparison of collection efficiencies for aerosols from coughs to (a) filtration efficiency of construction material; (b) airflow resistance; (c) fit on manikin headform (using N95 mode); and (d) fit on human test subjects (using Class 100 mode). Each dot corresponds to the mean result for one type of source control device.

mode mean fit factors ranged from 1.0 to 2.4. Neck gaiters and bandanas demonstrated N95 mode fit factors ranging from 1.0 to 1.7 and all particle size mode mean fit factors from 1.0 to 1.7. The performance of cloth masks sometimes varied considerably when worn by different subjects. The fit test results for individual subjects are shown in Table S3 in the SI.

The cough and exhalation aerosol collection efficiencies for all devices were well correlated with the fit factors when measured using the Class 100 mode ($\rho = 0.68$ and $p < 0.001$ for coughing, $\rho = 0.71$ and $p < 0.001$ for exhalation, Table 4). When looking at the results for the cloth masks, gaiters, and bandanas in the all sizes mode, the correlations were not as strong, with $\rho = 0.48$ for coughing ($p = 0.035$), and $\rho = 0.63$ for exhalation ($p = 0.003$; Table 4). In all cases, the correlation coefficients were higher when the fit tester was in the Class 100 mode than when the tester was in N95 mode.

Manikin fit tests

The manikin fit factor measurements found using the source control measurement system before the cough tests were 25 to 198 for the N95 respirators and the surgical mask and 1.3 to 7.4 for the procedure mask and cloth masks (Table 3). Before the breathing tests, the manikin fit factors were 28 to 133 for the N95 respirators and the surgical mask and 1.4 to 6.1 for the procedure mask and cloth masks. The cough aerosol collection efficiencies and the pre-cough manikin fit factors were not significantly correlated, with a ρ of 0.39 ($p = 0.076$) for all devices (Table 4 and Figure 6) and a ρ of only 0.03 ($p = 0.890$) for the cloth masks (Table 4). The correlation was better between the exhaled aerosol collection efficiency and pre-breathing manikin fit factors, with a ρ of 0.72 ($p < 0.001$) for all devices (Table 4 and Figure 7) and 0.68 ($p = 0.002$) for the cloth masks (Table 4).

Discussion

The COVID-19 pandemic has resulted in considerable interest in the performance characteristics of masks and respirators as a means of reducing the person-to-person transmission of SARS-CoV-2. Some studies have looked at the emission of particles from human volunteers wearing different face coverings, which has

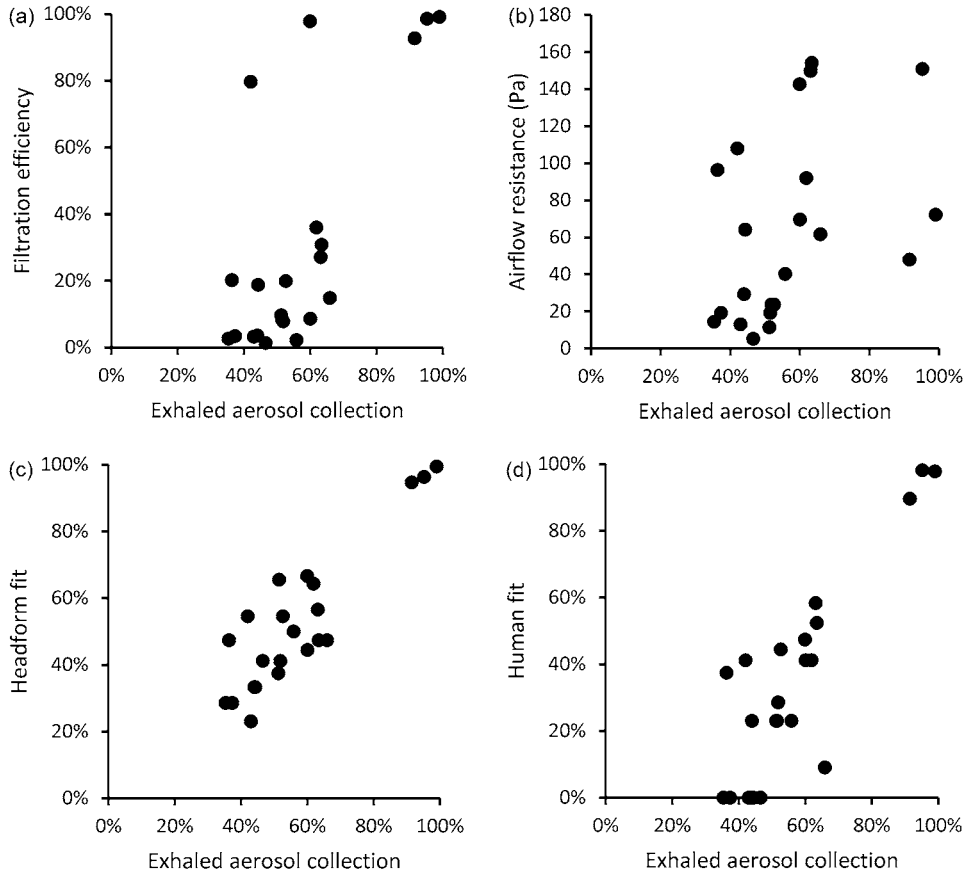

Figure 7. Comparison of collection efficiencies for exhaled aerosols from simulated breathing to (a) filtration efficiency of construction material; (b) airflow resistance; (c) fit on manikin headform (using N95 mode); and (d) fit on human test subjects (using Class 100 mode). Each dot shows the mean result for one type of source control device.

the advantage of directly examining the expulsion of aerosols into the environment by people (Asadi et al. 2020; Davies et al. 2013; Leung et al. 2020; Li, Niu, and Zhu 2021). However, the collection and measurement of human-generated respiratory aerosols is challenging and can be hazardous when the subject has a contagious respiratory infection. In addition, the amount and size distribution of aerosol particles produced by people during coughing, breathing and other respiratory activities varies tremendously from person to person and even for a particular person over time, which makes it difficult to compare results (Asadi et al. 2019; Fennelly 2020; Gralton et al. 2011; Lindsley et al. 2012). Consequently, lab-based surrogate techniques are more frequently used to study source control devices. The most commonly reported methods have been tests of filtration efficiencies and fit factors (Clapp et al. 2021; Guha et al. 2021; Konda et al. 2020; Wang et al. 2020; Zhao et al. 2020). Other studies have used manikins in a chamber or room to assess the efficacy of medical masks and cloth masks both as source control devices and as personal protective equipment (Pan et al. 2021; Patel et al. 2016; Rothamer et al. 2021). Experimental data have also been used to develop computational fluid dynamics models of medical and cloth masks performance (Dbouk and Drikakis 2020; Mittal, Ni, and Seo 2020). These studies have provided valuable information about the properties of masks and respirators. However, it is unclear how the various metrics used in these studies are related to source control performance.

The source control measurement system used in this study allows for a direct quantitative comparison of the ability of different types of source control devices to block the expulsion of simulated cough and exhaled breath aerosol particles into the environment (Lindsley et al. 2021). However, the system is complex and requires expertise to operate, and it is neither commercially sold nor easily constructed. In contrast, filtration measurement systems and respirator fit testers are widely available. If a methodology could be developed to gauge source control performance using existing commercially available equipment, it could be rapidly expanded and adopted by manufacturers and public health entities.

The filtration efficiency of a mask or respirator is a measurement of the ability of the mask material to remove aerosol particles from an airstream traveling through the fabric. Filtration efficiency tests typically use aerosol particles at or near the most-penetrating aerosol particle size, which is around 300 nm for an uncharged filter at low air velocities but shifts to smaller sizes at higher velocities and when the filter and particles are electrostatically charged (Martin and Moyer 2000; Rengasamy, BerryAnn, and Szalajda 2013; Rengasamy et al. 2017). The mechanisms by which filters collect aerosol particles are strongly dependent upon the size of the particles; for example, large particles are more likely to be collected by impaction or interception while small particles are more likely to be collected by diffusion (Lindsley 2016). Although the SARS-CoV-2 virus is about 100 nm in diameter, contagious humans do not shed bare viral particles. Instead, they expel aerosols and droplets of respiratory fluids that contain respiratory virus, and the size of these virus-laden aerosols and droplets can range from hundreds of nanometers to visible droplets of 1 mm or more (Fennelly 2020; Gralton et al. 2011). Thus, the collection efficiencies for 100-300 nm particles may not predict the performance for larger particles (Drewnick et al. 2021). In our experiments, the coughing and exhalation source control collection efficiencies increased as the particle size increased (Tables S1 and S2 in the SI) and in most cases were higher than the filtration efficiencies, likely because our coughing and exhalation test aerosols were much larger than the 75 nm aerosol used for filtration tests.

The fit factor is normally used to determine how well a respiratory protective device fits the wearer by measuring the degree to which aerosol particles can enter through gaps between the wearer's face and the respirator (face seal leaks). It is determined by placing the device on a person or on a manikin headform and measuring the ratio of the aerosol concentration outside the respirator to the aerosol concentration inside the respirator (Janssen and McKay 2017). For example, a fit factor of 10 means that the ambient aerosol concentration is 10 times higher than the concentration inside the respirator. Fit factor measurements are not intended to test the filtration efficiency of the device itself. In fact, the calculation of the fit factor for a respirator assumes that any ambient aerosol particles passing through respirator material are filtered out and that any particles detected inside the respirator are due to face seal leaks, not penetration of particles through the filter material (Halvorsen 1998). For example, a fit factor of 10 is interpreted as indicating that 90% of the air inside the respirator has passed through the respirator filtration media (with aerosol particles being completely removed) and that 10% of the air bypassed the media and entered through face seal leaks.

For high efficiency filters such as P100 respirator filters, which filter out 99.97% of airborne particles, a respirator fit test is performed by measuring the concentrations of aerosol particles of all sizes inside and outside the respirator (referred to here as Class 100 mode). However, N95 respirators can allow up to 5% of aerosol particles of the most penetrating size to pass through the filtration media. These particles would reduce the apparent fit factor if they were included in the calculation. Thus, when fit testing N95 respirators, the respirator fit tester used in our experiments has a size classifier to count only negatively charged aerosol particles near 55 nm in size (referred to here as N95 mode). For an N95 respirator, these charged 55 nm particles are almost entirely filtered out by the filtration media, and thus any particles detected inside the respirator can then be assumed to have entered through face seal leaks and not through the respirator (Halvorsen 1998; Han and Prell 2010).

It is important to note, however, that this assumption is not correct when using the fit tester with cloth masks. As can be seen in Table 3, the filtration efficiencies of most cloth masks are much lower than those of respirators, and ambient particles therefore can penetrate more easily through the cloth material. Thus, the fit factor for a cloth mask is not a true measurement of face seal leakage alone; instead, it represents a combination of face seal leakage and particle penetration through the mask material.

Our findings suggest that the results from filtration efficiency, airflow resistance and fit factor tests are correlated with measurements made using our source control measurement system. For the cloth masks, all but two of the standard performance metrics were significantly correlated with the cough and exhaled aerosol collection efficiencies, which suggests that these other measures could be useful as part of a method for testing the performance of cloth masks. However, none of the standard metrics were strong predictors of source control performance, and no metric was clearly superior to the others.

The limited correlations between the different test methods in our study likely have several explanations. First, filtration efficiency and airflow resistance measurements do not account for how well the devices fit the wearer or for face seal leaks around the edges of

the device. Thus, for example, the Artisan procedure mask had an 80% filtration efficiency but a 56% collection efficiency for cough aerosols and a 42% collection efficiency for exhaled aerosols. The most likely explanation is that this mask's material is an efficient filter but that aerosol particles were able to travel around the mask through face seal leaks because the Artisan mask fits loosely on the headform. On the other hand, the Hanes Defender cloth mask had only a 19% filtration efficiency but had similar aerosol collection efficiencies of 52% for coughs and 44% for exhalations. In this case, the cloth mask was not an effective filter for the 75 nm aerosol used in filtration testing, but the Hanes mask fit the manikin headform more tightly. Thus, much of the aerosol then flowed through the mask rather than around it during coughing and breathing tests and the larger aerosol particles that were used in the coughing and breathing tests were filtered out more effectively than the 75 nm particles used in filtration testing. The results presented here are consistent with a previous study by our group in which knotting the Artisan procedure mask to improve the fit increased the cough aerosol collection efficiency to 77%, while wearing a Hanes Defender cloth mask on top of an Artisan procedure mask increased the cough collection efficiency to 85% (Brooks et al. 2021). Together, these results also support the recommendation by Gandhi and Marr that members of the public wear a high-quality mask that fits tightly or wear a tight-fitting cloth mask over a surgical mask in order to reduce face seal leaks and improve the source control performance and protection offered by the masks (Gandhi and Marr 2021).

Fit tests are designed to measure the effects of face seal leaks but have their own limitations when applied to cloth masks. As noted above, fit factor measurements for cloth masks reflect some combination of particle penetration through the media and face seal leakage which will likely vary from mask to mask. Thus, it is neither clear how to interpret fit factor measurements for cloth masks nor is it clear how this relates to the effectiveness of the mask as a source control device. In addition, fit test results can vary greatly from person to person and even somewhat for the same person during repeated tests (Lawrence et al. 2006). Similarly, a comparison of fit tests between humans and a pliable skin manikin headform found significant differences (Bergman et al. 2015). Much of this discrepancy is likely due to facial variations and differences in how the mask is placed on the person or manikin headform. It is possible to shift, stretch, tighten, loosen, or adjust the masks in many ways,

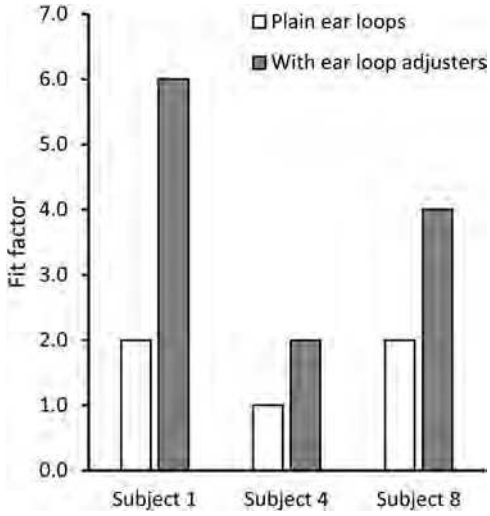

Figure 8. Effect on mask fit factor of adding ear loop adjusters to tighten the mask fit. Subjects were wearing the Excellent Artisan procedure mask. Tests were conducted with the fit tester in Class 100 mode. Each bar is the mean of three trials. All standard deviations were zero.

and small differences in how the mask is worn may have substantial effects on the fit test results. For example, in tests with three subjects using the Artisan procedure mask, we found that tightening the mask against the face by using silicone ear loop adjusters increased the mean fit factor from 1.7 to 4.0 (Figure 8). In experiments with cloth masks, the ρ value for the manikin headform fit tests done before coughing experiments compared with tests done before exhalation experiments was only 0.38, suggesting that differences were occurring even when the same model of mask was being placed on the same headform.

Finally, our study has several limitations. The source control measurement system produced a test aerosol with particles $\leq$7 µm in diameter, which is the size range of aerosol particles most likely to remain airborne and most difficult to block with source control devices. However, humans expel aerosol particles in a much broader range of sizes, particularly when coughing. We used a single cough flowrate profile and a single breathing ventilation rate for our studies; these parameters can vary greatly from person to person under different physiological conditions. Some internal losses of the test aerosol particles likely occurred due to settling or impaction on the surfaces of the collection chamber, which may affect the estimates of the collection efficiencies. We used representative examples of different types of source control devices, but many such devices are available with a wide range of shapes and compositions, which would be expected to affect their individual performance. As shown in Table 1, the instrumentation used for the

different performance metrics are based on different operating principles and thus caution should be used when comparing results; for example, the collection efficiency results from the impactors are based on aerosol mass, while the fit factor results from the PortaCount are based on particle counts. Lastly, because of the need to rapidly produce results in response to the COVID-19 pandemic, we only tested 2-3 samples of each source control device (each sample was used in two consecutive tests). By comparison, for example, the NIOSH procedure for evaluating N95 respirators calls for 20 samples to be tested (NIOSH 2019).

Current evidence indicates that masks like those tested in our experiments can substantially decrease the amount of respiratory aerosols released by the wearer, and also help reduce what the wearer breathes in (CDC 2020a). Both effects vary depending upon the material and construction of the mask, as well as how it is worn. In addition to consistent and correct mask use when in the company of others, other measures such as physical separation are important, particularly during brief exposures. In a room where someone sneezes, being six feet or further away is better than being closer. However, with prolonged exposure in the same space for more than a few minutes, the benefit of distance fades as exhaled respiratory aerosols drift, mix, and accumulate in the enclosed air space. Optimizing ventilation, air filtration, and the introduction of fresh air can help counter this effect, but at every distance, correct mask use reduces the risk for everyone.

Conclusions

The ongoing COVID-19 pandemic has created an urgent need for simple methods to evaluate cloth masks as respiratory aerosol source control devices and to produce meaningful performance metrics that can be used to determine the effectiveness of different materials and designs. Our results suggest that test methods such as filtration efficiency testing, airflow resistance testing, and fit factor measurements on manikin headforms or human subjects have potential as ways to estimate the performance of masks as source control devices for respiratory aerosols. However, more research and improvements in the test methodologies are needed before such methods can be reliably implemented. Until the factors controlling the performance of source control devices are better understood and better testing methodologies are developed, results from test methods such as filtration efficiency testing, airflow resistance testing, and fit factor measurements should be interpreted cautiously when used to evaluate source control devices for respiratory aerosols.

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Declaration of interests statement

The authors declare no competing interests.

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Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols

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ABSTRACT

Face masks are recommended to reduce community transmission of SARS-CoV-2. One of the primary benefits of face masks and other coverings is as source control devices to reduce the expulsion of respiratory aerosols during coughing, breathing, and speaking. Face shields and neck gaiters have been proposed as an alternative to face masks, but information about face shields and neck gaiters as source control devices is limited. We used a cough aerosol simulator with a pliable skin headform to propel small aerosol particles (0 to 7 μm) into different face coverings. An N95 respirator blocked 99% (standard deviation (SD) 0.3%) of the cough aerosol, a medical grade procedure mask blocked 59% (SD 6.9%), a 3-ply cotton cloth face mask blocked 51% (SD 7.7%), and a polyester neck gaiter blocked 47% (SD 7.5%) as a single layer and 60% (SD 7.2%) when folded into a double layer. In contrast, the face shield blocked 2% (SD 15.3%) of the cough aerosol. Our results suggest that face masks and neck gaiters are preferable to face shields as source control devices for cough aerosols.

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Introduction

SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), can be transmitted from person-to-person by large respiratory aerosols (airborne liquid droplets and dried particles greater than about 10 μm in diameter) produced by people who are infectious while they are talking, singing, coughing, breathing or sneezing (CDC 2020a; Hamner et al. 2020). Smaller aerosols also are emitted by people during these activities, suggesting that short-range airborne transmission of SARS-CoV-2 might be possible under some circumstances (Anderson et al. 2020; CDC 2020a; Fennelly 2020; Ma et al. 2020; Morawska and Milton 2020).

To interrupt this potential transmission route, the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and other public health organizations recommend the wearing of face masks or other face coverings by the general public during the ongoing COVID-19 pandemic (CDC 2020b, 2020c; Edelstein and Ramakrishnan 2020; WHO 2020). One of the primary benefits of face coverings is to act as source control devices to reduce the expulsion of aerosols containing the virus from people who are infectious during coughing, breathing, and speaking. Source control devices are intended to protect other people from infectious aerosols emitted by the wearer, as compared with personal protective equipment such as N95 respirators which are primarily intended to protect the wearer. A face covering can provide source control in two ways (Diaz and Smaldone 2010). First, and most importantly, the covering may collect aerosol particles by filtration, impaction, or other mechanisms, and thus prevent infectious aerosols from entering the environment. Second, the face covering may change the direction of travel and the velocity of the aerosol stream and thus possibly divert the aerosol away from a potential recipient. However, deflection is more uncertain as a source control mechanism. For example, if large aerosols are deflected downward, they may settle to the floor or otherwise be unable to reach the breathing zones of other people. However, since exhaled breath is often warmer than the surrounding air, this

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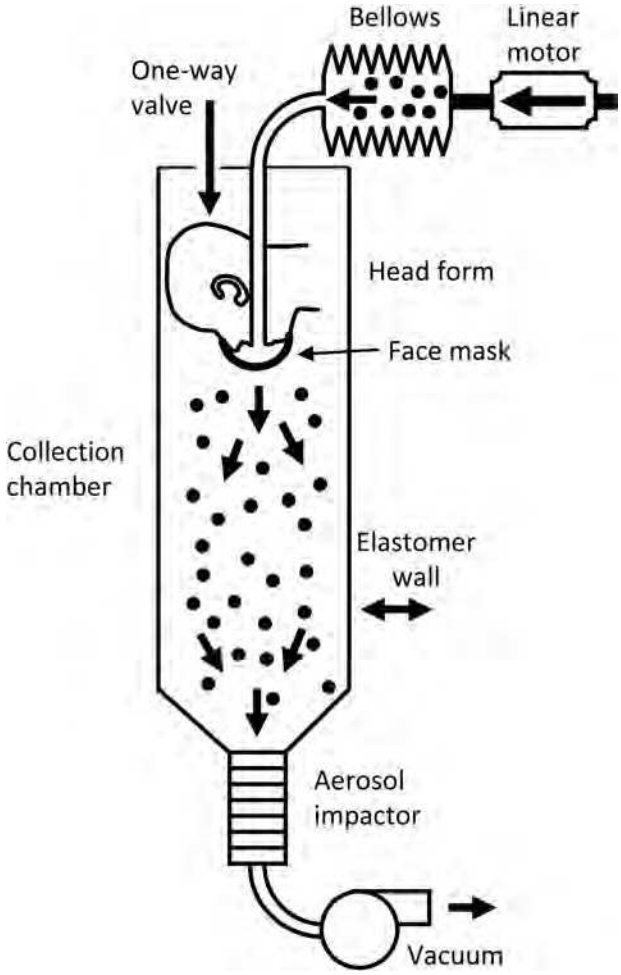

Figure 1. Cough aerosol simulator system for source control measurements. The system consists of an aerosol generation system, a bellows and linear motor to produce the simulated cough, a pliable skin head form on which the face mask, neck gaiter or face shield is placed, a 105 liter collection chamber into which the aerosol is coughed, and an Andersen impactor to separate the aerosol particles by size and collect them. More information about the cough aerosol simulator is provided in the SI.

downward deflection may be counteracted by the buoyancy of the breath for smaller aerosols. In addition, if the respiratory aerosols are deflected sideways, they may be diverted away from a person directly in front of the wearer but toward someone to the side or behind the wearer.

Studies using manikins (Lai, Poon, and Cheung 2012; Patel et al. 2016) and patients with respiratory infections (Leung et al. 2020; Milton et al. 2013) have shown that wearing medical face masks can reduce the dispersion of potentially infectious aerosols from patients. Two studies in which face masks were required for visitors and healthcare workers interacting with patients in bone marrow transplant centers found a reduction in respiratory viral infections among patients (Sokol et al. 2016; Sung et al. 2016). Studies of cloth face masks have suggested that they also can be effective at reducing the release of respiratory aerosols into the environment (Asadi et al. 2020; Davies et al. 2013; Konda et al. 2020). Several computational fluid dynamics studies have examined the generation and expulsion of respiratory aerosols and have provided important insights into the ability of face coverings to reduce the dispersion of large and small aerosols from the wearer (Dbouk and Drikakis 2020; Mittal, Ni, and Seo 2020).

Unfortunately, the use of face masks and other face coverings by the general public can present challenges. People often dislike wearing masks, and compliance can be low and inconsistent (Longtin et al. 2009). Mask wearers may repeatedly don, doff and adjust face masks, which can contaminate the hands and potentially lead to disease transmission, especially when the masks are reused (Brady et al. 2017; Casanova et al. 2008). For cloth masks, the filtration efficiency and air flow resistance of different textiles varies widely (Konda et al. 2020; Teesing et al. 2020; Wilson et al. 2020). Alternative face coverings such as neck gaiters (an elastic fabric tube that fits snugly around the head and neck) are commonly used, but information about their performance as source control devices is limited. Factors such as how well the mask fits the face and the coverage provided by a mask can have a substantial impact on the effectiveness of face masks (Davies et al. 2013; Lawrence et al. 2006). Comparisons of face coverings have found substantial differences in the ability of different types of these devices to reduce the release of respiratory aerosols (Asadi et al. 2020; Davies et al. 2013).

An opinion article in JAMA proposed that face shields would be more effective than face masks at reducing community disease transmission, in large part because the authors felt that face shields were more comfortable and thus that they were more likely to be widely adopted by the public (Perencevich, Diekema, and Edmond 2020). A previous study by our group of face shields used as personal protective devices showed that face shields protect the wearer from large cough aerosols directed at the face but are much less effective against smaller aerosols which were able to flow around the edges of the shield and be inhaled (Lindsley et al. 2014). However, very little work has been done examining face shields as source control devices. Two qualitative flow visualization studies of face shields and masks found that, although face shields deflected the air flow from the mouth, they did not stop aerosol particles from traveling around the face shield and entering the environment

(Verma, Dhanak, and Frankenfield 2020; Viola et al. 2020). Beyond these studies, quantitative data on the efficacy of face shields for source control are lacking.

The objective of our study was to conduct a quantitative comparison of the efficacy of an N95 respirator, a medical procedure mask, a commercial 3-ply cloth face mask, a single and double layer fabric neck gaiter, and a commercial disposable face shield as source control devices to reduce the expulsion of small cough-generated aerosol particles into the environment. Our results provide more information about the effectiveness of different types of source control devices and will help the public health community make recommendations about the best ways to use these devices to help reduce the spread of COVID-19.

Materials and methods

Experimental design

In our experiments, a cough aerosol simulator propelled a test aerosol through a headform into a collection chamber (Figure 1), and the amount of aerosol in the collection chamber was measured in each of six size fractions. The collection efficiency of each face mask, neck gaiter, or face shield was determined by comparing the amount of aerosol that was collected from the chamber with and without the device. Our test method was similar to the modified Greene and Vesley method used to test medical masks (Quesnel 1975), with the human test subject replaced by the cough aerosol simulator.

Cough aerosol simulator

The cough aerosol simulator is a modified version of the NIOSH cough aerosol simulator described previously (Lindsley et al. 2019; Lindsley et al. 2014; Lindsley et al. 2013). The experimental cough aerosol was generated by nebulizing a solution of 14% KCl and 0.4% sodium fluorescein using a single-jet Collison nebulizer (BGI, Butler, NJ, USA) at 103 kPa (15 lbs./in^2), passing the aerosol through a diffusion drier (Model 3062, TSI, Shoreview, MN, USA), and mixing it with 10 L/min of dry filtered air. The test aerosol was loaded into an elastomeric bellows, and the cough airflow was produced by a computer-controlled linear motor that compresses the bellows. The cough aerosol was expelled through the mouth of a headform into a collection chamber. The headform used in the study has pliable skin that mimics the elastic properties of human skin in order to create a realistic simulation of how each face covering or shield would fit a human face (Bergman et al. 2014).

Source control devices

The source control devices tested were an N95 medical respirator (3 M model 1860), a medical grade (ASTM Level 3) procedure mask with ear loops (Kimberly Clark model 47107), a cloth face mask with 3 layers of cotton fabric and ear loops (Hanes Defender), a fabric neck gaiter (FKGIONG Sun UV Protection Neck Gaiter, 95% polyester, 5% Spandex) and a disposable face shield (Fisher Scientific # 19-181-600 A). The neck gaiter was tested both as a single layer of fabric and doubled over to provide two layers of fabric. The masks and respirator were not equipped with exhalation valves. The face shield was 25 cm tall and extended from the forehead of the headform to 3 cm below the chin and around the side to 3 cm before the front of the ear. Photographs of the source control devices on the headform are shown in the online supplementary information (SI).

Mask fit test

For the experiments, either no device, a face mask, a neck gaiter, or a face shield were placed on the head form. Each device was used for two consecutive tests. For face masks and gaiters, a respirator fit test was performed using a PortaCount (TSI). The fit factor is a measure of the protection against airborne particles that is provided by a respiratory protective device. It is defined as the ratio of the aerosol concentration outside the respiratory protective device to the aerosol concentration inside the device (i.e., the aerosol concentration that is inhaled by the wearer). For example, a fit factor of 10 means that the ambient aerosol concentration is 10 times higher than the concentration inside the mask, and that the mask is therefore filtering out 90% of the ambient aerosol.

Aerosol collection and analysis

After placing the device on the headform and performing the fit test, the system was sealed. The test aerosol was then generated and propelled with a simulated cough through the headform and into the collection chamber. The Andersen impactor at the bottom of the collection chamber collected the aerosol particles that traveled through or around the device for 20 min after each cough. The Andersen impactor operates at a flow rate of 28.3 liters/minute and has six collection stages and a filter that separate the aerosol particles into seven size fractions based on the aerodynamic diameter of the particles: <0.6 µm; 0.6–1.1 µm; 1.1–2.1 µm; 2.1–3.3 µm; 3.3–4.7 µm;

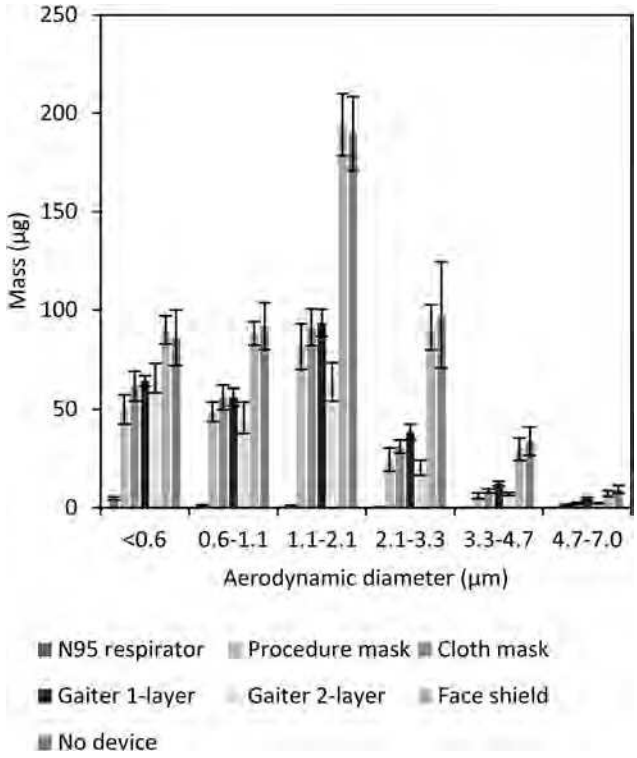

Figure 2. Mass of aerosol collected in each size fraction. The graph shows the amount of simulated respiratory aerosol that was collected from the collection chamber in each aerosol particle size fraction after a single simulated cough. The bars show the mean and standard deviation. A larger color version of this figure is shown in the SI.

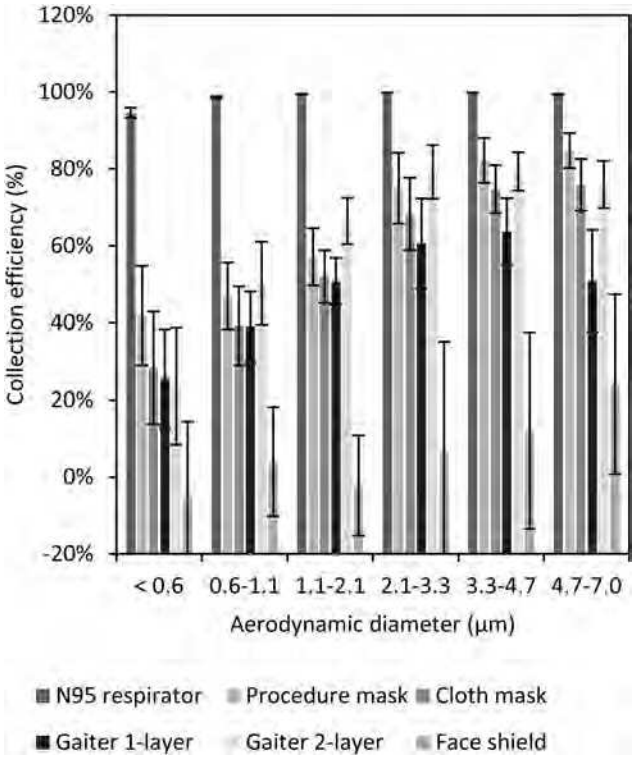

Figure 3. Collection efficiency of face masks, neck gaiter and face shield. The collection efficiency is the percentage of aerosol particles that were blocked by the face mask, neck gaiter or face shield compared with experiments without a device. The plot shows the means and standard deviations of the collection efficiency in each size fraction. A larger version of this figure is shown in color in the SI.

4.7–7.0 µm; and >7 µm. Because the amount of aerosol in the largest size fraction was small and because of possible losses due to settling of the large aerosol particles, data for the largest size fraction was not included in the analysis. The impactor collection plates were coated with a solution of glycerol and Brij 35 to prevent particles from bouncing off the plates during collection (Mitchell 2003). After aerosol collection was completed, the impactor plates were rinsed with 0.1 M Tris solution and the fluorescence of the solution was measured using a fluorometer (SpectraMax M4, Molecular Devices). The complete experimental protocol is given in the SI.

Statistical analysis

The performance of each device was evaluated by comparing the total mass of the aerosol particles from a single cough that passed through or around the device and was collected by the Andersen impactor. The results were evaluated using a one-way ANOVA and multiple comparisons among the different devices and the control experiments without a device were conducted using a Tukey-Kramer test. To control for variations in the amount of aerosol in each cough, a sample of each cough aerosol was collected from the bellows prior to coughing and used to normalize the aerosol mass collection results for each experiment.

Results

The cough aerosol simulator provides a cough with a controlled cough airflow rate containing a test aerosol with a consistent aerosol size distribution. The simulator allows for a direct quantitative comparison of the ability of different types of source control devices to block the expulsion of simulated cough aerosol particles of different sizes into the environment. The flow rate of the simulated cough used in our experiments was based on cough flow profiles recorded from influenza patients and had a volume of 4.2 L with a peak flow rate of 11 L/s (Lindsley et al. 2013). The cough aerosol collected from the control experiments without a face covering had a mass median aerodynamic diameter of 1.3 µm, a geometric standard deviation of 2.3 and a total aerosol mass of 505 µg (standard deviation 69).

For our study, we tested the collection efficiencies (that is, the fraction of the cough aerosol that was

Table 1. Total mass of aerosol expelled into collection chamber and device collection efficiencies.

Device tested	Number of experiments	Fit factor	Aerosol mass (μg)	Collection efficiency
No device	12	n/a	512 (64)	n/a
Procedure mask	6	2.9 (0.5)	212 (23)	58.5% (6.9%)
Cloth mask	6	1.3 (0.1)	251 (23)	50.9% (7.7%)
Neck gaiter (single layer)	6	1.7 (0.5)	270 (18)	47.2% (7.5%)
Neck gaiter (double layer)	6	1.9 (0.4)	206 (26)	59.8% (7.2%)
Face shield	6	n/a	502 (46)	1.8% (15.3%)
N95 respirator	6	198 (3.5)	7.2 (1.2)	98.6% (0.3%)

Note: The fit factor, aerosol mass, and collection efficiency are given as mean (standard deviation).

blocked) of a medical grade procedure mask, a cotton cloth face mask, a polyester neck gaiter, an N95 medical respirator and a disposable face shield. These source control devices were chosen to provide representative samples of the different types of face coverings and face shields that are in common use during the pandemic. Neck gaiters are typically worn either as a single layer of fabric over the mouth and nose or doubled over to provide two layers of fabric; for our experiments, we tested both configurations. The quantity of aerosol particles in six size fractions that were able to travel through or around each source control device are shown in Figure 2. The collection efficiencies of the devices are shown as a function of aerosol size in Figure 3. All the devices showed increased collection efficiencies as the aerosol size increased.

On average, the N95 respirator blocked 99% of the total mass of test aerosol from being released into the environment, while the medical procedure mask blocked 59%, the cloth face mask blocked 51%, the single-layer gaiter blocked 47%, the double-layer gaiter blocked 60%, and the face shield blocked 2% of the total aerosol (Table 1). The N95 respirator, procedure mask, cloth mask, and the single-layer and double-layer gaiters all significantly reduced the aerosol emitted into the environment compared with no device ($P < 0.0001$ for each), but the face shield did not ($P = 0.9993$). The collection efficiencies of the procedure mask, cloth mask, and the single and double-layer gaiters did not differ significantly from each other, but all blocked cough aerosols significantly better than did the face shield ($P < 0.0001$). The N95 respirator outperformed all the other devices ($P < 0.0001$) (Table 2).

Discussion

Humans continuously emit aerosols of respiratory fluids as they breathe, talk, cough, sneeze, sing, or carry out other respiratory activities. These respiratory aerosols can have a very broad size range, from tens of nanometers in diameter to visible droplets of a millimeter or more (Bourouiba, Dehandschoewercker, and Bush 2014; Fennelly 2020; Gralton et al. 2011; Morawska et al. 2009). Airborne particles larger than 100 μm are ballistic; that is, they are affected primarily by gravity and fall quickly to the ground. Respiratory aerosol particles in this size range tend to deposit within a few meters of the source (Prather et al. 2020). As the aerosol particle diameter decreases from 100 μm, a gradual transition occurs where the settling velocity rapidly decreases and the particles remain airborne for longer times. For example, a 100 μm aerosol particle takes 4 s to fall 1 m in still air, while a 10 μm aerosol particle takes 5.4 min and a 1 μm aerosol particle takes 8 h to settle the same distance (Hinds 1999). Air currents such as plumes of warm air rising from the body can lift these particles and extend the time for which they stay in the air. Thus, small aerosol particles can remain airborne for minutes to hours and can accumulate over time in environments with poor ventilation (Bahl et al. 2020). Small aerosol particles also are easier to inhale and can travel more deeply into the lungs (Vincent 2005).

The amount and sizes of aerosol particles containing SARS-CoV-2 that are expelled by people who are infected are not yet known. Two studies of aerosol samples collected in patient rooms found infectious (replication-competent) SARS-CoV-2 in aerosol particles <4 μm in diameter (Santarpia et al. 2020a) and <10 μm in diameter (Lednicky et al. 2020). Other studies have reported SARS-CoV-2 RNA in exhaled breath from infected patients (Ma et al. 2020), aerosol samples from biocontainment and quarantine units housing SARS-CoV-2 infected persons (Santarpia et al. 2020b), and in aerosol samples at multiple locations throughout two hospitals in Wuhan, China during a COVID-19 outbreak (Liu et al. 2020). The presence of small aerosol particles containing

Table 2. Comparison of aerosol mass expelled into the collection chamber while wearing face masks, neck gaiters and face shields.

		95% confidence intervals for mean differences (μg)			
PPE types compared		Lower limit	Mean difference	Upper limit	P-value
N95 respirator	No device	−567	−504	−442	<0.0001
Procedure mask	No device	−361	−299	−237	<0.0001
Cloth mask	No device	−322	−260	−198	<0.0001
Gaiter (single layer)	No device	−304	−241	−179	<0.0001
Gaiter (double layer)	No device	−368	−306	−243	<0.0001
Face shield	No device	−71	−9	53	0.9993
N95 respirator	Face shield	−567	−495	−423	<0.0001
Procedure mask	Face shield	−362	−290	−218	<0.0001
Cloth mask	Face shield	−323	−251	−179	<0.0001
Gaiter (single layer)	Face shield	−304	−232	−160	<0.0001
Gaiter (double layer)	Face shield	−369	−297	−225	<0.0001
N95 respirator	Gaiter (double layer)	−271	−199	−127	<0.0001
Procedure mask	Gaiter (double layer)	−65	7	79	0.9999
Cloth mask	Gaiter (double layer)	−26	46	118	0.4505
Gaiter (single layer)	Gaiter (double layer)	−7	64	136	0.1051
N95 respirator	Gaiter (single layer)	−335	−263	−191	<0.0001
Procedure mask	Gaiter (single layer)	−130	−58	14	0.1900
Cloth mask	Gaiter (single layer)	−91	−19	53	0.9825
N95 respirator	Cloth mask	−316	−244	−172	<0.0001
Procedure mask	Cloth mask	−111	−39	33	0.6336
N95 respirator	Procedure mask	−277	−205	−133	<0.0001

infectious SARS-CoV-2 detected in these studies suggests that in addition to large aerosols, these small aerosols might play a role in SARS-CoV-2 transmission (Anderson et al. 2020; Bahl et al. 2020; Ma et al. 2020; Morawska and Milton 2020).

Source control devices like face coverings and face shields collect respiratory particles larger than 0.3 μm primarily by impaction and interception of the aerosol particles against the fibers or solid surfaces of the device. As noted earlier, source control devices may also deflect aerosols, but this mechanism can be problematic as a means of source control because the infectious aerosol is not prevented from entering the surrounding environment; it is merely sent in a different direction which may or may not be protective depending upon local airflows and the locations of other people. Our experimental system measures particle collection only; any particles that are deflected but not collected by the face covering are still collected by the Andersen impactor. Thus, we are able to measure the particle collection efficiency of the face coverings without the potentially confounding variable of particle deflection. On the other hand, this does means that any potential benefits from, for example, deflecting large aerosol particles toward the ground were not measured by our system.

Small aerosols require much higher air velocities to deposit by impaction than do larger aerosols, and thus are more difficult to block with source control devices (Hinds 1999; Lindsley 2016). Consequently, small aerosols present the most challenging scenario for testing source control devices since devices that block small aerosol particles would be expected to block larger ones as well. Our results show that face masks and neck gaiters can significantly reduce the expulsion of small respiratory aerosol particles during coughing. This suggests that various types of face coverings can make an important contribution to reducing the quantity of aerosol particles containing SARS-CoV-2 released into the environment by people who are infected. N95 respirators, which are worn for personal protection by healthcare workers and others at highest risk of exposure, are also very effective source control devices. In contrast, the face shield blocked very little of the cough aerosol, indicating that face shields are not effective as source control devices for small respiratory aerosols.

The collection efficiencies of all the devices tested increased as the aerosol particle size increased, and this trend would be expected to continue for larger aerosol particles than were tested here. For example, the collection efficiency of the cloth face mask was 28% for the <0.6 μm particles and increased to 76% for the 4.7 to 7 μm particles. Similarly, the double-layer gaiter blocked 24% of the <0.6 μm particles and 76% of the 4.7 to 7 μm particles. These results suggest that cloth face coverings would be effective as source control devices against the large respiratory aerosols that are thought to play an important role in SARS-CoV-2 transmission.

Our study has several limitations. We used a single cough volume, air flow profile, and aerosol size distribution for our studies; these parameters can vary greatly from person to person. We examined the

performance of these devices during simulated coughing but not breathing or speaking, which have different air flow rates and aerosol size distributions. Some internal losses of the test aerosol particles likely occurred due to settling or impaction on the surfaces of the collection chamber, which may affect the estimates of the collection efficiencies. We only used a single representative example of each type of device. The shape and composition of face coverings vary widely, and this would be expected to affect the performance of individual devices. Some face masks have exhalation valves or vents which could reduce their efficacy as source control devices. The fit of a particular mask to an individual wearer and compliance in wearing the mask correctly (i.e., over the nose and mouth) also are important factors in how well the mask performs as a source control device. Because we used a < 0.6 to 7 µm test aerosol, our results do not indicate if face shields would be more effective as source control devices for large droplets. The face shield that we tested has a widely used design, but alternative designs are being marketed that provide greater facial coverage and, in some cases, include fabric skirts between the shield and the face. These alternative face shield designs might perform better as source control devices.

Previous studies have shown that face shields provide eye and facial protection to the wearer from droplets and splashes (Lindsley et al. 2014; Roberge 2016). When a face shield is worn in addition to a face mask, the face shield can also help reduce surface contamination of the mask by large aerosols and reduce the likelihood of hand contamination when the mask is removed or inadvertently touched (Lindsley et al. 2014). Our previous study showed that face shields provide some benefits as personal protective equipment when face masks cannot be worn (Lindsley et al. 2014), but as with all personal protection and source control devices, their limitations must be respected. Our results suggest that face masks and neck gaiters are more effective than face shields as source control devices to reduce the expulsion of respiratory aerosols into the environment as a public health measure to reduce the community transmission of SARS-CoV-2.

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Declaration of interests statement

The authors declare no competing interests.

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From: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>
Sent: Tuesday, January 11, 2022 2:05 PM
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
Cc: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>; McCalla, Haley (CDC/OD/OCS) <LNO3@cdc.gov>; Brunson, Juanita (CDC/DDNID/NCBDDD/DBDID) (CTR) <qrl8@cdc.gov>
Subject: N95 effectiveness as source control

Dear Partners,

We have had a number of questions from you and others about N95 effectiveness as source control and wanted to share some information back with you.

National Institute for Occupational Safety and Health (NIOSH) researchers have evaluated N95s as source control in two different peer reviewed publications. In the first paper (Lindsley et al. 2021a- attached), NIOSH researchers found that a N95 respirator (3M model 1860) was 99% effective at blocking cough aerosols. In a second paper (Lindsley et al. 2021b- attached), NIOSH researchers found that one N95 respirator (3M 1860 N95) was 99% effective at blocking coughed and exhaled aerosols, and a second N95 Respirator (BYD) was 83% effective at blocking cough aerosols and 95% effective at blocking exhaled aerosols.

References (attached)
Lindsley WG, et al. (2021a). Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols. AEROSOL SCIENCE AND TECHNOLOGY, VOL. 55, NO. 4, 449–457
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Many thanks,
Aliki

Aliki Pappas Weakland, MPH MSW (she/her/hers)
Lead, Policy & Public Health Partnerships
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Coronavirus Disease 2019 (COVID-19) | CDC

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Saturday, January 08, 2022 1:55 PM EST
To: CDC IMS 2019 NCOV Response STLT Policy and Public Health Partnerships <eocevent382@cdc.gov>
Subject: PARTNER ALERT: CDC Expands Booster Shot Eligibility

Dear Partners –

Yesterday, CDC adjusted our recommendation for when people can receive a booster shot, shortening the interval from 6 months to 5 months.

Earlier this week CDC made this recommendation for recipients of a Pfizer-BioNTech primary seriesand, after FDA action this morning, we're extending this recommendation to recipients of a Moderna primary series. This means that people 12 and older who initially received an mRNA vaccine series – two doses of Moderna or Pfizer-BioNTech – can now receive an mRNA booster shot 5 months after completing their initial series.

Recently CDC strengthened our COVID-19 vaccination recommendations for children, now recommending that:

- Moderately to severely immunocompromised children ages 5–11 years receive an additional primary dose of Pfizer-BioNTech to ensure optimal protection from the vaccine.
- Children and teens ages 12–17 years should receive a booster shot.

Thank you,

Vaccine Task Force
COVID-19 Response

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Jan. 22 (incl. WH National Strategy on COVID-19 Materials, MMWRs, Call Reminders and more)
Date:	Friday, January 22, 2021 1:47:13 PM
Attachments:	image001.png image002.png National Strategy for the COVID-19 Response and Pandemic Preparedness.msg FACT SHEET President Biden Takes Aggressive and Immediate Action to Contain COVID-19 Crisis.msg MMWR ER - January 22, 2021.pdf CDC COCA Call Treating Long COVID Clinician Experience with Post-Acute COVID-19 Care.msg MMWR Weekly – January 22, 2021.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of recent Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

- White House National Strategy for the COVID-19 Response and Pandemic Preparedness and Executive Order on a Data-Driven Response [Attachment, Link]
  - Yesterday, the White House released its National Strategy for the COVID-19 Response and Pandemic Preparedness, providing a roadmap to guide America out of the worst public health crisis in a century. An executive summary of the new National Strategy is attached, while the complete plan is linked above. A fact sheet summarizing the new National Strategy to quickly contain the COVID-19 crisis has also been released. [Link]
  - The White House also issued an executive order yesterday to ensure a "Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats." [Link]
  - White House activities – Thursday, January 21, 2021 [Link] and Friday, January 22, 2021 [Link]
- MMWR Early Release: "Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021" [Attachment, Link]
  - From the summary: *"During December 21, 2020–January 10, 2021, monitoring by the Vaccine Adverse Event Reporting System detected 10 cases of anaphylaxis after administration of a reported 4,041,396 first doses of Moderna COVID-19 vaccine (2.5 cases per million doses administered). In nine cases, onset occurred within 15 minutes of vaccination. No anaphylaxis-related deaths were reported."*
- Reminder: CSTE Webinar: COVID-19 during Pregnancy [Link]

- CSTE will host its next COVID-19 Response Membership Webinar, "COVID-19 during Pregnancy," **Friday, January 29, 2021** at **3:00 pm EST**. CDC will present the current evidence on COVID-19 in pregnant women and their babies and provide an overview of current surveillance efforts, including successes and challenges. Massachusetts will provide a state perspective on efforts to improve identification of SARS-CoV-2 infection during pregnancy through data linkages to existing data sources.
- Call capacity is limited to 1,000 participants, and is first-come, first-served. Call information is below:
    - Weblink: https://webinar.ringcentral.com/j/1487195918
    - Telephone: (470) 860-2200 *[East]* | (773) 231-9226 *[North]* | (469) 445-0100 *[South]* | (623) 404-9000 *[West]* | (720) 902-7700 *[Central]*
    - Meeting ID: 148 719 5918
    - One-Tap Mobile: *+1(470)8692200,,1487195918# [East] |+1(773)2319226,,1487195918# [North] | +1(469)4450100,,1487195918# [US South] | +1(623)4049000,,1487195918# [US West] | +1(720)9027700,,1487195918# [US Central]*

- Reminder: CDC Partner Update Call: Engaging Faith Leaders to Advance Effective COVID-19 Response: Lessons Learned through Global-Domestic Collaborations [Link]
    - CDC will host a webinar **Monday, January 25, 2021** at **3:00 pm EST**. During the call, Dr. Cliff McDonald will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Dr. Jay Butler will give a brief status report on the pandemic and an overview of prevention with a specific emphasis on opportunities for faith-based organizations. Dr. Susan Hillis will describe successes from other countries through shared collaborative leadership between faith and government partners. Ms. Lauren Erickson-Mamane will also discuss COVID-19 resources developed for Global Faith Leaders by the International Task Force.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 1/25" in the subject line. The call will be recorded and posted to CDC's website here.
- Reminder: COCA Call: Treating Long COVID: Clinician Experience with Post-Acute COVID-19 Care [Attachment]
    - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **Thursday, January 28, 2021** at **2:00 pm EST**. During this call, presenters will share their firsthand experiences with treating long COVID, focusing on the pulmonary, neurologic, and psychological aspects. They will also describe their experiences with establishing clinics that provide care for patients with these long-term effects.
        - Weblink: https://www.zoomgov.com/j/1606808037?pwd=NUx3a1hQd2tVWVZBU0JobFgxUDJ2Zz09
          Telephone: (669) 254 5252 or (646) 828 7666
          Webinar ID: 160 680 8037
          Passcode: 594536

Post-Event Recording:
https://emergency.cdc.gov/coca/calls/2021/callinfo_012821.asp

- CDC Media Statement: "Media Statement from CDC Director Rochelle P. Walensky, MD, MPH, on Extending the Eviction Moratorium" [Link]
  - From the statement: *"As a protective public health measure, I will extend the current order temporarily halting residential evictions until at least March 31, 2021. The COVID-19 pandemic has presented a historic threat to our nation's health. It has also triggered a housing affordability crisis that disproportionately affects some communities."*
- MMWR Release: "COVID-19 Case Investigation and Contact Tracing Efforts from Health Departments — United States, June 25–July 24, 2020" [Attachment, Link]
  - From the summary: *"An analysis of 56 health departments found wide variation in capacity and capability to conduct timely and effective case investigation and contact tracing. The study found that case interviews were less timely and fewer contacts were identified when caseloads were higher, implying that high numbers of cases compromised the prompt and complete identification of contacts."*
- Reminder: Request Form for CSTE COVID-19 Call Topics [Link]

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CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: Centers for Disease Control and Prevention <no-reply@emailupdates.cdc.gov>
Sent: Thursday, January 14, 2021 12:05 PM EST
To: Command Center <CommandCenter@cste.org>
Subject: CDC COCA Call: Treating Long COVID: Clinician Experience with Post-Acute COVID-19 Care

Treating Long COVID: Clinician Experience with Post-Acute COVID-19 Care

Overview

For some people, the effects of COVID-19 can last well beyond the immediate illness. Patients and clinicians across the United States are reporting long-term effects of COVID-19, commonly referred to as long COVID. Symptoms may include cognitive difficulties, fatigue, and shortness of breath. In some patients, critical illness from COVID-19 may be the cause of persistent symptoms, but many patients with long-term effects had mild or asymptomatic acute COVID-19 infection. During this COCA Call, presenters will share their firsthand experiences with treating long COVID, focusing on the pulmonary, neurologic, and psychological aspects. They will also describe their experiences with establishing clinics that provide care for patients with these long-term effects.

If you are unable to attend the live COCA Call, the recording will be available for viewing on the COCA Call webpage a few hours after the live event ends.

The slide set will be available on the day of the call under "Call Materials" on the COCA Call webpage.

Free Continuing Education (CE) will be offered for this COCA Call.

Advanced registration is not required.

a doctor consulting her patient

Date: Thursday, January 28, 2021

Time: 2:00 PM – 3:00 PM ET

A few minutes before the webinar starts, please click on the Zoom link below to join:
https://www.zoomgov.com/j/1606808037?pwd=NUx3a1hQd2tVWVZBU0JobFgxUDJ2Zz09

Passcode: 594536

Or Telephone:
US: +1 669 254 5252
or +1 646 828 7666
or +1 669 216 1590
or +1 551 285 1373

Or iPhone one-tap:
US:+16692545252,,1606808037#,,,,,,0#,,594536#
or +16468287666,,1606808037#,,,,,,0#,,594536#

Webinar ID: 160 680 8037

International numbers available: https://www.zoomgov.com/u/adQOV17URb

Activity-specific Objectives

At the conclusion of the session, the participant will be able to accomplish the following—

1. Identify signs and symptoms of long COVID which occur after the acute phase of SARS-CoV-2 infection.
2. Identify potential multidisciplinary teams for patient care.
3. Describe common challenges to post-acute COVID-19 care.
4. Describe examples of patient-centered, interdisciplinary post-acute COVID-19 care.

COCA Call Objectives

At the conclusion of the session, the participant will be able to accomplish the following—

1. Cite background information on the topic covered during the presentation.
2. Discuss CDC's role in the topic covered during the presentation.
3. Describe the topic's implications for clinicians.
4. Discuss concerns and/or issues related to preparedness for and/or response to urgent public health threats.
5. Promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an interprofessional team of health care providers.

Presenters

Alfonso C Hernandez-Romieu, MD, MPH
LCDR, U.S. Public Health Service
Sequelae Unit, Clinical Team
COVID-19 Response
Centers for Disease Control and Prevention

Jennifer Possick, MD
Associate Professor, Section of Pulmonary, Critical Care and Sleep Medicine
Department of Internal Medicine
Yale University School of Medicine

Allison Navis, MD
Assistant Professor, Division Neuro-Infectious Diseases
Icahn School of Medicine at Mount Sinai
Mount Sinai Health System

Instructions for Obtaining Continuing Education

To receive continuing education (CE) for **WC2922-012821** – Clinician Outreach and Communication Activity (COCA) Calls/Webinars – **Treating Long COVID: Clinician Experience with Post-Acute COVID-19 Care, Thursday, January 28, 2021** please visit TCEO and follow these 9 Simple Steps by **Monday, March 1, 2021.**

To receive continuing education (CE) for **WD2922-012821** (Web on Demand) – Clinician Outreach and Communication Activity (COCA) Calls/Webinars - **Treating Long COVID: Clinician Experience with Post-Acute COVID-19 Care, Thursday, January 28, 2021,** please visit TCEO and follow these 9 Simple Steps by **Thursday, March 2, 2023.**

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Sent: Friday, January 22, 2021 11:40 AM EST
To: CSTE Emergency Response <Preparedness@cste.org>
Subject: FACT SHEET: President Biden Takes Aggressive and Immediate Action to Contain COVID-19 Crisis

From: White House Press Office <whopress@who.eop.gov>
Sent: Thursday, January 21, 2021 5:55 AM
To: Cisneros, Eduardo EOP/WHO <Eduardo.Cisneros@who.eop.gov>
Subject: FACT SHEET: President Biden Takes Aggressive and Immediate Action to Contain COVID-19 Crisis

FOR IMMEDIATE RELEASE
January 21, 2021

FACT SHEET:
President Biden Takes Aggressive and Immediate Action to Contain COVID-19 Crisis

The President to Release National COVID-19 Strategy and Sign Executive Actions to Expand Testing, Administer Vaccines, Advance Racial Equity, and Safely Reopen Schools and Businesses

Today, President Joe Biden will release the National Strategy for the COVID-19 Response and Pandemic Preparedness -- a comprehensive roadmap to guide America out of this pandemic. To jumpstart this strategy, he will immediately sign 10 Executive Orders and other directives and take additional actions to move quickly to contain the COVID-19 crisis by expanding testing, administering vaccines, advancing racial equity, and safely reopening schools and businesses. These steps build on actions President Biden took yesterday to rejoin the World Health Organization, encourage masking, and to create his White House COVID-19 Response Team.

Below are more details on the steps that President Biden will take today to immediately put his National Strategy into action.

IMMEDIATELY EXPAND EMERGENCY RELIEF AND EXERCISE THE DEFENSE PRODUCTION ACT (DPA)

Manufacture and Deliver Supplies for Vaccination, Testing, and Personal Protective Equipment (PPE)
President Biden is taking immediate action to fill supply shortfalls for vaccination supplies, testing supplies, and PPE, and to ensure that these critical supplies equitably reach American communities, especially communities of color and other underserved communities hit hardest by the virus. The President will issue an Executive Order directing relevant agencies to exercise all appropriate authorities, including the DPA, to accelerate manufacturing, delivery, and administration to meet shortfalls in equipment and supplies needed for the COVID-19 response, beginning with action to increase the availability of critical supplies such as N95 masks, isolation gowns, nitrile gloves, PCR sample collection swabs, test reagents, pipette tips, laboratory analysis machines for PCR tests, high-absorbency foam swabs, nitrocellulose material for rapid antigen tests, rapid test kits, and all the necessary equipment and material to accelerate the manufacture, delivery, and administration of COVID-19 vaccine.

Reimburse States So They Can Deploy the Emergency Personnel and Supplies Americans Need

The President will issue a Presidential Memorandum directing the Federal Emergency Management Administration (FEMA) to increase federal reimbursement to states and Tribes from 75 percent to 100 percent of the cost for National Guard personnel and emergency supplies, such as PPE, cleaning and sanitizing efforts, and the personnel and equipment needed to create vaccination centers. The order also includes restoring full reimbursement for eligible costs necessary to support safe school reopening through the FEMA Disaster Relief Fund. To help address the health and financial crises faced by Tribal Nations throughout our country and to advance Tribal sovereignty in our COVID-19 response, this Memorandum also expands FEMA resources for Tribal governments.

MITIGATE SPREAD THROUGH EXPANDING TESTING, TREATMENT, AND THE PUBLIC HEALTH WORKFORCE, AND ESTABLISHING CLEAR PUBLIC HEALTH STANDARDS

Establish the Pandemic Testing Board, Expand Testing, and Strengthen the Public Health Workforce

To control the COVID-19 pandemic and safely reopen schools and businesses, the U.S. must have wide-spread testing. President Biden will issue an Executive Order that establishes the COVID-19 Pandemic Testing Board to bring the full force of the federal government's expertise to expanding testing supply and increasing access to testing. The federal government will increase testing capacity by directing the use of the DPA and other authorities to procure more tests and expand manufacturing capacity where possible. The Executive Order will promote surge capacity for testing in the United States, onshore test manufacturing, expand the public health workforce, support COVID-19 screening for schools, and ensure that underserved communities, including communities of color, can equitably access tests.

Bolster Access to COVID-19 Treatments and Clinical Care

Effective treatments for COVID-19 are critical to saving lives. President Biden will sign an Executive Order directing studies, including large-scale randomized trials, to identify treatments for COVID-19 and to ensure that such studies address the needs of diverse populations. The Executive Order establishes a comprehensive, integrated, equitable, and coordinated preclinical drug discovery and development program to allow therapeutics to be evaluated and developed in response to pandemic threats. The Order also outlines steps to improve clinical care, provide assistance to long-term care facilities and intermediate care facilities for people with disabilities, increase health care workforce capacity, expand access to programs designed to meet long-term health needs of patients recovering from COVID-19, and support access to safe and effective COVID-19 therapies for those without coverage.

Improve Data to Combat COVID-19

Metrics and metric-driven public health guidance will be essential to controlling the pandemic. President Biden's Executive Order will enhance the United States' collection, production, sharing, and analysis of data to support an equitable COVID-19 response and recovery. The federal government will work with state, local, Tribal and territorial governments to aggregate and analyze data to track access to vaccines and testing, reopen schools and businesses, and address disparities in COVID-19 infections and health outcomes. And, the federal government will create publicly available dashboards with national and state-by-state level information, consistent with privacy protections, on cases, testing, vaccinations, and hospital admissions to make real-time information available to policymakers and the public.

MOUNT A SAFE, EFFECTIVE, COMPREHENSIVE VACCINATION CAMPAIGN

Take Immediate Actions to Convert Vaccines into Vaccinations

The Biden-Harris Administration will spare no effort to ensure the public can get vaccinated safely, effectively and equitably. To meet the aggressive vaccination target of 100 million shots by the end of his first 100 days in office, President Biden will take immediate action to improve the vaccination

program. Yesterday, he directed FEMA to begin standing up the first federally-supported community vaccination centers, with the goal of standing up 100 centers in the next month. The Centers for Disease Control and Prevention (CDC) will also launch the federal pharmacy program -- making vaccines available to communities in their local pharmacies beginning next month. And, he tasked the U.S. Public Health Services Commissioned Corps with expanding its workforce and preparing for deployment. Central to this effort will be expanded support and collaboration with state, local, Tribal and territorial governments, including the establishment of COVID Response Liaisons for each state -- a model based on the response to Hurricane Sandy.

SAFELY REOPEN SCHOOLS, BUSINESSES, AND TRAVEL WHILE PROTECTING OUR WORKERS

Direct Action to Support Students & Safely Reopen Schools
President Biden will issue an Executive Order directing the Departments of Education and Health and Human Services (HHS) to provide guidance on safe reopening and operating for schools, child care providers, and institutions of higher education. Ensuring the safety of students and educators and adherence to science will be paramount. And, the Order directs the Departments of Education and Health and Human Services to collect data around reopening and school closures so state and local officials have metrics to inform decision-making and can better understand the impact of closures on students from families with low-incomes, students of color, English-language learners, students with disabilities and others.

The COVID-19 Response Team will work to ensure that testing materials, support for contact tracing, and vaccinations for teachers are equitably provided to support in-person care and learning. Finally, the order encourages the Federal Communications Commission to increase connectivity options for students lacking reliable home broadband, so that they can continue to learn if their schools are operating remotely.

This work will be supported by the Presidential Memorandum directing FEMA to offer reimbursement for eligible emergency supplies, such as PPE for schools and child care providers.

The Administration will engage with educators and their unions, students and their families, state and local education and public health officials, civil rights advocates, and other experts in the field. And, the Department of Education will work with HHS to ensure that guidance for schools is updated based on the latest science and any developments in the pandemic, including the spread of new coronavirus variants that may have a higher transmission rate. The Administration will always be honest about the challenges we face, directly addressing how and whether changes in the pandemic may impact the reopening of schools or the ability of schools to remain open.

Help Protect Workers from COVID-19
Millions of Americans, many of whom are people of color, immigrants, and low-wage workers, continue to put their lives on the line to keep the country functioning through the pandemic. President Biden will sign an Executive Order calling on the Occupational Safety and Health Administration (OSHA) to immediately release clear guidance for employers to help keep workers safe from COVID-19 exposure. It also asks OSHA and Mine Safety and Health Administration to determine whether to establish emergency temporary standards that require employers to take steps to keep workers safe from COVID-19 and it directs OSHA to enforce worker health and safety requirements, targeting the worst violators. With the goal of protecting all workers from COVID-19, the order instructs agencies to explore ways to protect workers who are not always covered by OSHA standards, such as those who are self-employed.

Promote Safe Travel
To protect travelers from COVID-19, President Biden will issue an Executive Order to require mask-wearing in airports, on certain modes of public

transportation, including many trains, airplanes, maritime vessels, and intercity buses. For air travel, this Executive Order also requires international travelers to produce proof of a negative COVID-19 test prior to departing for the United States and to comply with CDC guidelines for self-isolation and self-quarantine upon arrival. The Executive Order also calls for the consideration of additional public health measures in domestic travel and for consultation with foreign governments and other stakeholders to implement public health measures for safe travel, including at land and sea borders.

PROTECT THOSE MOST AT RISK AND ADDRESS INEQUITIES FACED BY COMMUNITIES OF COLOR AND OTHER UNDERSERVED GROUPS

Advance Health Equity in the Nation's COVID-19 Response
In order to address the disproportionate and severe impact of COVID-19 on communities of color and other underserved populations, President Biden will issue an Executive Order to ensure an equitable pandemic response and recovery. The order establishes a COVID-19 Health Equity Task Force to provide specific recommendations to the President for allocating resources and funding in communities with inequities in COVID-19 outcomes by race, ethnicity, geography, disability, and other considerations. The federal government will expand equity data collection; increase access to PPE, testing, therapies, and vaccines in underserved communities and high-risk settings; and assess and update pandemic response plans to ensure equity. The health workforce, including community-based workers, will be expanded to assist with contact tracing, vaccination, and linkage to care. Additionally, the Biden Administration will work with states, local jurisdictions, Tribal communities, and territories to address unmet basic needs, including food, housing, and childcare, for individuals and families affected by COVID-19.

RESTORE U.S. GLOBAL LEADERSHIP AND BUILD BETTER PREPAREDNESS

Advance U.S. Global Leadership, Support the Health and Humanitarian Response to COVID-19, and Protect Against Future Biological Threats
America's withdrawal from the world stage and retreat from the World Health Organization has impeded progress on the global COVID-19 response and left the United States and the world more vulnerable to future pandemics. Yesterday, President Biden signed letters to the United Nations Secretary General and World Health Organization Director General to cease America's withdrawal from the organization and to outline U.S. intent to work constructively with the WHO to strengthen and reform it.
Today, President Biden will sign a Presidential Directive to restore America's leadership, support the international pandemic response effort, promote resilience for future threats, and advance global health security and the Global Health Security Agenda. This directive restores U.S. leadership and seeks to support the international health and humanitarian response to the COVID-19 pandemic and its secondary impacts, global health security and diplomacy, and better biopreparedness and resilience for emerging and future biological threats.

RACIAL EQUITY IMPACT

The COVID-19 crisis has shined a light on and exacerbated the persistent racial inequities in our healthcare system and our economy. Americans of color are being infected and dying from COVID-19 at higher rates, while workers of color disproportionately put themselves at risk of exposure to COVID-19 on the frontline of this crisis to keep our country running. Changing the course of the COVID-19 crisis requires mobilizing an equitable response across the whole of our government. The new COVID-19 Health Equity Task Force will intensely focus on these issues. The actions to expand the availability of testing and vaccines in communities of color, and other underserved communities, ensure that new clinical treatments are developed to serve diverse Americans, and safely reopen our schools so that children who are facing disproportionately

high risks of learning loss can get back into the classroom. These actions will also support Native communities and Tribal governments to address the health and economic crises in Indian country.

WORKER IMPACT

These executive actions will help keep millions of workers healthy and safe from COVID-19. They direct agencies to provide new guidance so that employers and schools know what they need to do to keep workers safe. They'll increase access to personal protective equipment, testing, and vaccines that will help reduce the spread of COVID-19 in workplaces across the country. They'll help ensure more people are wearing masks when they travel, immediately providing more protection to many airline workers, bus drivers, and other transportation workers, and providing Americans safe ways to travel to work.

With the support of funding from the President's American Rescue Package, the President's plan to safely reopen schools will help students engage in in-person learning, parents return to work and prevent more educators from being laid off, as we combat the virus and make schools safe for students and educators again.

These measures will help keep workers safe and healthy, get more Americans back to work, and ultimately reduce the spread of the virus.

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Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Centers for Disease Control and Prevention
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Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021

CDC COVID-19 Response Team; Food and Drug Administration

As of January 20, 2021, a total of 24,135,690 cases of coronavirus disease 2019 (COVID-19) and 400,306 associated deaths had been reported in the United States (https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days). On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Moderna COVID-19 vaccine administered as 2 doses, 1 month apart to prevent COVID-19. On December 19, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of Moderna COVID-19 vaccine (*1*). As of January 10, 2021, a reported 4,041,396 first doses of Moderna COVID-19 vaccine had been administered in the United States, and reports of 1,266 (0.03%) adverse events after receipt of Moderna COVID-19 vaccine were submitted to the Vaccine Adverse Event Reporting System (VAERS). Among these, 108 case reports were identified for further review as possible cases of severe allergic reaction, including anaphylaxis. Anaphylaxis is a life-threatening allergic reaction that occurs rarely after vaccination, with onset typically within minutes to hours (*2*). Among these case reports, 10 cases were determined to be anaphylaxis (a rate of 2.5 anaphylaxis cases per million Moderna COVID-19 vaccine doses administered), including nine in persons with a documented history of allergies or allergic reactions, five of whom had a previous history of anaphylaxis. The median interval from vaccine receipt to symptom onset was 7.5 minutes (range = 1–45 minutes). Among eight persons with follow-up information available, all had recovered or been discharged home. Among the remaining case reports that were determined not to be anaphylaxis, 47 were assessed to be nonanaphylaxis allergic reactions, and 47 were considered nonallergic adverse events. For four case reports, investigators have been unable to obtain sufficient information to assess the likelihood of anaphylaxis. This report summarizes the clinical and epidemiologic characteristics of case reports of allergic reactions, including anaphylaxis and nonanaphylaxis allergic reactions, after receipt of the first dose of Moderna COVID-19 vaccine during December 21, 2020–January 10, 2021, in the United States. CDC has issued updated interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States (*3*) and interim considerations for preparing for the potential management of anaphylaxis (*4*).

Using methods previously described (*5*), CDC and FDA identified reports of suspected anaphylaxis in VAERS, the national passive surveillance (i.e., spontaneous reporting) system for monitoring adverse events after immunization (*6*). CDC physicians screened VAERS reports describing suspected severe allergic reactions and anaphylaxis and applied Brighton Collaboration case definition criteria for anaphylaxis* (*7*). After initial screening, reports with sufficient evidence to suggest anaphylaxis were followed up by collecting information from medical records and through direct outreach to health care facilities and treating health care providers, and, in some cases, vaccine recipients. Physician reviewers classified all initially identified case reports as anaphylaxis or not anaphylaxis and used clinical judgment to further categorize reports that were considered not anaphylaxis as nonanaphylaxis allergic reactions or nonallergic adverse events. Nonallergic adverse events, mostly vasovagal (e.g., fainting or the sensation of fainting) or suspected anxiety-related, were excluded from the final

* Brighton level 1 represents the highest level of diagnostic certainty that a reported case is indeed a case of anaphylaxis; levels 2 and 3 represent successively lower levels of diagnostic certainty. Level 4 is a case reported as "anaphylaxis" but that does not meet the Brighton Collaboration case definition. Level 5 is a case that was neither reported as anaphylaxis nor meets the case definition.

U.S. Department of Health and Human Services
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analyses. Anaphylaxis and nonanaphylaxis allergic reaction cases with symptom onset occurring later than the day after vaccination (i.e., outside the 0–1-day risk window) were also excluded because of the difficulty in clearly attributing allergic reactions with onset later than this to vaccination.[†]

During December 21, 2020–January 10, 2021, the administration of 4,041,396 first doses of Moderna COVID-19 vaccine (2,465,411 to females [61%], 1,450,966 to males [36%], and 125,019 to persons whose sex was not recorded [3%]) was reported to CDC. During the same period, reports of 1,266 (0.03%) adverse events after receipt of the first dose of Moderna COVID-19 vaccine had been submitted to VAERS. Among these, 108 case reports were identified for further review as possible cases of severe allergic reaction, including anaphylaxis, based on descriptions of signs and symptoms; 10 of these reports, all describing events in females, met the Brighton Collaboration case definition criteria for anaphylaxis (Table 1), corresponding to an initial estimated rate of 2.5 anaphylaxis cases per million first Moderna COVID-19 vaccine doses administered. The median age of persons with anaphylaxis was 47 years (range = 31–63 years). The median interval from vaccine receipt to symptom onset was 7.5 minutes (range = 1–45 minutes); nine patients had onset within 15 minutes, and one had onset after 30 minutes (Figure). In all 10 reports, patients received epinephrine as part of initial emergency treatment; the route of administration was confirmed or presumed to be intramuscular based on the description of treatment and the clinical course of the event as documented in the VAERS report. Six patients were hospitalized (including five in intensive care, four of whom required endotracheal intubation), and four were treated in an emergency department; eight patients with follow-up information available are known to have been discharged home or had recovered at the time of report to VAERS. No deaths from anaphylaxis were reported after receipt of Moderna COVID-19 vaccine. Nine of the 10 anaphylaxis

[†] Anaphylaxis and nonanaphylaxis allergic reaction cases with symptom onset occurring later than the day after vaccination (i.e., outside of the 0–1-day risk window) were excluded because of the difficulty in clearly attributing allergic reactions with onset outside this risk window to vaccination.

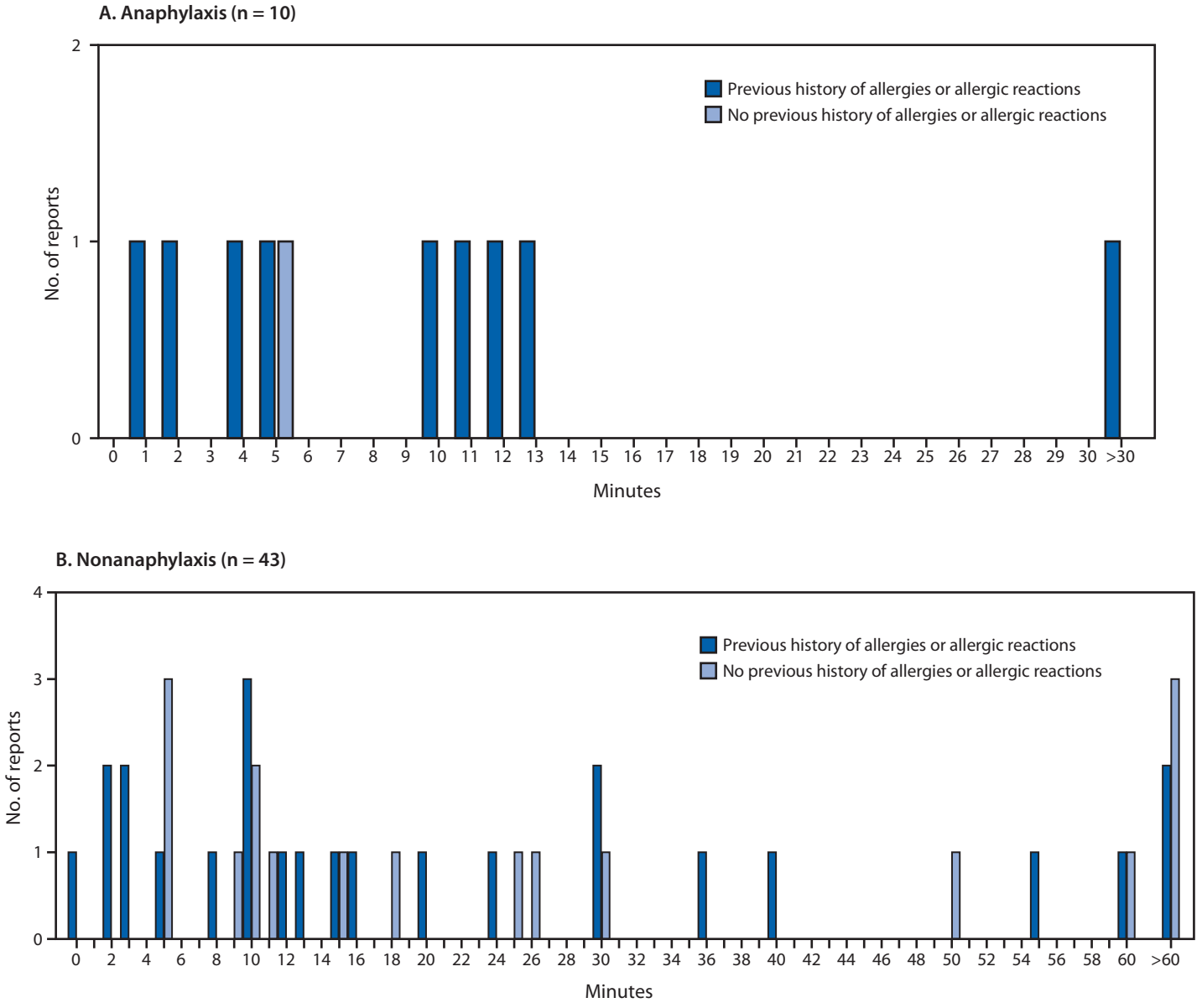
TABLE 1. Characteristics of reported cases of anaphylaxis (n = 10) after receipt of the first dose of Moderna COVID-19 vaccine — Vaccine Adverse Events Reporting System (VAERS), United States, December 21, 2020–January 10, 2021

Age, yrs	Sex	Past history: Allergies or allergic reactions*	Past history: Previous anaphylaxis episode	Onset after receipt (mins)	Signs and symptoms	Treatment setting[†]	Epi received	Brighton level[§]	Outcome or disposition[¶]
37	F	Penicillin, phenytoin, ibuprofen	No	1	Respiratory failure, vomiting	Inpatient	Yes	2	Discharged home
39	F	Penicillin, aloe	Yes, penicillin	2	Decreased peripheral perfusion, persistent dry cough, nausea	Inpatient	Yes	3	Discharged home
63	F	Acetaminophen, azithromycin	No	4	Periorbital edema, nausea	ED	Yes	2	Not specified
55	F	Multiple unspecified environmental and food allergies	Yes, unspecified	5	Hypotension, wheezing	Inpatient	Yes	2	Not specified
31	F	No	No	5	Diffuse erythematous rash, throat swelling	ED	Yes	1	Discharged home
49	F	Gadolinium, iodine	Yes, gadolinium, iodine	10	Diffuse erythematous rash, tongue swelling, wheezing	ED	Yes	1	Recovered at time of report
37	F	Unspecified intravenous contrast dye, penicillin	Yes, intravenous contrast dye	11	Generalized urticarial rash, tongue swelling	Inpatient	Yes	1	Discharged home
50	F	Unspecified allergies or allergic reactions	Yes, unspecified	12	Diffuse erythematous rash, wheezing	Inpatient	Yes	1	Discharged home
57	F	Multiple drugs including penicillin and sulfa	No	13	Periorbital edema, tongue swelling	ED	Yes	1	Recovered at time of report
44	F	Morphine, codeine	No	45	Diffuse erythematous rash, marked tongue swelling	Inpatient	Yes	1	Discharged home

Abbreviations: COVID-19 = coronavirus disease 2019; ED = emergency department; Epi = epinephrine; F = female.
* As documented in the VAERS report or medical records, or through confirmation with the treating health care provider or the patients themselves.
[†] Inpatient hospitalization.
[§] The Brighton Collaboration case definition uses combinations of symptoms to define levels of diagnostic certainty. Brighton level 1 represents the highest level of diagnostic certainty that a reported case is indeed a case of anaphylaxis; levels 2 and 3 are successively lower levels of diagnostic certainty. Level 4 is a case reported as anaphylaxis but that does not meet the Brighton Collaboration case definition. Level 5 is a case that was neither reported as anaphylaxis nor meets the case definition (https://doi.org/10.1016/j.vaccine.2007.02.064).
[¶] As documented in the description of the adverse event in the VAERS report in Box 18 or as documented in recovery status in Box 20.

MS-DOH-21-1816-A-002083

FIGURE. Minutes from vaccine receipt to onset of anaphylaxis (A)* and nonanaphylaxis allergic reactions (B)† after receipt of the first dose of Moderna COVID-19 vaccine — Vaccine Adverse Events Reporting System (VAERS), United States, December 21, 2020–January 10, 2021



Abbreviation: COVID-19 = coronavirus disease 2019.

* The interval from vaccine receipt to symptom onset was >30 minutes for one anaphylaxis case (45 minutes).

† The interval from vaccine receipt to symptom onset was ≥60 minutes for three nonanaphylaxis patients who had a documented history of allergies or allergic reactions at 60, 90, and 98 minutes and for four who did not have a documented history of allergies or allergic reactions (60 minutes, 10 hours, 20 hours, and 24 hours). The interval from vaccine receipt to symptom onset was missing in two case reports, both of which documented a history of allergies or allergic reactions. Four cases of nonanaphylaxis allergic reactions with symptom onset occurring later than the day after vaccination (i.e., outside of the 0–1-day risk window) were excluded from the final analysis.

case reports included a patient history of allergies or allergic reactions, including to drugs (six), contrast media (two), and foods (one); five patients had experienced an episode of anaphylaxis in the past, none of which was associated with receipt of a vaccine (Table 2). No geographic clustering of anaphylaxis cases was observed, and the cases occurred after receipt of doses from multiple vaccine lots. At the time of this publication, despite follow-up efforts, investigators have been unable to obtain sufficient information to assess the likelihood of anaphylaxis in four of the initial 108 suspected cases reported.

MS-DOH-21-1816-A-002084

TABLE 2. Characteristics of patients with reported anaphylaxis and nonanaphylaxis allergic reactions after receipt of the first dose of Moderna COVID-19 vaccine — Vaccine Adverse Events Reporting System (VAERS), United States, December 21, 2020–January 10, 2021

Characteristic	Type of reported reaction, no. (%)	
	Anaphylaxis (n = 10)	Nonanaphylaxis allergic reactions (n = 43)*
Median age, yrs (range)	47 (31–63)	43 (22–96)
Female	10 (100)	39 (91)
Minutes to symptom onset, median (range)	7.5 (1–45)	15 (<1–1,440 [24 hrs])
Symptom onset ≤15 mins	9 (90)	21 (51)†
Symptom onset ≤30 mins	9 (90)	30 (73)†
Documented history of allergies or allergic reactions	9 (90)§	26 (60)

Abbreviation: COVID-19 = coronavirus disease 2019.

* Four of the initial 47 nonanaphylaxis allergic reaction reports were excluded from the final analysis because symptom onset occurred later than the day after vaccination (i.e., outside the 0–1-day risk window).

† Two nonanaphylaxis allergic reaction reports were missing information on time of symptom onset; percentage calculated among 41 case reports with onset documented.

§ Five anaphylaxis reports included a patient history of a previous anaphylaxis episode.

Summary

What is already known about this topic?

Anaphylaxis is a severe, life-threatening allergic reaction that occurs rarely after vaccination.

What is added by this report?

During December 21, 2020–January 10, 2021, monitoring by the Vaccine Adverse Event Reporting System detected 10 cases of anaphylaxis after administration of a reported 4,041,396 first doses of Moderna COVID-19 vaccine (2.5 cases per million doses administered). In nine cases, onset occurred within 15 minutes of vaccination. No anaphylaxis-related deaths were reported.

What are the implications for public health practice?

Locations administering COVID-19 vaccines should adhere to CDC guidance, including screening recipients for contraindications and precautions, having necessary supplies and staff members available to manage anaphylaxis, implementing recommended postvaccination observation periods, and immediately treating suspected anaphylaxis with intramuscular epinephrine injection.

Among the 43 cases of nonanaphylaxis allergic reaction after receipt of Moderna COVID-19 vaccination with symptom onset within the 0–1-day risk window, 26 (60%) were classified as nonserious.§ Commonly reported symptoms included pruritus, rash, itchy sensations in the mouth and throat, sensations of throat closure, and respiratory symptoms. The median patient age was 43 years (range = 22–96 years), and 39 (91%) of the reported reactions occurred in women. The median interval from vaccine receipt to symptom onset was 15 minutes (range = <1 minute–24 hours); in 30 (73%) cases, onset occurred within 30 minutes, in 11 cases, onset occurred after 30 minutes, and for two cases, time of onset was missing. For 26 (60%) case reports, a past history of allergies or allergic reactions, mostly to foods and drugs, was documented (Figure).

Discussion

Early safety monitoring of Moderna COVID-19 vaccine detected 10 cases of anaphylaxis after reported administration of 4,041,396 first doses of Moderna COVID-19 vaccine (2.5 cases per million Moderna COVID-19 vaccine doses administered) as well as cases of less severe nonanaphylaxis allergic reactions, based on U.S. data for December 21, 2020–January 10, 2021. Anaphylaxis is potentially life-threatening and requires immediate treatment (*4*). Based on this early monitoring, anaphylaxis after receipt of Moderna COVID-19 vaccine appears to be a rare event; however, comparisons of anaphylaxis risk with that associated with non–COVID-19 vaccines are constrained at this time by the limited data available this early in the COVID-19 vaccination program. A previous analysis of the Pfizer-BioNTech COVID-19 vaccine, also an mRNA vaccine, estimated an initial rate of 11.1 cases per million doses administered after receipt of the first dose of the Pfizer-BioNTech vaccine (*5*). CDC and FDA will continue enhanced monitoring for anaphylaxis among recipients of COVID-19 vaccines and will review case reports to VAERS.

In nine of 10 cases of anaphylaxis after receipt of Moderna COVID-19 vaccine, patients had symptom onset within 30 minutes of vaccination, and nine anaphylaxis patients also had a history of allergies or allergic reactions, including some with previous anaphylaxis events; up to 30% of persons in the general population might have some type of allergy or history of allergic reactions.¶ All 10 anaphylaxis cases reported after receipt of Moderna COVID-19 vaccine occurred in women. Whereas a previous review of anaphylaxis reports to VAERS found that 80% of cases reported in adults involved females (*8*), the current finding could be affected by the observation that more women than men had received a first dose of Moderna COVID-19 vaccine during the analytic period (61% of doses administered versus 36%, respectively). In a previous analysis of the Pfizer-BioNTech COVID-19 vaccine, two thirds of first doses were administered in women (*5*). The clinical and

§ Four of the initial 47 nonanaphylaxis allergic reactions were excluded from the final analysis. Based on the Code of Federal Regulations, a serious adverse event is defined if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly, or birth defect. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr = 312.32

¶ https://www.aaaai.org/about-aaaai/newsroom/allergy-statistics

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epidemiologic characteristics of anaphylaxis case reports after receipt of Moderna COVID-19 vaccine are similar to those reported after receipt of the Pfizer-BioNTech COVID-19 vaccine (*5*). For both vaccines, symptom onset after vaccination occurred quickly, usually within minutes. A strong female predominance of anaphylaxis case reports exists for both vaccines. Finally, many persons experiencing anaphylaxis after receiving either vaccine had a history of allergies or allergic reactions, with several having experienced an anaphylaxis episode in the past. Similar patient characteristics in case reports of nonanaphylaxis allergic reactions were observed among the two vaccines.

The findings in this report are subject to at least two limitations. First, analyses of passive surveillance data include reporting biases, both underreporting because of lack of awareness or compliance with reporting requirements and reporting guidance, as well as stimulated reporting related to increased awareness from media or other public information sources. Second, incomplete information in reports and potential data lags because of processing times might result in an undercount of cases, and lags in reporting for vaccine doses administered might underestimate denominator data. However, reporting efficiency to VAERS for clinically severe adverse events is believed to be high (*9*). It is reasonable to expect that diagnosis and reporting of an acute and clinically severe condition such as anaphylaxis occurs relatively quickly, and VAERS is likely sensitive at capturing anaphylaxis cases occurring after COVID-19 vaccination.

Mortality from COVID-19 in populations at increased risk for severe illness is substantial (*10*), and treatment options are limited. Widespread vaccination against COVID-19 with highly effective vaccines represents a critical tool in efforts to control the pandemic and save lives. CDC and FDA will continue to monitor for adverse events, including anaphylaxis, after administration of COVID-19 vaccines and will regularly assess the benefits and risks of vaccination in the context of the evolving epidemiology of the pandemic. Continued monitoring in VAERS and additional monitoring in population-based surveillance systems, such as the CDC's Vaccine Safety Datalink (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html), will help to further characterize the risk for anaphylaxis after administration of COVID-19 vaccines.

CDC guidance on use of mRNA COVID-19 vaccines and management of anaphylaxis is available (*3*,*4*). Persons with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines. In addition to screening for contraindications and precautions before administering COVID-19 vaccines, vaccine locations should have the necessary supplies and trained staff members available to manage anaphylaxis, implement postvaccination observation periods, immediately treat persons experiencing anaphylaxis signs and symptoms with intramuscular injection of epinephrine, and transport patients to facilities where they can receive advanced medical care. In addition, all patients should be instructed to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination location. Health care providers can play an important role in vaccine safety monitoring by being vigilant in recognizing and reporting adverse events after immunization to VAERS at https://vaers.hhs.gov/reportevent.html.

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Investigators from the Clinical Immunization Safety Assessment Project.

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Percentage of Adolescents Meeting Federal Fruit and Vegetable Intake Recommendations — Youth Risk Behavior Surveillance System, United States, 2017

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According to the 2020–2025 Dietary Guidelines for Americans, persons should consume fruits and vegetables as part of a healthy eating pattern to reduce their risk for diet-related chronic diseases, such as cardiovascular disease, type 2 diabetes, some cancers, and obesity.* A healthy diet is important for healthy growth in adolescence, especially because adolescent health behaviors might continue into adulthood (*1*). The U.S. Department of Agriculture (USDA) recommends minimum daily intake of 1.5 cups of fruit and 2.5 cups of vegetables for females aged 14–18 years and 2 cups of fruit and 3 cups of vegetables for males aged 14–18 years.† Despite the benefits of fruit and vegetable consumption, few adolescents consume these recommended amounts (*2–4*). In 2013, only 8.5% of high school students met the recommendation for fruit consumption, and only 2.1% met the recommendation for vegetable consumption (*2*). To update the 2013 data, CDC analyzed data from the 2017 national and state Youth Risk Behavior Surveys (YRBSs) to describe the percentage of students who met intake recommendations, overall and by sex, school grade, and race/ethnicity. The median frequencies of fruit and vegetable consumption nationally were 0.9 and 1.1 times per day, respectively. Nationally, 7.1% of students met USDA intake recommendations for fruits (95% confidence interval [CI] = 4.0–10.3) and 2.0% for vegetables (upper 95% confidence limit = 7.9) using previously established scoring algorithms. State-specific estimates of the percentage of students meeting fruit intake recommendations ranged from 4.0% (Connecticut) to 9.3% (Louisiana), and the percentage meeting vegetable intake recommendations ranged from 0.6% (Kansas) to 3.7% (New Mexico). Additional efforts to expand the reach of existing school and community programs or to identify new effective strategies, such as social media approaches, might help address barriers and improve adolescent fruit and vegetable consumption.

The Youth Risk Behavior Surveillance System monitors prevalence of youth health behaviors that contribute to the leading causes of death and disability at the national, state, territorial, tribal, and large urban school district levels.§ Students

* https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf.

† These amounts are appropriate for persons who get <30 minutes per day of moderate physical activity, beyond normal daily activities. Those who are more physically active might be able to consume more while staying within calorie needs. https://www.choosemyplate.gov/eathealthy/vegetables, https://www.choosemyplate.gov/eathealthy/fruits.

§ Methodology of the Youth Risk Behavior Surveillance System–2013 https://www.cdc.gov/mmwr/pdf/rr/rr6201.pdf.

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complete anonymous, self-administered questionnaires during one class period. CDC conducts the national YRBS biennially and uses a three-stage cluster sample design to obtain nationally representative samples of students in grades 9–12 who attend public and private schools. In 2017, the school and student response rates were 75% and 81% respectively, resulting in an overall response rate of 60%.¶

State education and health agencies conduct state YRBSs and employ a two-stage cluster sample design to obtain state-representative samples of students in grades 9–12 who attend public schools. These samples are independent of the national YRBS. Among 46 states that administered YRBS in 2017, 33 states asked all six questions included in the national YRBS about fruits and vegetables, had sufficient response rates (>60%) to obtain weighted state-representative data, and gave CDC permission to include their data. State response rates ranged from 60% to 82%.

The six questions about fruit and vegetable consumption in the 2017 YRBS assess how many times per day or week students consumed 100% fruit juice, fruit, green salad, potatoes (excluding French fries, fried potatoes, and potato chips), carrots, and other vegetables.** The seven response options were 0, 1–3 or 4–6 times during the past 7 days; or 1, 2, 3, or 4 or more times daily. Daily frequency of fruit and vegetable intake was calculated by using the midpoint for intake ranges (e.g., five for 4–6 times during past 7 days) and dividing by seven for intakes reported by week. Student-reported race/ethnicity was classified into non-Hispanic White, non-Hispanic Black, Hispanic, and non-Hispanic other. Estimates for non-Hispanic other are not presented because this category includes multiple racial groups, which makes it difficult to provide meaningful interpretation, but are included in overall and other demographic estimates.

Among 14,765 students in the national YRBS, 1,411 (9.6%) were excluded, including 988 who did not answer fruit and vegetable questions; 376 who did not report sex, grade, or race/ethnicity; and 47 who were aged ≤14 years (to correspond to the age range used in the algorithm described in this report). The final analytic sample was 13,354 students. Similar exclusions were made on state-specific data with 5%–18% excluded across the states.

Median frequencies of fruit and vegetable intake were determined nationally and for 33 states. Previously established scoring algorithms (*2*), developed using 24-hour recall data from the National Health and Nutrition Examination Survey, were used to predict whether students met recommendations for their age and sex based on the number of times per day they reported consuming fruits and vegetables, separately, and accounting for race/ethnicity (*2*). Balanced repeated replication, replicate weights, and Taylor linearization were used to

¶ https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/ss6708.pdf.
** https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/2017_yrbs_national_hs_questionnaire.pdf.

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calculate 95% CIs for the percentage meeting recommendations (*2*). For vegetables, given CIs that include zero, only upper bounds are shown. T-tests were used to examine statistical differences by demographics (p-value <0.05). Analyses were performed using SAS (version 9.4; SAS Institute) survey procedures to account for complex sampling designs and Stata (version 14.0; StataCorp) to conduct t-tests.

Among students in grades 9–12 in 2017, the median reported daily intake was 0.9 times per day for fruits and 1.1 times per day for vegetables (Table 1). Nationally, 7.1% of high school students met federal intake recommendations for fruits (95% CI = 4.0–10.3), and 2.0% met these recommendations for vegetables (upper 95% CI = 7.9). State-specific estimates ranged from 4.0% (Connecticut) to 9.3% (Louisiana) for fruits and from 0.6% (Kansas) to 3.7% (New Mexico) for vegetables. Estimates were consistently low across demographic groups. Nationally, the percentage of students meeting recommendations for fruit consumption was higher among males (9.7%) than among females (4.7%), and higher among non-Hispanic Black persons (11.9%) and Hispanic persons (7.9%) than among

TABLE 1. Median consumption and percentages of high school students meeting U.S. Department of Agriculture fruit and vegetable* intake recommendations — Youth Risk Behavior Surveillance System, national and 33 states, 2017

		Median times per day		Percent meeting recommendations†	
				Fruit	Vegetable
State	No.§	Fruit	Vegetable	% (95% CI)	% (Upper 95% CL)¶
National	**13,354**	**0.9**	**1.1**	**7.1 (4.0–10.3)**	**2.0 (7.9)**
Alaska	1,239	0.8	1.0	5.6 (1.9–9.3)	2.3 (8.8)
Arizona	1,936	0.8	1.0	4.8 (1.4–8.2)	1.2 (7.4)
Arkansas	1,376	0.7	0.9	7.6 (3.4–11.9)	3.6 (11.4)
California	1,640	0.9	1.0	6.1 (2.7–9.4)	1.8 (8.0)
Connecticut	2,109	0.9	1.2	4.0 (0.8–7.2)	1.0 (7.1)
Florida	5,644	0.9	1.0	7.4 (4.1–10.7)	2.2 (8.6)
Hawaii	5,174	0.7	1.0	4.4 (1.4–7.5)	1.7 (7.5)
Idaho	1,729	0.9	1.1	5.2 (1.7–8.7)	1.3 (7.4)
Illinois	4,331	0.8	1.0	5.4 (1.9–9.0)	1.3 (7.5)
Iowa	1,552	0.8	1.0	5.4 (1.5–9.2)	1.4 (7.7)
Kansas	2,288	0.9	1.1	4.2 (0.8–7.6)	0.6 (6.7)
Kentucky	1,867	0.7	0.9	5.0 (1.6–8.4)	1.0 (7.0)
Louisiana	1,070	0.7	0.8	9.3 (5.1–13.5)	1.9 (8.7)
Maryland	43,802	0.8	1.0	5.6 (2.7–8.4)	1.2 (7.2)
Massachusetts	2,998	0.9	1.1	5.2 (1.8–8.6)	1.1 (7.2)
Michigan	1,506	0.9	1.0	5.8 (1.8–9.7)	1.6 (8.0)
Missouri	1,648	0.7	1.0	4.8 (1.4–8.1)	1.0 (7.1)
Montana	4,475	0.8	1.1	4.6 (1.2–7.9)	1.6 (7.6)
Nebraska	1,306	0.8	1.1	4.5 (0.9–8.0)	1.0 (7.3)
New Mexico	5,333	0.8	1.1	7.5 (4.5–10.6)	3.7 (10.1)
North Carolina	2,837	0.8	1.0	6.1 (2.6–9.6)	1.2 (7.4)
North Dakota	2,009	0.9	1.1	5.3 (1.5–9.0)	1.4 (7.4)
Oklahoma	1,526	0.7	0.9	4.9 (1.6–8.3)	1.1 (7.2)
Pennsylvania	3,344	0.8	1.1	5.7 (2.2–9.1)	1.1 (7.2)
Rhode Island	2,017	0.8	1.0	5.9 (2.5–9.3)	2.2 (8.7)
South Carolina	1,310	0.7	0.9	7.0 (2.9–11.1)	0.9 (7.3)
Tennessee	1,894	0.8	0.9	6.3 (2.5–10.0)	1.6 (7.9)
Texas	1,955	0.8	0.9	6.0 (2.9–9.0)	1.6 (7.9)
Utah	1,712	0.8	1.1	4.6 (1.2–8.1)	1.7 (7.9)
Vermont	19,126	1.0	1.4	5.6 (2.4–8.9)	2.0 (7.9)
Virginia	3,431	0.8	1.1	5.5 (2.1–8.8)	1.7 (7.9)
West Virginia	1,414	0.8	1.0	6.8 (3.1–10.6)	1.5 (7.5)
Wisconsin	1,894	0.9	1.1	4.6 (1.0–8.3)	1.2 (7.5)

Abbreviations: CI = confidence interval; CL = confidence limit.

* Fruit consists of solid fruit and 100% fruit juice. Vegetable consists of green salad, potatoes (excluding French fries, fried potatoes, and potato chips), carrots, and other vegetables.

† Minimum daily intake recommendations for adolescents aged 14–18 years are: 1.5 cups of fruit and 2.5 cups of vegetables for females, and 2 cups of fruit and 3 cups of vegetables for males, per the U.S. Department of Agriculture. Additional information available at https://www.choosemyplate.gov/eathealthy/vegetables and https://www.choosemyplate.gov/eathealthy/fruits. Previously established scoring algorithms, developed using 24-hour recall data from the National Health and Nutritional Examination Survey, were used to predict whether students met recommendations for their age and sex based on the number of times per day they reported consuming fruits and vegetables, separately, and accounting for race/ethnicity.

§ Number of respondents aged 14–18 years with complete data for fruit and vegetable intake and demographic information.

¶ One-sided 95% CLs (i.e., upper bound only) are presented because of low prevalence of percentage meeting vegetable recommendations and CIs that include zero.

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non-Hispanic White persons (5.9%). These differences were not statistically significant, and patterns were similar in most states (Table 2). Similar, albeit less pronounced differences by sex and race/ethnicity were observed for the percentage of students meeting vegetable recommendations, nationally and in some states (Table 3). Estimates were similar across grade levels.

Discussion

The proportion of U.S. high school students meeting federal intake recommendations remained low in 2017, with 7.1% consuming enough fruits and 2.0% consuming enough vegetables to meet USDA recommendations. Although estimating the tail ends of distributions can be less precise than estimating mean intake (2), results still indicate that consumption across all demographic groups was insufficient to meet dietary recommendations. These findings are consistent with other studies indicating that adolescents consume fruits and vegetables much less frequently than is recommended for proper nutrition (*2*–*4*).

Reasons for insufficient consumption of fruits and vegetables by adolescents are complex. Adolescents might face barriers to consumption, including high availability of inexpensive, unhealthy food options, lack of taste preference for fruits and vegetables, and lack of home availability (*5*). Interventions to address some of these barriers are occurring in schools and community programs. For example, the National School Lunch Program†† requires that meals include a fruit and vegetable option daily. However, on average, 39% of high school

†† https://www.fns.usda.gov/nslp.

TABLE 2. National and state-specific percentages* and 95% confidence intervals (CIs) of high school students meeting U.S. Department of Agriculture fruit intake recommendations by sex, grade, and race/ethnicity — Youth Risk Behavior Surveillance System, national and 33 states, 2017

		% (95% CI)								
		Sex		Grade				Race/Ethnicity†		
State	No.	Female§	Male	9§	10	11	12	White§	Black	Hispanic
National	**13,354**	**4.7 (0.6–8.8)**	**9.7 (4.8–14.6)**	**7.6 (3.4–11.9)**	**7.6 (3.6–11.6)**	**6.7 (2.6–10.7)**	**6.4 (2.3–10.6)**	**5.9 (1.8–10.0)**	**11.9 (5.5–18.3)**	**7.9 (4.1–11.7)**
Alaska	1,239	3.6 (0.0¶–7.8)	7.5 (1.8–13.1)	6.5 (1.5–11.5)	5.8 (0.9–10.6)	4.9 (0.0–9.9)	5.1 (0.0–10.2)	4.1 (0.0–8.5)	—**	8.0 (1.3–14.7)
Arizona	1,936	2.3 (0.0–6.6)	7.3 (2.2–12.3)	6.0 (1.6–10.5)	5.0 (0.3–9.7)	4.0 (0.0–8.4)	4.1 (0.0–9.4)	4.0 (0.0–8.2)	—	5.2 (1.0–9.4)
Arkansas	1,376	5.2 (0.0–11.3)	10.0 (4.3–15.7)	7.9 (2.9–12.9)	6.7 (1.6–11.8)	6.3 (0.5–12.0)	9.7 (2.4–17.1)	6.2 (1.8–10.5)	11.8 (5.1–18.6)	5.2 (1.1–9.2)
California	1,640	3.6 (0.0–8.4)	8.6 (3.8–13.4)	5.8 (1.3–10.2)	6.0 (1.4–10.6)	6.9 (1.8–12.0)	5.7 (0.8–10.6)	5.3 (0.0–10.8)	5.8 (0.0–13.2)	6.9 (2.9–11.0)
Connecticut	2,109	2.2 (0.0–6.5)	5.8 (0.7–10.9)	4.4 (0.0–8.8)	3.7 (0.0–8.0)	4.3 (0.0–8.6)	3.6 (0.0–8.0)	3.2 (0.0–7.2)	5.1 (0.0–12.3)	5.3 (1.3–9.3)
Florida	5,644	5.2 (0.1–10.2)	9.6 (5.0–14.2)	7.8 (3.5–12.1)	7.4 (2.8–11.9)	8.1 (3.6–12.5)	6.3 (1.8–10.8)	5.1 (1.1–9.2)	9.8 (3.8–15.9)	8.2 (4.4–12.0)
Hawaii	5,174	2.8 (0.0–6.3)	6.2 (0.9–11.5)	5.2 (0.8–9.5)	4.0 (0.0–8.1)	4.1 (0.0–8.2)	4.4 (0.3–8.6)	4.3 (0.0–8.9)	—	5.2 (0.9–9.6)
Idaho	1,729	2.5 (0.0–6.3)	7.9 (2.0–13.8)	5.6 (1.0–10.3)	5.4 (1.1–9.7)	4.9 (0.1–9.6)	4.7 (0.0–9.6)	4.7 (0.4–9.1)	—	6.6 (2.1–11.2)
Illinois	4,331	3.8 (0.0–8.5)	7.1 (1.7–12.5)	5.1 (0.4–9.8)	4.9 (0.1–9.6)	5.5 (0.5–10.5)	6.3 (0.9–11.6)	4.2 (0.0–8.8)	7.4 (1.0–13.8)	6.7 (2.7–10.7)
Iowa	1,552	2.8 (0.0–7.1)	7.9 (1.4–14.3)	5.3 (0.1–10.5)	6.9 (1.3–12.5)	5.1 (0.0–10.4)	4.1 (0.0–9.6)	4.8 (0.5–9.2)	6.7 (0.0–15.6)	9.0 (1.1–16.9)
Kansas	2,288	2.4 (0.0–6.6)	5.9 (0.5–11.3)	4.8 (0.3–9.4)	3.4 (0.0–7.5)	4.0 (0.0–8.4)	4.6 (0.0–9.3)	3.8 (0.0–7.9)	4.7 (0.0–12.7)	4.9 (0.7–9.1)
Kentucky	1,867	2.9 (0.0–6.9)	7.1 (1.5–12.6)	5.0 (0.3–9.7)	4.4 (0.2–8.7)	6.6 (1.3–12)	4.0 (0.0–8.6)	4.8 (0.8–8.9)	5.2 (0.0–11.9)	7.6 (1.0–14.1)
Louisiana	1,070	7.6 (1.4–13.7)	11.1 (4.9–17.4)	8.9 (3.0–14.8)	8.0 (1.7–14.2)	9.1 (1.7–16.6)	11.5 (4.0–19.0)	7.3 (2.2–12.5)	11.6 (4.3–19.0)	—
Maryland	43,802	3.7 (0.0–7.9)	7.5 (3.2–11.7)	5.5 (1.8–9.3)	5.8 (1.9–9.6)	5.5 (1.7–9.3)	5.3 (1.5–9.2)	4.3 (0.7–7.8)	7.3 (2.4–12.1)	6.2 (3.0–9.4)
Massachusetts	2,998	3.1 (0.0–7.2)	7.4 (2.0–12.7)	4.4 (0.1–8.7)	6.4 (1.6–11.3)	5.0 (0.1–10.0)	5.0 (0.6–9.3)	4.3 (0.0–8.5)	10.2 (3.6–16.8)	5.8 (1.9–9.7)
Michigan	1,506	3.2 (0.0–7.8)	8.3 (2.1–14.4)	5.2 (0.2–10.1)	6.9 (1.1–12.7)	5.4 (0.2–10.6)	5.6 (0.0–11.2)	4.7 (0.5–8.9)	10.5 (2.9–18.1)	8.6 (3.2–14.0)
Missouri	1,648	2.1 (0.0–6.1)	7.5 (2.1–12.9)	4.3 (0.0–8.8)	6.1 (1.3–11.0)	4.7 (0.0–9.6)	3.8 (0.0–8.5)	4.3 (0.5–8.2)	5.6 (0.0–12.3)	6.8 (1.6–11.9)
Montana	4,475	2.5 (0.0–6.0)	6.5 (0.8–12.2)	5.0 (0.7–9.4)	4.9 (0.7–9.1)	4.1 (0.0–8.4)	4.1 (0.0–8.4)	4.1 (0.3–7.9)	—	7.9 (3.3–12.5)
Nebraska	1,306	2.2 (0.0–6.5)	6.7 (1.0–12.4)	6.2 (1.0–11.4)	3.9 (0.0–9.1)	4.6 (0.0–9.5)	3.1 (0.0–7.9)	4.0 (0.0–8.2)	—	6.0 (0.5–11.5)
New Mexico	5,333	5.3 (0.5–10.2)	9.7 (5.6–13.8)	7.7 (3.6–11.9)	7.2 (3.1–11.3)	7.5 (3.4–11.5)	7.6 (3.3–12.0)	5.8 (1.5–10.2)	—	7.5 (3.9–11.0)
North Carolina	2,837	4.0 (0.0–9.0)	8.2 (3.1–13.4)	5.4 (0.9–9.9)	5.6 (1.2–10.1)	7.6 (2.2–13.0)	5.8 (1.1–10.5)	4.3 (0.1–8.5)	8.9 (2.0–15.8)	7.2 (2.1–12.3)
North Dakota	2,009	2.6 (0.0–6.4)	7.8 (1.5–14.2)	5.4 (0.6–10.1)	4.9 (0.2–9.6)	5.5 (0.0–11.4)	5.4 (0.3–10.5)	4.6 (0.3–9.0)	—	8.1 (2.1–14.0)
Oklahoma	1,526	2.2 (0.0–6.0)	7.8 (2.2–13.3)	3.6 (0.0–7.6)	7.3 (2.1–12.5)	5.1 (0.2–10.1)	3.6 (0.0–8.5)	4.7 (0.3–9.1)	—	6.1 (1.7–10.4)
Pennsylvania	3,344	3.3 (0.0–7.4)	8.0 (2.4–13.6)	6.3 (1.4–11.2)	6.1 (1.3–10.9)	5.2 (0.5–9.9)	5.0 (0.5–9.6)	4.5 (0.4–8.5)	9.7 (2.8–16.6)††	11.1 (6.0–16.1)
Rhode Island	2,017	3.0 (0.0–7.4)	8.6 (3.0–14.2)	6.7 (1.7–11.7)	7.1 (1.8–12.3)	5.3 (0.3–10.3)	4.1 (0.0–8.8)	5.0 (0.6–9.4)	8.5 (0.9–16.1)	6.9 (2.4–11.4)
South Carolina	1,310	6.1 (0.0–12.1)	8.0 (2.5–13.6)	8.9 (2.9–14.9)	7.2 (1.9–12.5)	5.7 (0.0–11.5)	6.0 (0.0–12.4)	4.5 (0.1–9.0)	10.7 (3.6–17.8)	8.8 (1.3–16.3)
Tennessee	1,894	4.3 (0.0–9.0)	8.2 (2.3–14.0)	6.3 (1.1–11.6)	6.2 (1.3–11.1)	7.0 (1.8–12.1)	5.5 (0.5–10.6)	5.5 (1.0–10.1)	8.0 (1.8–14.3)	6.7 (1.6–11.8)
Texas	1,955	4.6 (0.0–9.7)	7.3 (3.1–11.6)	7.8 (3.4–12.1)	4.8 (0.4–9.2)	5.0 (0.0–10.0)	6.1 (1.0–11.2)	4.4 (0.0–9.0)	9.7 (2.2–17.3)	5.8 (2.3–9.3)
Utah	1,712	2.1 (0.0–5.9)	7.1 (1.3–12.9)	5.2 (0.3–10.2)	4.8 (0.1–9.5)	4.3 (0.0–8.8)	4.1 (0.0–8.9)	4.1 (0.0–8.3)	—	6.5 (1.8–11.2)
Vermont	19,126	2.7 (0.0–6.1)	8.4 (2.9–13.9)	5.6 (1.6–9.7)	5.7 (1.7–9.8)	5.5 (1.5–9.5)	5.6 (1.6–9.6)	5.2 (1.4–9.0)	10.5 (4.3–16.6)	8.4 (4.1–12.7)
Virginia	3,431	3.2 (0.0–7.8)	7.6 (2.7–12.6)	6.1 (1.5–10.8)	5.1 (0.6–9.5)	5.7 (0.9–10.6)	4.9 (0.2–9.5)	4.0 (0.1–8.0)	8.0 (1.5–14.4)	6.7 (2.3–11.0)
West Virginia	1,414	4.6 (0.2–8.9)	9.1 (2.8–15.3)	7.5 (2.0–13.0)	7.8 (2.1–13.4)	6.7 (1.7–11.6)	5.3 (0.2–10.4)	6.5 (2.3–10.8)	—	—
Wisconsin	1,894	1.8 (0.0–5.7)	7.4 (1.5–13.4)	4.6 (0.0–9.4)	6.2 (1.3–11.1)	3.9 (0.0–8.6)	3.9 (0.0–8.4)	4.3 (0.0–8.6)	6.8 (0.1–13.5)	5.2 (0.7–9.6)

* National data are weighted and representative of all private and public school students in grades 9–12 in the United States. State data are weighted and representative of all public school students in grades 9–12 in the respective jurisdiction.
† White and Black students are non-Hispanic. Hispanic students could be of any race. Non-Hispanic other group not reported because this group includes multiple racial groups, which makes it difficult to provide meaningful interpretation, but included in overall estimates and estimates by other demographic characteristics.
§ Female sex, grade 9, and White race/ethnicity were used as referents.
¶ Negative values for lower CI bounds were truncated at zero.
** Dashes indicate that estimates in states where the sample size was <100 were considered unstable and were not reported.
†† P <0.05 for t-test comparing differences by demographic groups to the referent group.

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TABLE 3. National and state-specific percentages* and one-sided 95% upper confidence limits (CLs) of high school students meeting U.S. Department of Agriculture vegetable intake recommendations by sex, grade, and race/ethnicity — Youth Risk Behavior Surveillance System, national and 33 states, 2017

		% (95% CL)†								
		Sex		Grade				Race/Ethnicity§		
State	No.	Female¶	Male	9¶	10	11	12	White¶	Black	Hispanic
National	**13,354**	**1.1 (2.8)**	**3.0 (14.8)**	**2.2 (8.3)**	**2.4 (8.5)**	**1.5 (7.5)**	**2.0 (8.2)**	**1.7 (7.4)**	**2.2 (10.1)**	**2.6 (9.1)**
Alaska	1,239	0.9 (3.1)	3.7 (16.0)	2.1 (9.1)	2.9 (10.3)	1.3 (8.3)	3.0 (10.6)	1.4 (8.0)	—**	4.1 (13.9)
Arizona	1,936	0.6 (1.8)	1.9 (13.8)	2.0 (8.5)	0.9 (7.3)	0.6 (6.8)	1.4 (8.2)	1.0 (7.3)	—	1.7 (8.2)
Arkansas	1,376	2.6 (7.9)	4.6 (18.4)	3.4 (11.3)	3.0 (10.7)	1.6 (8.2)	6.7 (19.9)	3.0 (11.1)	5.4 (15.6)	3.8 (13.9)
California	1,640	0.8 (2.2)	2.7 (15.1)	2.1 (8.8)	1.5 (8.3)	2.5 (9.4)	1.0 (7.8)	0.2 (5.7)	0.0 (7.5)	3.0 (9.8)
Connecticut	2,109	0.6 (2.0)	1.4 (13.4)	1.7 (8.3)	1.0 (7.4)	0.9 (7.1)	0.4 (6.7)	1.0 (7.2)	0.7 (7.8)	1.2 (8.2)
Florida	5,644	1.0 (2.8)	3.4 (15.8)	2.1 (8.6)	2.6 (9.6)	2.0 (8.7)	2.2 (8.9)	2.3 (8.6)	1.5 (9.4)	2.6 (8.7)
Hawaii	5,174	0.9 (2.7)	2.6 (14.4)	1.9 (8.2)	1.8 (8.1)	1.4 (7.5)	1.7 (7.9)	2.1 (9.4)	—	1.6 (7.7)
Idaho	1,729	0.7 (2.5)	1.9 (13.8)	1.6 (8.1)	0.9 (7.4)	1.4 (7.9)	1.3 (7.9)	1.0 (7.0)	—	2.4 (9.3)
Illinois	4,331	0.6 (2.0)	2.0 (14.3)	1.2 (7.5)	1.2 (7.6)	0.8 (7.2)	2.0 (9.1)	1.0 (7.1)	0.9 (8.3)	2.0 (9.2)
Iowa	1,552	0.9 (2.4)	2.0 (14.1)	1.3 (8.1)	3.3 (11.5)	0.9 (7.2)	0.1 (6.4)	1.3 (7.4)	2.0 (12.4)	1.4 (10.6)
Kansas	2,288	0.4 (1.5)	0.8 (12.6)	0.5 (6.8)	0.3 (6.4)	0.8 (7.4)	0.8 (7.3)	0.6 (6.7)	0.3 (7.4)	0.7 (7.1)
Kentucky	1,867	0.4 (1.4)	1.6 (13.5)	1.5 (8.1)	0.4 (6.5)	1.2 (7.7)	1.0 (7.5)	1.0 (7.0)	0.1 (7.9)	2.4 (11.7)
Louisiana	1,070	0.6 (2.0)	3.2 (17.2)	2.1 (9.9)	2.0 (9.0)	1.4 (8.4)	2.1 (11.5)	2.5 (9.9)	1.2 (8.6)	—
Maryland	43,802	0.6 (1.6)	1.9 (14.0)	1.4 (7.6)	1.1 (7.2)	1.3 (7.4)	1.2 (7.2)	1.1 (6.7)	1.1 (8.2)	2.0 (8.3)
Massachusetts	2,998	0.6 (1.9)	1.7 (13.6)	1.0 (7.4)	1.3 (7.8)	1.5 (8.3)	0.8 (6.9)	0.8 (6.7)	0.8 (9.2)	2.0 (8.6)
Michigan	1,506	0.4 (1.8)	2.7 (15.2)	1.6 (8.2)	1.5 (8.5)	1.7 (9.0)	1.5 (8.5)	1.3 (7.5)	1.6 (11.2)	3.7 (11.9)
Missouri	1,648	0.2 (1.0)	1.9 (14.0)	1.4 (8.1)	1.3 (7.9)	0.6 (6.6)	0.8 (7.1)	1.0 (6.7)	0.0 (8.2)	3.1 (11.8)
Montana	4,475	0.7 (2.4)	2.3 (13.9)	1.4 (7.8)	1.2 (7.6)	1.6 (8.0)	2.0 (8.4)	1.3 (7.3)	—	3.6 (11.6)
Nebraska	1,306	0.4 (1.5)	1.6 (14.0)	0.4 (6.7)	1.4 (8.1)	0.6 (7.0)	1.7 (9.4)	0.8 (7.0)	—	0.4 (7.2)
New Mexico	5,333	1.7 (4.0)	5.7 (18.1)	4.3 (11.2)	2.6 (9.2)	4.3 (11.4)	3.7 (10.4)	2.9 (9.9)	—	4.0 (10.5)
North Carolina	2,837	0.8 (2.1)	1.7 (14.0)	1.2 (7.8)	1.1 (7.4)	1.1 (7.8)	1.5 (8.0)	1.1 (7.2)	1.0 (8.5)	2.1 (8.9)
North Dakota	2,009	0.6 (2.4)	2.1 (13.9)	1.1 (7.5)	1.5 (7.9)	1.4 (7.8)	1.5 (8.4)	1.3 (7.3)	—	3.9 (12.7)
Oklahoma	1,526	0.6 (2.1)	1.7 (13.6)	0.8 (6.9)	2.0 (8.7)	0.9 (7.4)	0.8 (7.7)	1.0 (7.2)	—	1.6 (8.5)
Pennsylvania	3,344	0.6 (1.7)	1.7 (13.6)	2.1 (8.8)	1.0 (7.5)	0.8 (7.2)	0.7 (7.0)	1.0 (7.0)	1.0 (9.6)	3.3 (10.6)
Rhode Island	2,017	0.8 (2.5)	3.6 (15.8)	2.5 (9.7)	2.8 (10.0)	1.8 (8.4)	1.7 (8.8)	1.9 (8.3)	2.2 (12.8)	2.7 (10.3)
South Carolina	1,310	0.8 (2.7)	1.1 (13.6)	1.2 (8.4)	0.8 (7.7)	1.1 (7.5)	0.5 (7.3)	1.1 (7.6)	0.5 (7.6)	1.6 (9.2)
Tennessee	1,894	0.7 (2.1)	2.6 (14.9)	1.5 (8.6)	1.5 (8.5)	1.3 (7.8)	2.3 (9.6)	1.4 (7.5)	1.8 (10.4)	2.7 (10.2)
Texas	1,955	0.5 (1.9)	2.7 (15.1)	1.8 (8.7)	0.6 (7.3)	1.1 (7.7)	2.9 (10.4)	0.6 (6.5)	3.6 (13.9)	1.6 (7.9)
Utah	1,712	0.7 (2.7)	2.7 (14.6)	1.4 (7.7)	1.7 (8.5)	1.4 (8.2)	2.5 (,9.3)	1.4 (7.7)	—	3.2 (10.6)
Vermont	19,126	1.0 (2.8)	2.9 (14.4)	1.9 (7.9)	2.1 (8.1)	1.7 (7.9)	2.1 (8.3)	1.7 (7.5)	3.8 (13.8)	4.9 (12.8)
Virginia	3,431	0.7 (2.2)	2.7 (14.9)	2.2 (9.0)	1.5 (8.0)	1.5 (8.2)	1.8 (8.4)	1.4 (7.6)	1.1 (8.7)	3.7 (11.7)
West Virginia	1,414	0.8 (2.2)	2.2 (13.9)	0.8 (7.2)	2.6 (9.8)	2.0 (8.5)	0.5 (6.5)	1.6 (7.5)	—	—
Wisconsin	1,894	0.6 (2.0)	1.9 (14.2)	1.0 (7.6)	1.4 (8.4)	1.3 (8.0)	1.2 (8.1)	1.2 (7.3)	1.7 (11.5)	1.2 (9.3)

* National data are weighted and representative of all private and public school students in grades 9–12 in the United States. State data are weighted and representative of all public school students in grades 9–12 in the respective jurisdiction.
† One-sided 95% CLs (i.e., upper bound only) are presented because of low prevalence of percentage meeting vegetable recommendations and CIs that include zero.
§ White and Black students are non-Hispanic. Hispanic students could be of any race. Non-Hispanic other group not reported because this group includes multiple racial groups, which makes it difficult to provide meaningful interpretation, but included in overall estimates and estimates by other demographic characteristics.
¶ Female sex, grade 9, and White race/ethnicity were used as referents.
** Dashes indicate that estimates in states where the sample sizes were <100 were considered unstable and were not reported.

students participate in the National School Lunch Program (*6*), and fewer (14%) participate in the School Breakfast Program; participation is particularly low among students who do not qualify for free or reduced-price meals. Smart Snacks Standards ensure that foods and beverages sold in vending machines, school stores, and fundraisers include nutritious options, including fruits and vegetables (*7*). In addition, state and local farm-to-school programs support experiential learning activities, including cooking and taste-testing, to engage students in preparing and eating fruits and vegetables.§§

Community programs can also reduce barriers to fruit and vegetable consumption, including lack of home availability of fruits and vegetables, which is a consistent correlate of intake among adolescents (*8*). For example, projects funded by the Gus Schumacher Nutrition Incentive Program¶¶ support families with low income by providing financial incentives to purchase more produce. Additional communication approaches, including parent-directed messaging about exposing children to nutritious foods early and repeatedly at home,*** might enhance preferences for fruits and vegetables. Further, social marketing and health-branding strategies, such as those used by the FNV Campaign,††† to positively influence attitudes

§§ https://www.fns.usda.gov/cfs/farm-school-grant-program.

¶¶ https://nifa.usda.gov/program/gus-schumacher-nutrition-incentive-grant-program.
*** https://www.healthychildren.org/English/healthy-living/growing-healthy/Pages/preschool-food-and-feeding.aspx#none.
††† https://fnv.com/about/.

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and societal norms about eating fruits and vegetables, might appeal to adolescents, particularly those who use social media. Consistently low fruit and vegetable intake among adolescents suggests that additional efforts are needed to expand the reach of existing programs or to identify new effective strategies such as communication approaches including social media.

The findings in this report are subject to at least two limitations. First, YRBS data are self-reported, which might overestimate fruit and vegetable intake (*9*). Second, intake recommendations are based on adolescents who do not engage in ≥30 minutes of physical activity daily, and active persons should consume more. These results might overestimate percentages meeting recommendations because 46.5% of U.S. students were active for ≥60 minutes per day on 5 or more days.[§§§]

YRBS data are highly representative of the adolescent population because 96% of adolescents aged 14–17 years attend school (*10*). Despite the benefits of healthy eating, these findings indicate that most high school students do not consume enough fruits and vegetables to meet USDA recommendations. Continued efforts to identify and address barriers to consumption might help adolescents eat more fruits and vegetables and support their overall health.

[§§§] https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/ss6708.pdf.

Summary

What is already known about this topic?

Consuming fruits and vegetables is associated with reduced risk for cardiovascular disease, type 2 diabetes, some cancers, and obesity. Healthy dietary habits established during adolescence might continue into adulthood. However, few U.S. high-school students eat enough fruits and vegetables to meet U.S. Department of Agriculture recommendations.

What is added by this report?

Adolescents in all demographic groups consume too few fruits and vegetables, consistent with previous findings. In 2017, 7.1% met fruit intake recommendations, and 2.0% met vegetable intake recommendations.

What are the implications for practice?

Efforts to expand the reach of existing school and community programs as well as identify new strategies, such as social media approaches, might be needed to increase fruit and vegetable consumption among adolescents.

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Vaccination Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2019–20 School Year

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State and local school vaccination requirements serve to protect students against vaccine-preventable diseases (*1*). This report summarizes data collected by state and local immunization programs* on vaccination coverage among children in kindergarten (kindergartners) in 48 states, exemptions for kindergartners in 49 states, and provisional enrollment and grace period status for kindergartners in 28 states for the 2019–20 school year, which was more than halfway completed when most schools moved to virtual learning in the spring because of the coronavirus 2019 (COVID-19) pandemic. Nationally, vaccination coverage† was 94.9% for the state-required number of doses of diphtheria and tetanus toxoids, and acellular pertussis vaccine (DTaP); 95.2% for 2 doses of measles, mumps, and rubella vaccine (MMR); and 94.8% for the state-required number of varicella vaccine doses. Although 2.5% of kindergartners had an exemption from at least one vaccine,§ another 2.3% were not up to date for MMR and did not have a vaccine exemption. Schools and immunization programs can work together to ensure that undervaccinated students are caught up on vaccinations in preparation for returning to in-person learning. This follow-up is especially important in the current school year, in which undervaccination is likely higher because of disruptions in vaccination during the ongoing COVID-19 pandemic (*2–4*).

To meet state and local school entry requirements, parents and guardians submit children's vaccination records or exemption forms to schools, or schools obtain records from state immunization information systems. Federally funded immunization programs work with departments of education, school nurses, and other school personnel to assess vaccination and exemption status of children, typically those aged 4–6 years, enrolled in public and private kindergartens and to report unweighted counts, aggregated by school type, to CDC via a web-based questionnaire in the Secure Access Management System.¶ CDC uses these data to produce state- and national-level estimates of vaccination coverage (*5*). During the 2019–20 school year, 48 states reported coverage for all state-required vaccines among public school kindergartners, and 47 states reported on private school kindergartners.** Forty-nine states reported exemption data among public school kindergartners, and 48 states reported on private school kindergartners.** This report provides data on overall national and median vaccination coverage for the state-required number of doses of DTaP, MMR, and varicella vaccine. Hepatitis B and poliovirus vaccination coverage data, which are not included in this report, are available at SchoolVaxView (*6*). Twenty-eight states reported data on kindergartners who, at the time of assessment, were attending school under a grace period (attendance without proof of complete vaccination or exemption during a set interval) or provisional enrollment (school attendance while completing a catch-up vaccination schedule). Coverage and exemptions from U.S. territories and associated

* Federally funded immunization programs are located in the 50 states and the District of Columbia (DC), five other cities or counties, and eight U.S territories and freely associated states (territories). Two cities reported data to CDC, which were also included in data by their state, to calculate medians and national estimates. Immunization programs in U.S. territories reported vaccination coverage and exemptions to CDC; however, these data were not included in overall national calculations.

† National and median vaccination coverage was determined using estimates for 48 states; Alaska, Delaware, and the District of Columbia did not report school coverage data because of problems with data collection. Data from cities were included with their state data. Data from territories were not included in national and median calculations.

§ National and median exemption rates were determined using estimates for 49 states; Colorado, Minnesota, and Missouri did not collect information on the number of kindergartners with an exemption but instead reported the number of exemptions for each vaccine, which could count some children more than once. For these states, the percentage of kindergartners exempt from the vaccine with the highest number of exemptions (the lower bound of the potential range of exemptions) was included in the national and median exemption rates. Delaware and the District of Columbia did not report school vaccine exemption data because of problems with data collection. Data from cities were included with their state data. Data from territories were not included in national estimates.

¶ Assessment date varied by state and area. Four states assess on the first day of school; 14 states assess by December 31; 16 states assess by some other date, ranging from 30 days after admission to April 30; 15 states assess on a rolling basis.

** Ten states reported coverage and exemption data for at least some homeschooled kindergartners as follows: California included data for students who attend virtual partial or full charter schools with some or all online instruction and students receiving individualized education program services because they are medically unable to attend school in public school data, and data for homeschools with six or more students in private school data. Kansas included data for students educated through public virtual schools in the public school data. New Mexico included all homeschooled students in public school data. North Dakota reported some homeschool data separately. Oregon reported data for students enrolled in exclusively online homeschool programs separately; online students of otherwise traditional public schools were included in the public school data. Pennsylvania included all homeschooled students in their public school data. South Carolina and Wisconsin included homeschooled students in their public or private school data if the students also attended classes, extracurricular activities, or had other contact with a school. Vermont included homeschooled students in their public and private school data if the students were enrolled in one or more classes at a school. Wyoming reported homeschooled students in their public school data if the students also attend classes or extracurricular activities at a public school.

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states are presented; however, national estimates, medians, and summary measures include only U.S. states.

Vaccination coverage and exemption estimates were adjusted according to survey type and response rates.[††] National estimates measure coverage and exemptions among all kindergartners, and medians measure the midpoint of state-level coverage regardless of population size. Reported estimates for the 2019–20 school year are based on 3,675,882 kindergartners surveyed for vaccination coverage, 3,914,961 for exemptions, and 2,955,220 for grace period and provisional enrollment among the 4,025,574 children reported as enrolled in kindergarten by immunization programs for 49 states.[§§] Potentially achievable coverage with MMR, defined as the sum of the percentage of children who are up to date with 2 doses of MMR and those with no documented vaccination exemption but who are not up to date, was calculated for each state. Nonexempt students include those provisionally enrolled, in a grace period, or otherwise without documentation of vaccination. SAS (version 9.4; SAS Institute Inc.) was used for all analyses.

Vaccination assessments varied by immunization program because of differences in states' required vaccines and number of doses, vaccines assessed, methods of data collection, and data reported (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/100473). The majority of states reported kindergartners as up to date for a given vaccine if they had received all doses of that vaccine required for school entry.[¶¶] Seven states[***] reported kindergartners as up-to-date for any given vaccine only if they had received all doses of all vaccines required for school entry.

Nationally, 2-dose MMR coverage was 95.2% (range = ≥86.6% [Alabama] to ≥99.1% [Mississippi]). Coverage of ≥95% was reported by 20 states and coverage of <90% by three states (Table). DTaP coverage was 94.9% (range = 84.0% [Indiana] to ≥99.1% [Mississippi]), with 20 states reporting coverage of ≥95%, and three states reporting <90% coverage. Coverage with 2 doses (or 1 dose, as required) of varicella vaccine was 94.8% (range = ≥86.6% [Alabama] to ≥99.1% [Mississippi]), with 21 states reporting coverage ≥95%, and four states reporting <90% coverage.

The percentage of kindergartners with an exemption from one or more required vaccines (not limited to MMR, DTaP, and varicella vaccines) remained unchanged from the 2018–19 school year at 2.5% (range = 0.1% [New York and West Virginia] to 7.6% [Idaho]) (Table). Nationally, 0.3% of kindergartners had a medical exemption, and 2.2% had a nonmedical exemption (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/100473). Only 95.2% of kindergartners were up to date with MMR; 2.5% had an exemption from at least one vaccine,[§] and another 2.3% were not up to date with MMR and did not have a vaccine exemption (Table).

The percentage of kindergartners attending school within a grace period or provisionally enrolled among the 28 states reporting these data was 1.6% (range = <0.1% [Hawaii and Mississippi] to 6.1% [Ohio]) (Table). Of the 28 states with MMR coverage <95%, 24 states could potentially achieve ≥95% MMR coverage if all nonexempt kindergartners, many of whom were within a grace period or provisionally enrolled, were vaccinated (Figure 1). Among the 30 states reporting a decrease in the percentage of kindergartners who were not up to date for MMR and did not have an exemption in 2019–2020 compared with 2018–2019, an increase of MMR coverage in 2019–2020 was also reported by 26 states (Figure 2). In three states with MMR coverage <95% in 2018–2019 (Illinois, North Carolina, and South Carolina), coverage increased to ≥95% in 2019–2020.

Discussion

The purpose of vaccination assessment is to identify populations at risk and aid in taking programmatic steps to increase vaccination coverage. Although the COVID-19 pandemic led to late, truncated, or incomplete assessment of kindergarten vaccination status in the 2019–20 school year compared with the 2018–19 school year in some states (*7*), most student vaccinations would have already occurred before the start of the 2019–20 school year and would not have been affected by the pandemic. National coverage among kindergartners remained approximately 95% (*5*) for MMR, DTaP, and varicella vaccines. However, coverage and exemption rates varied by state. Measles outbreaks that affected school-aged children across multiple states during the 2018–19 school year underscore the importance of both school vaccination requirements for preventing

[††] Most immunization programs that used census or voluntary response provided CDC with data aggregated at the state or local (city or territory) level. Coverage and exemption data based on a census or voluntary response were adjusted for nonresponse using the inverse of the response rate, stratified by school type (public, private, and homeschool, where available). Programs that used complex sample surveys provided CDC with deidentified data aggregated at the school or county level for weighted analysis. Weights were calculated to account for sample design and adjusted for nonresponse for data collected through complex sample design wherever possible.

[§§] The totals reported here are the summations of the kindergartners surveyed among programs reporting data for coverage, exemptions, grace periods, and provisional enrollment. Data from cities and territories were not included in these totals.

[¶¶] All states required 2 doses of a measles-containing vaccine. Local DTaP requirements varied: Nebraska required 3 doses, four states (Illinois, Maryland, Virginia, and Wisconsin) required 4 doses, and all other states required 5 doses, unless the fouth dose was administered on or after the fourth birthday. The reported coverage estimates represent the percentage of kindergartners with the state-required number of DTaP doses, except for Kentucky, which required 5 doses of DTaP by age 5 years but reported 4-dose coverage for kindergartners. Seven states required 1 dose of varicella vaccine; 44 states required 2 doses.

[***] Alabama, Florida, Georgia, Iowa, Mississippi, New Hampshire, and New Jersey did not assess coverage for individual vaccines, but instead considered kindergartners up to date only if they had received all doses of all vaccines required for school entry. For these states, estimates are shown with the "≥" symbol.

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TABLE. Estimated* coverage† with measles, mumps, and rubella vaccine (MMR), diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP), and varicella vaccines, grace period/provisional enrollment,§ and any exemption¶ among children enrolled in kindergarten, by immunization program — United States, territories, and associated states, 2019–20 school year

Immunization program	Kindergarten population**	No. (%) surveyed††	Coverage (%)			Grace period/ Provisional enrollment (%)	Any exemption (%)	Percentage point change in any exemption, 2018 to 2019
			MMR§§ 2 doses	DTaP¶¶ 5 doses	Varicella*** 2 doses			
National estimate†††	4,025,574	3,675,882 (91.3)	95.2	94.9	94.8	1.6	2.5	—
Median†††	**NA**	**NA**	**94.6**	**94.4**	**94.6**	**1.6**	**2.7**	**0.1**
Alabama§§§	59,477	56,416 (94.9)	≥86.6	≥86.6	≥86.6	NP	1.2	0.4
Alaska§§§,¶¶¶	10,381	8,580 (82.7)	NR	NR	NR	NR	5.9	−1.2
Arizona****	83,976	82,848 (98.7)	92.8	92.6	95.3	NR	5.5	−0.5
Arkansas††††	39,510	37,997 (96.2)	94.3	93.2	93.9	456 (1.2)	1.9	0.1
California††††	566,155	554,250 (97.9)	96.5	96.2	96.1	8,262 (1.5)	0.8	0.2
Colorado§§§§	69,088	67,876 (98.2)	91.1	92.8	90.1	500 (0.7)	4.9	—
Connecticut§§§,¶¶¶¶	38,888	38,888 (100.0)	96.2	96.2	95.9	NP	2.5	−0.2
Delaware§§§	NR	NR	NR	NR	NR	NR	NR	NA
District of Columbia§§§	NR	NR	NR	NR	NR	NR	NR	NA
Florida§§§,¶¶¶¶,*****	228,298	228,298 (100.0)	≥93.5	≥93.5	≥93.5	6,737 (3.0)	3.4	0.2
Georgia§§§,¶¶¶¶	130,102	130,102 (100.0)	≥93.1	≥93.1	≥93.1	292 (0.2)	3.0	0.5
Hawaii§§§	15,695	1,403 (8.9)	89.7	91.1	91.8	0 (<0.1)	6.1	1.7
Idaho	23,301	22,950 (98.5)	89.1	89.0	88.5	373 (1.6)	7.6	−0.1
Illinois§§§,¶¶¶¶	145,891	145,891 (100.0)	96.6	96.5	96.4	925 (0.6)	2.0	0.2
Indiana§§§	88,253	57,968 (65.7)	94.4	84.0	94.0	NR	2.2	0.9
Iowa§§§,¶¶¶¶	40,812	40,812 (100.0)	≥93.2	≥93.2	≥93.2	1,255 (3.1)	2.5	0.1
Kansas§§§,††††,†††††	37,865	12,996 (34.3)	90.4	90.0	89.6	NR	2.1	—
Kentucky§§§,††††,*****	59,233	55,031 (92.9)	93.1	93.3	92.5	NR	1.8	0.4
Louisiana¶¶¶¶	59,685	59,685 (100.0)	95.6	97.2	95.0	NP	1.5	0.3
Maine	13,450	13,395 (99.6)	94.1	94.1	96.2	NR	5.9	−0.3
Maryland§§§,††††	72,443	71,225 (98.3)	97.9	98.2	97.5	NR	1.4	−0.1
Massachusetts§§§,¶¶¶¶,††††	66,756	66,756 (100.0)	97.3	97.2	97.0	NP	1.3	−0.1
Michigan¶¶¶¶	120,565	120,565 (100.0)	94.8	94.7	94.4	798 (0.7)	4.4	−0.1
Minnesota§§§§,*****	71,223	70,284 (98.7)	92.6	92.3	92.0	NR	3.8	0.1
Mississippi§§§,****,¶¶¶¶,	37,870	37,870 (100.0)	≥99.1	≥99.1	≥99.1	17 (<0.1)	0.2	0.1
Missouri§§§§,¶¶¶¶	72,324	72,324 (100.0)	94.6	94.5	94.2	NR	2.7	—
Montana§§§,¶¶¶¶	12,501	12,501 (100.0)	93.6	93.2	93.2	231 (1.8)	4.3	−0.2
Nebraska§§§,††††	26,893	26,012 (96.7)	96.3	96.9	95.6	440 (1.6)	2.2	0.1
Nevada§§§	37,724	37,678 (99.9)	95.4	94.0	94.6	896 (2.4)	4.0	0.7
New Hampshire§§§,¶¶¶¶	12,447	12,447 (100.0)	≥91.5	≥91.5	≥91.5	561 (4.5)	3.1	−0.2
New Jersey¶¶¶¶,¶¶¶	107,900	107,900 (100.0)	≥95.9	≥95.9	≥95.9	958 (0.9)	2.6	0.1
New Mexico§§§	23,087	23,087 (100.0)	97.0	96.7	96.7	369 (1.6)	1.5	—
New York (incl. New York City)§§§,****	234,165	234,031 (99.9)	98.6	97.8	98.1	3,827 (1.6)	0.1	−1.2
New York City§§§,****	96,581	96,447 (99.9)	98.1	97.3	97.7	846 (0.9)	0.1	−0.6
North Carolina §§§, ††††,*****	124,548	121,835 (97.8)	95.5	95.5	95.3	1,499 (1.2)	1.7	0.1
North Dakota	10,587	10,536 (99.5)	94.8	94.4	94.8	NR	3.9	−0.4
Ohio	139,103	137,441 (98.8)	92.4	92.3	91.9	8,515 (6.1)	2.8	−0.1
Oklahoma	55,348	47,374 (85.6)	93.0	93.9	96.9	NR	2.7	0.1
Oregon††††,¶¶¶¶	45,959	45,959 (100.0)	93.4	92.6	94.6	NR	7.1	−0.6
Pennsylvania	140,197	138,573 (98.8)	96.6	96.8	96.3	3,085 (2.2)	3.0	0.1
Rhode Island§§§,††††,*****	11,219	11,054 (98.5)	97.7	97.4	97.0	NR	1.3	—
South Carolina§§§	65,938	18,104 (27.5)	95.0	95.2	94.5	174 (0.3)	2.6	—
South Dakota§§§	12,367	12,337 (99.8)	96.0	95.9	95.2	NR	2.7	0.1
Tennessee§§§,††††,¶¶¶¶	80,595	80,595 (100.0)	96.8	96.4	96.5	1,529 (1.9)	2.0	0.1
Texas (including Houston) ††††,*****	398,680	397,093 (99.6)	96.9	96.6	96.4	5,507 (1.4)	2.5	0.1
Houston††††,*****	38,868	38,655 (99.5)	96.3	96.4	95.2	415 (1.1)	1.5	—
Utah¶¶¶¶	49,208	49,208 (100.0)	92.7	92.2	92.4	1,144 (2.3)	5.4	−0.3
Vermont§§§,¶¶¶¶	6,293	6,293 (100.0)	94.5	94.1	93.9	262 (4.2)	3.7	−1.0
Virginia§§§,†††††	99,399	1,200 (1.2)	94.6	97.6	93.3	NR	1.7	—
Washington*****	87,757	80,623 (91.9)	94.4	92.8	92.7	1,234 (1.4)	5.7	0.7
West Virginia§§§,****,§§§§§	17,114	8,481 (49.6)	98.2	98.8	97.8	16 (0.1)	0.1	−0.7
Wisconsin††††,*****,†††††	67,391	1,777 (2.6)	92.8	94.5	91.6	68 (0.1)	5.7	−0.2
Wyoming¶¶¶¶	7,913	7,913 (100.0)	94.5	94.4	85.6	152 (1.9)	3.5	0.6

See table footnotes on the next page.

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TABLE. (*Continued*) Estimated* coverage† with measles, mumps, and rubella vaccine (MMR), diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP), and varicella vaccines, grace period/provisional enrollment,§ and any exemption¶ among children enrolled in kindergarten, by immunization program — United States, territories, and associated states, 2019–20 school year

Immunization program	Kindergarten population**	No. (%) surveyed††	Coverage (%)			Grace period/ Provisional enrollment (%)	Any exemption (%)	Percentage point change in any exemption, 2018 to 2019
			MMR§§ 2 doses	DTaP¶¶ 5 doses	Varicella*** 2 doses			
Territories and associated states								
American Samoa§§§,¶¶¶¶,§§§§§	781	781 (100.0)	91.9	71.4	21.0	NP	—	NA
Federated States of Micronesia¶¶¶¶	1,532	1,532 (100.0)	90.7	76.8	NReq	NR	—	—
Guam§§§	2,513	2,492 (99.2)	93.7	92.9	NReq	NR	0.1	—
Marshall Islands§§§,****,¶¶¶¶	1,115	1,115 (100.0)	92.0	90.3	NReq	NR	—	—
Northern Mariana Islands¶¶¶¶	895	895 (100.0)	95.3	97.3	95.0	NR	—	—
Palau¶¶¶¶,¶¶¶¶¶	273	273 (100.0)	90.1	90.1	NReq	NR	—	—
Puerto Rico	26,980	1,266 (4.7)	93.5	89.9	93.0	NR	2.0	0.4
U.S. Virgin Islands	NR	NR	NR	NR	NR	NR	NR	NA

Abbreviations: NA = not available; NP = no grace period/provisional policy; NR = not reported to CDC; NReq = not required for school entry.

* Estimates are adjusted for nonresponse and weighted for sampling where appropriate.

† Estimates based on a completed vaccine series (i.e., not vaccine-specific) use the "≥" symbol. Coverage might include history of disease or laboratory evidence of immunity.

§ A grace period is a set number of days during which a student can be enrolled and attend school without proof of complete vaccination or exemption. Provisional enrollment allows a student without complete vaccination or exemption to attend school while completing a catch-up vaccination schedule. In states with one or both of these policies, the estimates represent the number of kindergartners within a grace period, provisionally enrolled, or some combination of these categories.

¶ Exemptions, grace period/provisional enrollment and vaccination coverage status might not be mutually exclusive. Some children enrolled under a grace period/provisional enrollment might be exempt from one or more vaccinations, while children with exemptions might be fully vaccinated with one or more required vaccines.

** The kindergarten population is an approximation provided by each program.†† The number surveyed represents the number of kindergartners surveyed for vaccination coverage. For Alaska, this number represents the number surveyed for exemptions as coverage was not reported. The national total excludes the 10,381 kindergartners from Alaska. Exemption estimates are based on 34,011 kindergartners for Kansas, 65,938 kindergartners for South Carolina, 97,236 kindergartners for Virginia, and 67,391 kindergartners for Wisconsin.

§§ Most states require 2 doses of MMR; Alaska, New Jersey, and Oregon require 2 doses of measles, 1 dose of mumps, and 1 dose of rubella vaccines. California, Georgia, New York, New York City, North Carolina, and Virginia require 2 doses of measles and mumps and 1 dose of rubella vaccines. Iowa requires 2 doses of measles and 2 doses of rubella vaccines.

¶¶ Pertussis vaccination coverage might include some diphtheria, tetanus toxoids, and pertussis vaccine (DTP) vaccinations if administered in another country or by a vaccination provider who continued to use DTP after 2000. Most states require 5 doses of DTaP for school entry, or 4 doses if the fourth dose was received on or after the fourth birthday; Illinois, Maryland, Virginia, and Wisconsin require 4 doses; Nebraska requires 3 doses. The reported coverage estimates represent the percentage of kindergartners with the state-required number of DTaP doses, except for Kentucky, which requires ≥5 but reports ≥4 doses of DTaP.

*** Most states require 2 doses of varicella vaccine for school entry; Alabama, Arizona, Hawaii, Maine, New Jersey, Oklahoma, and Oregon require 1 dose. Reporting of varicella vaccination status for kindergartners with a history of varicella disease varied within and among states; some were reported as vaccinated against varicella and others as medically exempt.

††† National coverage estimates and medians calculated from data from 48 states (i.e., do not include Alaska, Delaware, and the District of Columbia). National grace period/provisional enrollment estimates and medians were calculated from data from 28 states that have either a grace period or a provisional enrollment policy and that reported relevant data to CDC. National exemption estimates and medians were calculated from data from 49 states (i.e., do not include Delaware and the District of Columbia). Other jurisdictions excluded were Houston, New York City, American Samoa, Guam, Marshall Islands, Federated States of Micronesia, North Mariana Islands, Palau, Puerto Rico, or U.S. Virgin Islands. Data reported from 3,675,882 kindergartners assessed for coverage, 3,914,961 for exemptions, and 2,955,220 for grace period/provisional enrollment. Estimates represent rates for populations of 4,015,193; 4,025,574; and 3,056,534 kindergartners for coverage, exemptions, and grace period/provisional enrollment, respectively.

§§§ Philosophical exemptions were not allowed.

¶¶¶ Alaska did not report kindergarten vaccination coverage because of problems with data collection. Vaccination coverage among children aged 6 years in VacTrAK, Alaska's Immunization Information System, was 75.5% for MMR, 85.1 for DTaP, and 73.0 for varicella vaccine.

**** Religious exemptions were not allowed.

†††† Counted some or all vaccine doses received regardless of Advisory Committee on Immunization Practices—recommended age and time interval; vaccination coverage rates reported might be higher than those calculated using only valid doses.

§§§§ Program did not report the number of children with exemptions, but instead reported the number of exemptions for each vaccine, which could count some children more than once. Lower bounds of the percentage of children with any exemptions were estimated using the individual vaccines with the highest number of exemptions.

¶¶¶¶ The proportion surveyed likely was <100% but is reported as 100% based on incomplete information about the actual current enrollment.

***** Did not include some types of schools, such as online schools or those located in military bases or correctional facilities, or tribal lands.

††††† Kindergarten vaccination coverage data were collected from a sample, and exemption data were collected from a census of kindergartners.

§§§§§ Reported public school data only.

¶¶¶¶¶ For Palau, estimates represent coverage among children in first grade.

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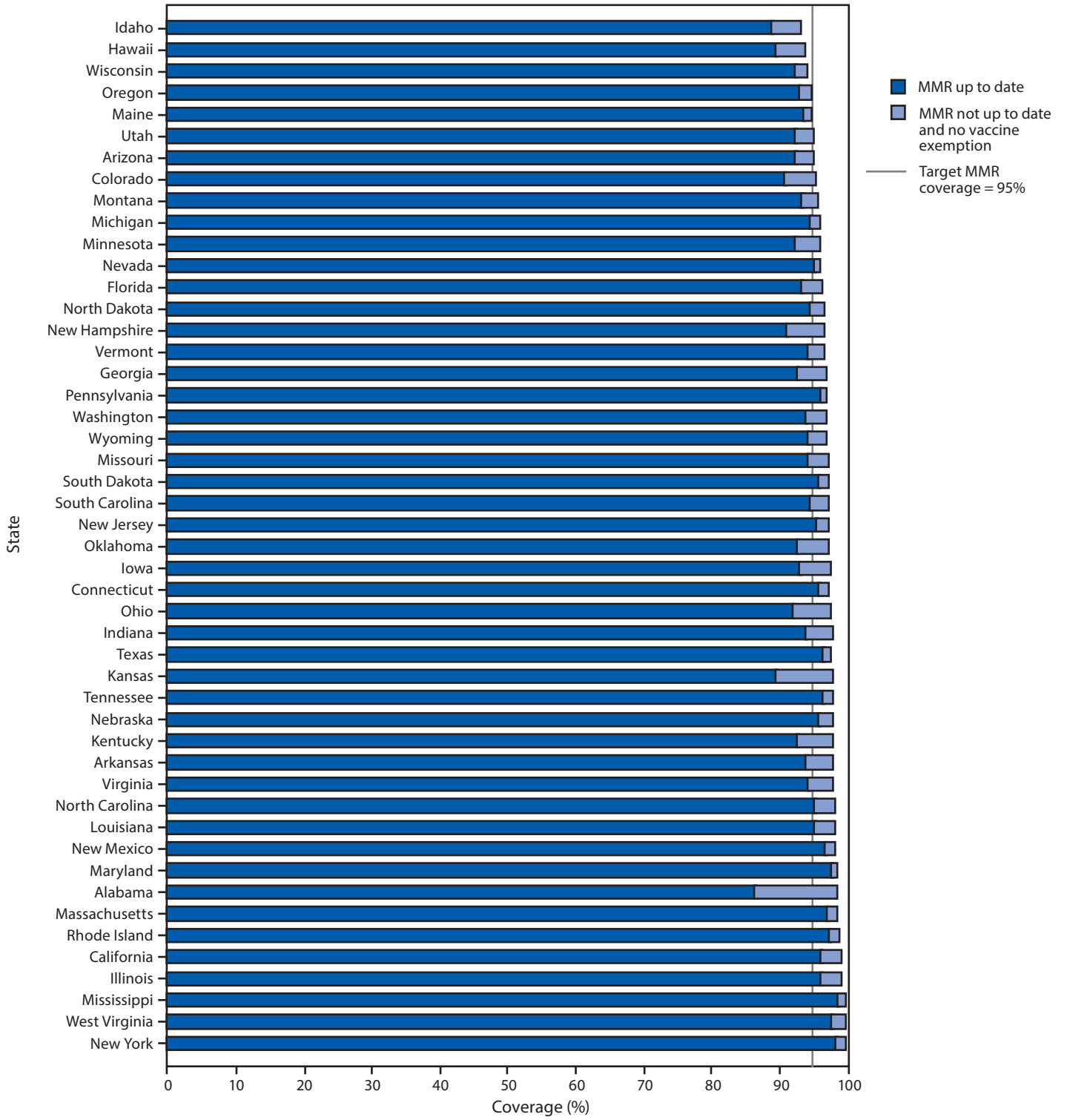
FIGURE 1. Potentially achievable coverage*,†,§ with measles, mumps, and rubella vaccine (MMR) among kindergartners, by state — 48 states, 2019–20 school year



* States are ranked from lowest to highest potentially achievable coverage. Potentially achievable coverage is estimated as the sum of the percentage of students with up-to-date MMR and the percentage of students without up-to-date MMR and without a documented vaccine exemption.

† The exemptions used to calculate the potential increase in MMR coverage for Arizona, Arkansas, Colorado, Idaho, Illinois, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, Texas, Utah, Vermont, Wisconsin, and Wyoming are the number of children with exemptions specifically for MMR vaccine. For all other states, numbers are based on an exemption to any vaccine.

§ Alaska, Delaware, and the District of Columbia did not report kindergarten vaccination coverage for the 2019–20 school year and are excluded from this analysis.

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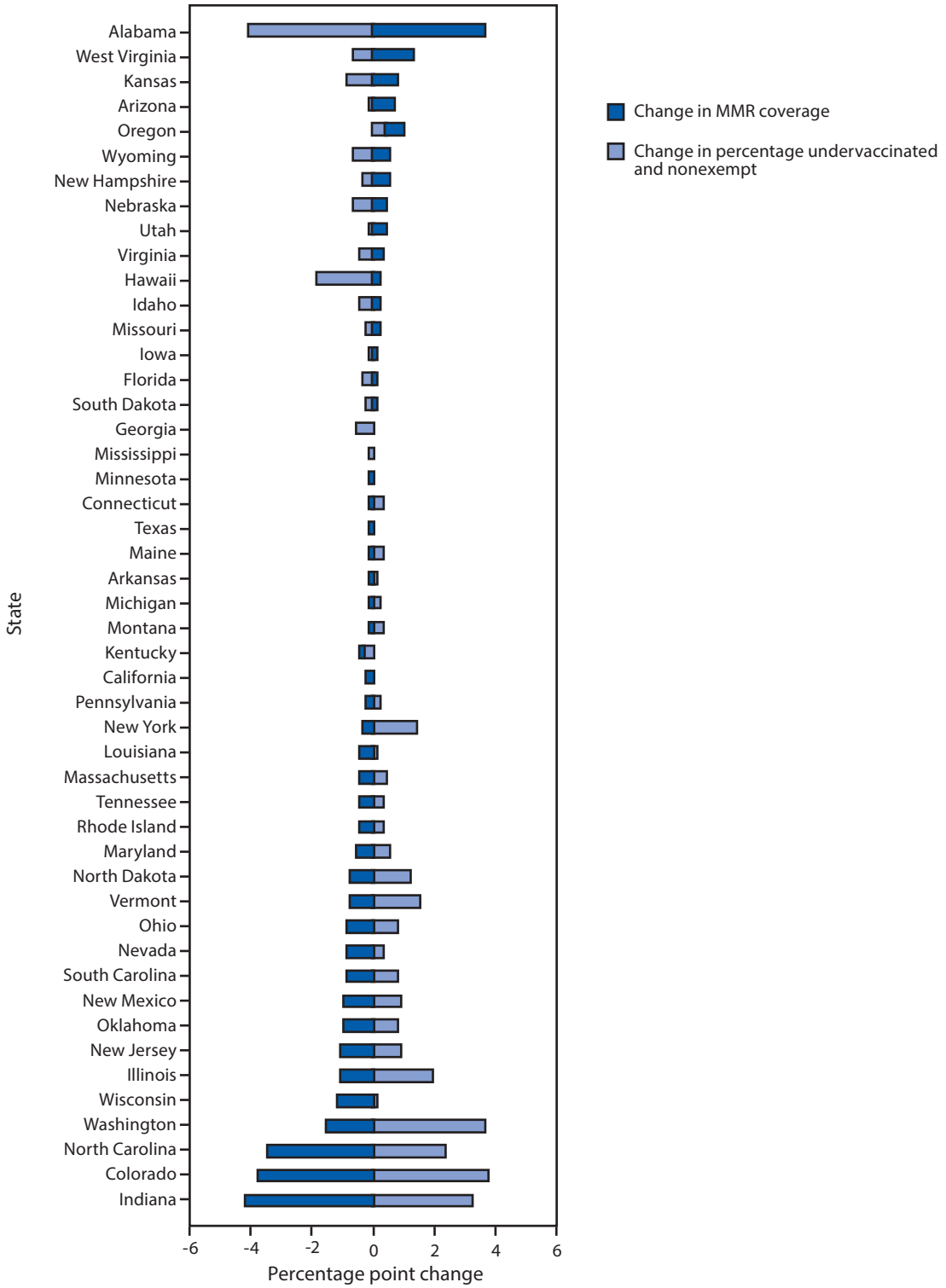
FIGURE 2. Change in percentage of kindergartners who are fully vaccinated with measles, mumps, and rubella vaccine (MMR) and in the percentage who are undervaccinated and nonexempt,*,†,§ by state — 48 states, 2018–19 to 2019–20 school years



* States are ranked from greatest decrease to highest increase in the percentage of kindergartners who are undervaccinated and nonexempt. The exemptions used to calculate the MMR not up to date and no documented vaccine exemptions for Arizona, Arkansas, Colorado, Idaho, Illinois, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, Texas, Utah, Vermont, Wisconsin, and Wyoming are the number of children with exemptions specifically for MMR vaccine. For all other states, numbers are based on an exemption to any vaccine.

† Alaska, Delaware, and the District of Columbia did not report kindergarten vaccination coverage for the 2019–20 school year and are excluded from this analysis.

§ California, Michigan, New Jersey, New York, Oregon, Pennsylvania, Texas, and Washington experienced >15 cases of measles during the 2018–2019 outbreak.

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disease spread and school coverage assessments to identify pockets of low coverage (*8*). Among eight states with measles outbreaks of ≥15 cases during the 2018–19 school year (*8*), six reported increases in MMR coverage during 2019–2020. Increases in some states were likely attributable to changes in state laws eliminating nonmedical vaccination exemptions (*9*), and vaccination campaigns in response to the outbreaks could also have contributed to the increases in MMR coverage.

The overall percentage of children with an exemption remained at approximately 2.5%; children with exemptions represent a small proportion of kindergartners nationally and in most states. In 25 states, the number of nonexempt undervaccinated kindergartners equaled or exceeded the number of those with exemptions. In many states, nonexempt undervaccinated students are attending school in a grace period or are provisionally enrolled. Follow-up with undervaccinated students can increase vaccination coverage in this group.

Twenty-six states successfully increased MMR coverage by reducing the number of nonexempt students who are not up to date, with three states (Illinois, North Carolina, and South Carolina) reaching coverage of ≥95%. Some states have implemented policies and activities focused on improving coverage. In Colorado, MMR coverage increased from 87.4% in 2018–2019 to 91.1% in 2019–2020. This was accomplished by prioritizing high MMR coverage. In addition to providing technical assistance, media toolkits, strategies, and local kindergarten MMR data and targets, the state health department furnished lists of elementary schools with low coverage to local public health agencies, which implemented community-specific strategies. These included digital media campaigns aimed at parents, vaccination reminder/recall, efforts to improve school compliance, outbreak tabletop exercises with schools, and incentives to families (Diana Herrero, Colorado Department of Public Health and Environment, personal communication, November 13, 2020). Almost all states could achieve ≥95% MMR coverage if nonexempt undervaccinated children were vaccinated according to local and state vaccination policies.

The findings in this report are subject to at least six limitations. First, comparability is limited because of variation in states' requirements, data collection methods, exemptions allowed, and definitions of grace period and provisional enrollment. Second, representativeness might be negatively affected because of data collection methods that missed some schools or students or occurred at different times. Third, results might be underestimated or overestimated because of incomplete documentation. Fourth, national coverage estimates include only 48 of 50 states but use lower bound estimates for seven states; exemption estimates include 49 states but use lower bound estimates for three states; and grace period or provisional enrollment estimates include only 28 states for the 2019–20 school year. Fifth, estimates of potentially achievable MMR coverage are approximations and are underestimated for states that do not report vaccine-specific exemptions (*5*,*7*). Finally, because of the COVID-19 pandemic, schools were closed, and state and local health department staff members were deployed to response activities, limiting the quantity and quality of student vaccination data collected and reported to CDC (CDC, unpublished data, 2020).

Based on measurements from other data sources, CDC expects that the COVID-19 pandemic has already reduced actual vaccination coverage of kindergarten-aged children through reduced appointment availability at providers' offices, parents delaying preventive health care visits, and other barriers to vaccination, and that those disruptions will reduce kindergarten vaccination coverage in the 2020–21 school year (*2*–*4*). In addition, schools in many states began the 2020–21 school year remotely and might not have enforced the usual vaccination policies. Providers, schools, and immunization programs will need to increase follow-up with undervaccinated students and find ways to overcome pandemic-related barriers to maintain the high level of vaccination coverage necessary to continue protecting school-aged children, their family members, and communities from vaccine-preventable diseases during virtual learning and as schools return to in-person instruction. Jurisdictions should provide resources as appropriate, such as guidance to parents about the importance of maintaining preventive care during the pandemic, lists of immunization providers in the area for children who are unable to be vaccinated by their usual health care provider, or special vaccination clinics at schools or health departments.

Summary

What is already known about this topic?

State immunization programs conduct annual kindergarten vaccination assessments to monitor school-entry vaccination coverage with all state-required vaccines.

What is added by this report?

For the 2019–20 school year, national coverage was approximately 95% for diphtheria and tetanus toxoids, and acellular pertussis; measles, mumps, and rubella; and varicella vaccines. The national exemption rate remained low at 2.5%.

What are the implications for public health practice?

Disruptions caused by the COVID-19 pandemic are expected to reduce vaccination coverage in the 2020–21 school year. Increased follow-up of undervaccinated students is needed from schools and immunization programs to maintain the high vaccination coverage necessary to protect students in preparation for schools returning to in-person learning.

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COVID-19 Case Investigation and Contact Tracing Efforts from Health Departments — United States, June 25–July 24, 2020

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Case investigation and contact tracing are core public health tools used to interrupt transmission of pathogens, including SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19); timeliness is critical to effectiveness (*1*,*2*). In May 2020, CDC funded* 64 state, local, and territorial health departments† to support COVID-19 response activities. As part of the monitoring process, case investigation and contact tracing metrics for June 25–July 24, 2020, were submitted to CDC by 62 health departments. Descriptive analyses of case investigation and contact tracing load, timeliness, and yield (i.e., the number of contacts elicited divided by the number of patients prioritized for interview) were performed. A median of 57% of patients were interviewed within 24 hours of report of the case to a health department (interquartile range [IQR] = 27%–82%); a median of 1.15 contacts were identified per patient prioritized for interview§ (IQR = 0.62–1.76), and a median of 55% of contacts were notified within 24 hours of identification by a patient (IQR = 32%–79%). With higher caseloads, the percentage of patients interviewed within 24 hours of case report was lower (Spearman coefficient = –0.68), and the number of contacts identified per patient prioritized for interview also decreased (Spearman coefficient = –0.60). The capacity to conduct timely contact tracing varied among health departments, largely driven by investigators' caseloads. Incomplete identification of contacts affects the ability to reduce transmission of SARS-CoV-2. Enhanced staffing capacity and ability and improved community engagement could lead to more timely interviews and identification of more contacts.

During July 31–August 14, 2020, baseline data on four metrics for June 25–July 24, 2020 (the evaluation period) were submitted by 62 of 64 (97%) health departments funded through the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases Cooperative Agreement (ELC)¶ to the Research Electronic Data Capture (REDCap) platform (*3*). These metrics, developed by the CDC COVID-19 Contact Tracing Innovations Support Team, were vetted by public health partners, including a number of ELC-funded health departments, and include the following: 1) average caseload per case investigator (the total number of probable and confirmed COVID-19 patients assigned for interview during the evaluation period divided by the total number of case investigators), average contact tracing load (the total number of contacts assigned for follow-up divided by the total number of contact tracers), and staffing model (separate, mostly separate, or the same health department staffing for case investigation and contact tracing); 2) case investigation timeliness (the percentage of persons with probable and confirmed COVID-19 prioritized for interview successfully reached within 24 hours by a health department staff member or representative); 3) contact tracing timeliness (the percentage of contacts notified of potential exposure to COVID-19 within 24 hours of elicitation of contact information by a patient); and 4) contact tracing yield, calculated as the number of contacts elicited divided by number of patients prioritized for interview. Because guidance for prioritization of patient interviews was not provided, health departments developed their own criteria, examples of which included interviewing patients when they became known to the health department or prioritizing patient interviews based on whether the patients were symptomatic, had underlying medical conditions, lived in congregate settings, or worked in health care occupations. Descriptive analyses of the four metrics were performed using SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.**

Among the 62 funded health departments, four (6.5%) (all U.S.-affiliated Pacific islands) reported no cases, and two (3.2%) submitted partial data and were excluded. Data from the remaining 56†† (90%) health departments were analyzed.

* https://www.cdc.gov/media/releases/2020/p0423-CARES-act.html; https://www.cdc.gov/media/releases/2020/p0518-hhs-funding-expand-testing-states.html.

† 50 U.S. states, Chicago, Houston, New York City, Philadelphia, Washington D.C., Los Angeles County, American Samoa, Northern Mariana Islands, Federated States of Micronesia, Guam, Palau, Puerto Rico, Marshall Islands, and U.S. Virgin Islands.

§ Patients prioritized for interview refer to persons with confirmed and probable COVID-19 reported to the health department in the official case report system. Prioritization of patients is defined differently by different health departments.

¶ https://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html.

** 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

†† Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, Chicago, Houston, New York City, Philadelphia, Los Angeles County, Northern Mariana Islands, Guam, Puerto Rico, and U.S. Virgin Islands

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Because completeness of reporting by health departments varied by metric, denominators varied. Health departments with incomplete data for a metric were excluded for that specific metric.

Among reporting health departments, the median caseload per investigator during the evaluation period was 31, ranging from one to 196, among 54 (96%) health departments with complete data for this metric (Table). Among patients prioritized for interview by these 54 health departments, a median of 57% were interviewed within 24 hours of report to the health department. Among 53 health departments that provided information on the average number of contacts assigned for follow-up per contact tracer, the median was 29, ranging from 0.5 to 200; a median of 55% of contacts were notified within 24 hours of elicitation by a patient. Among 48 health departments that reported information on contact notification, 27 (56%) reported that at least one half of contacts were notified within 24 hours of elicitation. However, 12 health departments reported that fewer than one third (<32%) of contacts were reached within 24 hours.

Caseload and timeliness of case investigation were inversely correlated among 49 health departments with complete data for these metrics (Spearman correlation coefficient = –0.68) (Figure 1). Health departments with smaller average caseloads per investigator completed a larger proportion of patient interviews within 24 hours of report. Among four health departments that interviewed >90% of patients within 24 hours, investigators' average caseloads were fewer than 30 patients each, whereas among four health departments with average caseloads >130 patients per investigator, <30% of interviews were completed within 24 hours.

When restricted to patients prioritized for interview (9,013), among 53 health departments that submitted complete data, 42 (79%) reported fewer than two contacts elicited per patient (median = 1.15). The number of contacts elicited per patient prioritized for interview was smaller in health departments with larger caseloads (Spearman correlation coefficient = –0.60) (Figure 2). These trends persisted in jurisdictions that allocated different staff members, mostly different staff members, or the same staff members to be case investigators and contact tracers (Spearman correlation coefficients = –0.89, –0.69, and –0.32, respectively).

Discussion

Health departments' capacity and ability to conduct timely and effective case investigation and contact tracing varied widely across the United States. The ideal workforce size to adequately conduct case investigation and contact tracing per jurisdiction[§§] likely depends on several factors (*4*); however, the inverse relationship between staff member workload and completeness and timeliness of case investigation and contact tracing suggest that increases in staffing capacity might help reduce delays in interviewing patients and identify more contacts. Most state health departments are hiring more staff members to perform contact tracing[¶¶] (*1*). Health departments might choose to prioritize case investigation and contact tracing based on whether persons are likely to be at higher risk for severe disease, live or work in congregate settings, or are part of a known cluster (*5*). Surges in cases might exceed the workforce capacity of jurisdictions to maintain high coverage of case investigation and contact tracing. Continued efforts to ensure notification of patients of their infection and contacts of their exposure are needed. CDC recommends use of prioritization measures to reach populations at risk as well as use of innovative technologies (*6*) to support this public health imperative.

Approximately one half of health departments were able to achieve a median interval of ≤24 hours from first notification of the patient to interview; likewise, approximately one half also were able to achieve a median interval of ≤24 hours from patient interview to contact notification, although these two groups did not always comprise the same health departments. These findings

[§§] https://www.gwhwi.org/estimator-613404.html.

[¶¶] https://www.npr.org/sections/health-shots/2020/06/18/879787448/as-states-reopen-do-they-have-the-workforce-they-need-to-stop-coronavirus-outbre.

TABLE. COVID-19 case investigation and contact tracing metrics — 56 health departments, United States, June 25–July 24, 2020

Metric	Median* (IQR) [total range]	No. (%) of health departments
Case investigation		
Total cases assigned for interview during reporting period	8,306 (1,781–19,671) [22–280,033]	56 (100)
Average no. of cases assigned for interview per case investigator (caseload)	31 (15–68) [1–196]	54 (96)
Prioritized persons interviewed within 24 hrs	57 (27–82) [1–100]	54 (96)
Contact tracing		
Contacts elicited from cases during reporting period	7,498 (2,236–19,937) [124–95,775]	54 (96)
Average no. of contacts assigned for follow-up per contact tracer (contact tracing load)	29 (17–44) [0.5–200]	53 (95)
Contacts notified within 24 hrs of identification by a patient	55 (32–79) [4–100]	48 (86)

Abbreviations: COVID-19 = coronavirus disease 2019; IQR = interquartile range.
* Median caseload and contact tracing loads represent the median of the average per investigator or contact tracer.

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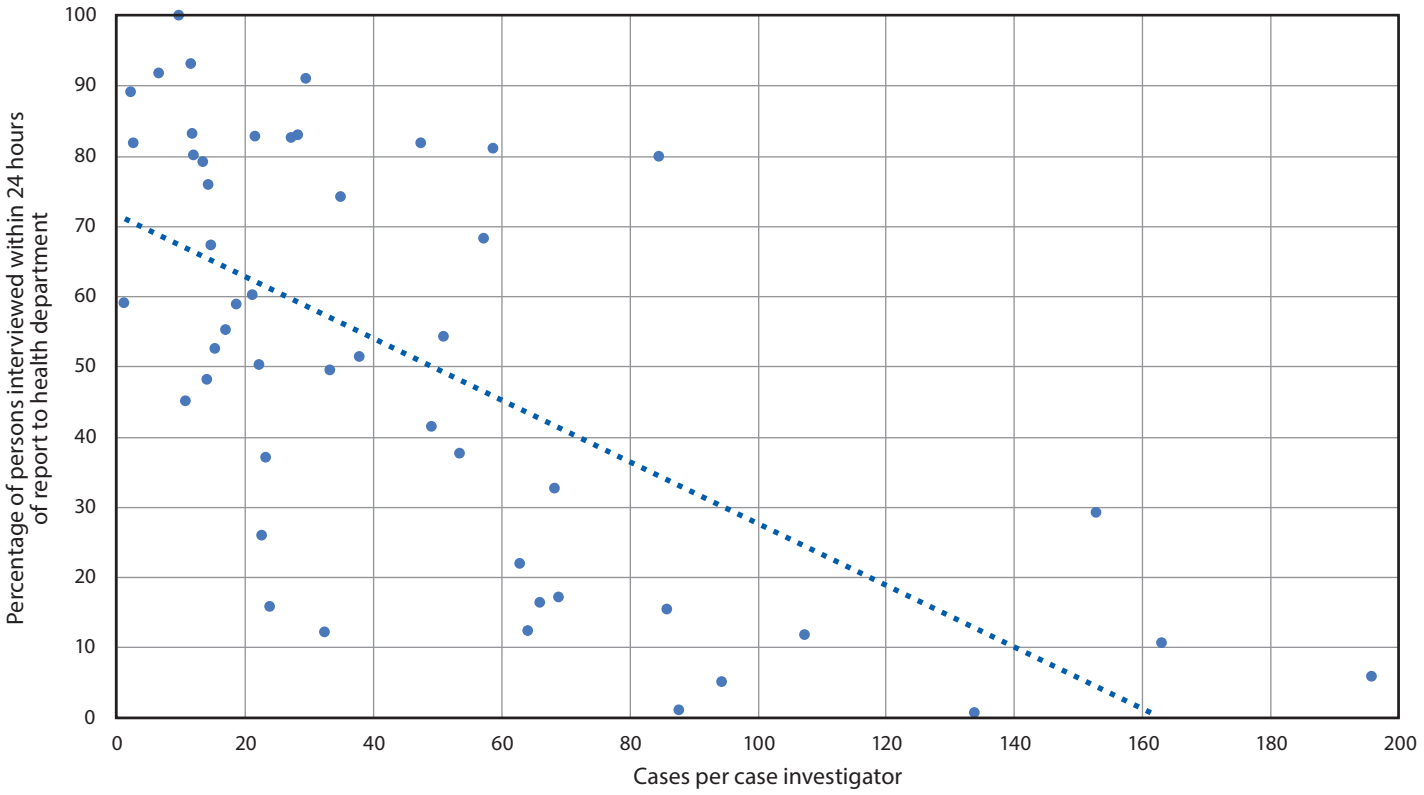
FIGURE 1. Association between COVID-19 caseload per health department investigator and timeliness of case interviews — 49 health departments, United States, June 25–July 24, 2020*



Abbreviation: COVID-19 = coronavirus disease 2019.
* The trendline represents the inverse correlation between the average caseload per case investigator and the timeliness of case investigations among 49 health departments.

are comparable with those in recent reports that described median intervals of 1 day from patient report to interview and 1 and 3 days from case investigation to contact notification in two U.S. counties (*1*,*7*). The evaluation period in this report, June 25–July 24, 2020, corresponded to a time of increased COVID-19 incidence (*8*); the capacity of health departments in jurisdictions with large numbers of cases to conduct timely patient follow-up and contact notification could be overwhelmed.

The median number of contacts elicited per patient prioritized for interview was 1.15. The number of contacts elicited per patient would have been higher if limited to the number of patients who completed an interview rather than those who were prioritized for an interview; however, the number of patients who completed an interview was not collected at this time, and the calculation was not possible. A recent assessment of two North Carolina counties reported an average of 3.0 and 4.6 contacts named per interviewed patient during a similar time frame (*1*). A contact tracing team in central Pennsylvania identified 953 contacts elicited among 536 confirmed patients (1.8 contacts per patient) during March 24–May 28; the lower number of contacts per patient might be related to the widespread stay-at-home orders that were in effect during that time (*9*).

One contributor to low numbers of contacts elicited might be related to reluctance to engage in contact tracing efforts*** or to name persons other than household contacts (*1*). The number of contacts elicited might vary by caseload, owing to worker fatigue or inexperience; with higher caseloads, contact tracers might be less likely to persist with questioning to identify additional contacts.

The findings in this report are subject to at least four limitations. First, these data are self-reported by health departments and were likely generated from new data systems designed to monitor case investigation and contact tracing. New systems could be prone to errors and might not reflect complete performance within the jurisdiction. Second, data validity might be affected by health departments' varying interpretations of definitions of metrics. These data include that obtained during health departments' first reporting period on these metrics, which will continue to be refined. Third, these data precluded calculation of the average number of contacts elicited per patient who completed an interview, and therefore do not align with other

*** https://www.scientificamerican.com/article/contact-tracing-a-key-way-to-slow-covid-19-is-badly-underused-by-the-u-s/.

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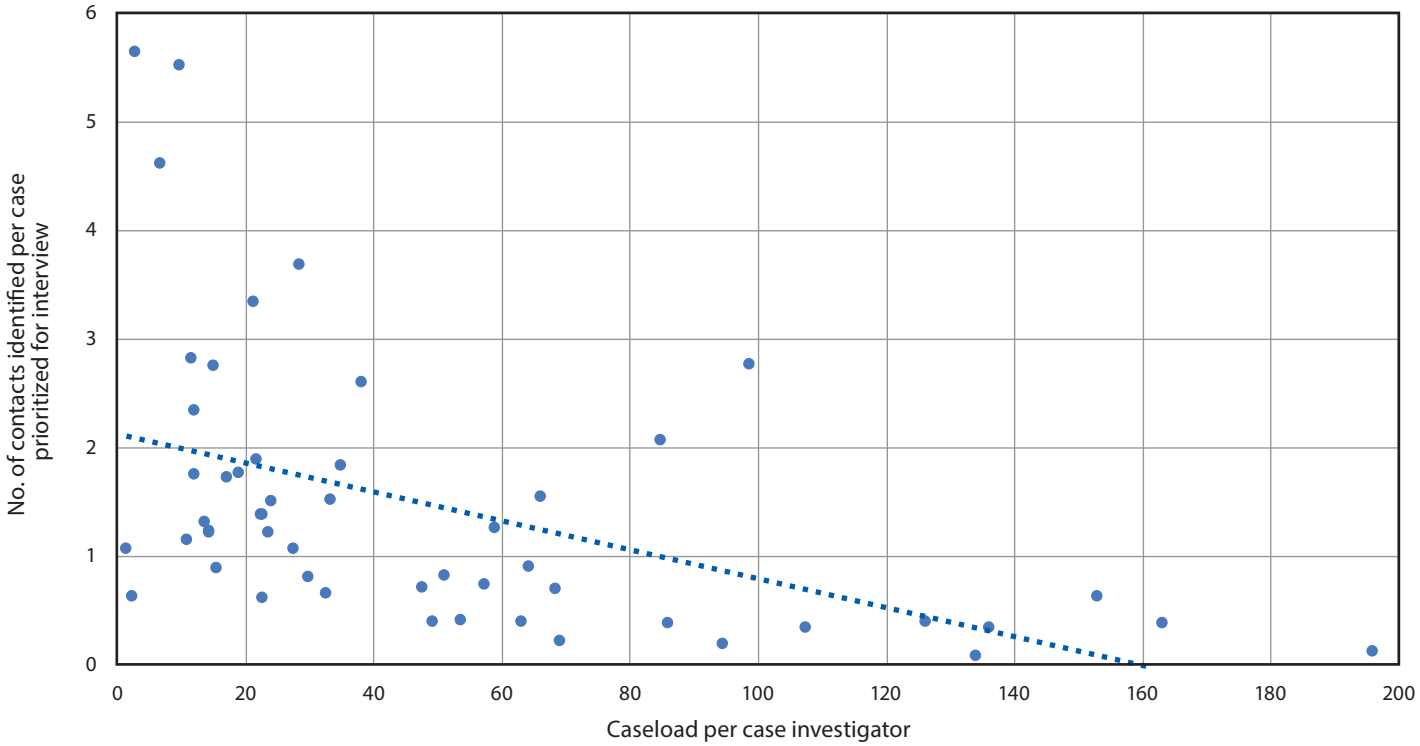
FIGURE 2. Association between the COVID-19 caseload per health department investigator and number of close contacts identified per case prioritized for interview — 52 health departments, United States, June 25–July 24, 2020*



Abbreviation: COVID-19 = coronavirus disease 2019.
* The trendline represents the inverse correlation between the average caseload per case investigator and the number of contacts elicited per patient prioritized for interview among 52 health departments.

studies' methods of calculating contacts elicited (*1*); the actual number is likely higher, warranting cautious interpretation. Finally, an important component of contact tracing is laboratory test timeliness, which is not included in these data. During the COVID-19 pandemic, delays from the time of laboratory specimen collection to report to the health department can have substantial impact on total time to reach a contact (*2*,*9*); the absence of these data in an assessment of contact tracing timeliness is an especially important limitation of this report.

Delays in interviewing COVID-19 patients decrease the likelihood of quickly identifying and quarantining contacts. Low ascertainment of contacts affects the nation's potential to interrupt the transmission of SARS-CoV-2 through rapid notification, quarantining, and testing. Caseloads within jurisdictions influence how quickly health departments can reach patients, which might influence the completeness of data used to reach contacts. Increasing staffing capacity might improve the timeliness of case interviews. Strengthening awareness regarding state and local health department contact tracing efforts might improve community perception or willingness to provide more complete lists of contacts.

Summary

What is already known about this topic?

Resources have been allocated to supplement the U.S. case investigation and contact tracing workforce as a public health tool to interrupt the spread of COVID-19.

What is added by this report?

Analysis of case investigation and contact tracing metric data reported by 56 U.S. health departments found wide variation in capacity and ability to conduct timely and effective contact tracing. Investigator caseload was inversely related to timely interviewing of patients and number of contacts identified per case.

What are the implications for public health practice?

Enhanced staffing capacity and ability and improved community engagement could lead to more timely contact tracing interviews and identification of more contacts.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Alison Stargel reports employment as the duty epidemiologist on the Washington State Department of Health COVID-19 response during April–June 2020. No other potential conflicts of interest were disclosed.

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COVID-19 Trends Among Persons Aged 0–24 Years — United States, March 1–December 12, 2020

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On January 13, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

Coronavirus disease 2019 (COVID-19) case and electronic laboratory data reported to CDC were analyzed to describe demographic characteristics, underlying health conditions, and clinical outcomes, as well as trends in laboratory-confirmed COVID-19 incidence and testing volume among U.S. children, adolescents, and young adults (persons aged 0–24 years). This analysis provides a critical update and expansion of previously published data, to include trends after fall school reopenings, and adds preschool-aged children (0–4 years) and college-aged young adults (18–24 years) (*1*). Among children, adolescents, and young adults, weekly incidence (cases per 100,000 persons) increased with age and was highest during the final week of the review period (the week of December 6) among all age groups. Time trends in weekly reported incidence for children and adolescents aged 0–17 years tracked consistently with trends observed among adults since June, with both incidence and positive test results tending to increase since September after summer declines. Reported incidence and positive test results among children aged 0–10 years were consistently lower than those in older age groups. To reduce community transmission, which will support schools in operating more safely for in-person learning, communities and schools should fully implement and strictly adhere to recommended mitigation strategies, especially universal and proper masking, to reduce COVID-19 incidence.

Children, adolescents, and young adults were stratified into five age groups: 0–4, 5–10, 11–13, 14–17, and 18–24 years to align with educational groupings (i.e., pre-, elementary, middle, and high schools, and institutions of higher education), and trends in these groups were compared with those in adults aged ≥25 years. Confirmed COVID-19 cases, defined as positive real-time reverse transcription–polymerase chain reaction (RT-PCR) test results for SARS-CoV-2, the virus that causes COVID-19, were identified from individual-level case reports submitted by state and territorial health departments during March 1–December 12, 2020.* COVID-19 case data for all confirmed cases were analyzed to examine demographic characteristics, underlying health conditions,† and outcomes. Trends in COVID-19 incidence were analyzed using a daily 7-day moving average, aggregated by week,§ and expressed as cases per 100,000 persons.¶

Trends in laboratory testing volume and percentage of positive test results were assessed using COVID-19 electronic laboratory reporting data. SARS-CoV-2 RT-PCR test results for May 31–December 12, 2020 were obtained from electronic laboratory reporting data submitted to CDC by health departments from 44 states, the District of Columbia, two territories, and one freely associated state; when information was unavailable in state-submitted data, records submitted directly by public health, commercial, and reference laboratories were used.** Data represent test results, not number of persons receiving tests; test result date was used for analyses. The weekly percentage of positive SARS-CoV-2 RT-PCR test results was calculated as the number of positive test results divided by the sum of positive and negative test results. Because some data elements are incomplete for more than 47% of cases, percentages were calculated only from among those with available information. This project was deemed nonresearch public health practice by the CDC and conducted consistent with applicable federal law and CDC policy.†† Analyses were conducted using R software (version 4.0.2; The R Foundation).

* CDC official counts of COVID-19 cases and deaths, released daily at https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html, are aggregate counts from reporting jurisdictions. Individual-level case report data were available for approximately 75% of the aggregate number of confirmed cases. Cases reported without sex or age data and in persons repatriated to the United States from Wuhan, China, or the Diamond Princess cruise ship were excluded from this analysis.

† Underlying health conditions were defined based on the categories included in the COVID-19 Case Report Form. https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf.

§ Weekly incidence date based on the earliest symptom onset date reported for each COVID-19 case. If symptom onset date was missing, earliest onset date was populated with the earliest date in a series of variables submitted by the jurisdiction, including symptom resolution date, positive specimen date, diagnosis date, specimen collection date (for sputum, nasopharyngeal, oropharyngeal, or other specimen type), hospital or ICU admission or discharge date, date of death, or the date of case reporting to CDC.

¶ Population estimates used in calculating incidence were obtained from the Kids Count Data Center. https://datacenter.kidscount.org/data.

** COVID-19 Electronic Laboratory Reporting data submitted by state health departments from all laboratories performing SARS-CoV-2 RT-PCR testing were used for 44 states, the District of Columbia, Guam, Marshall Islands, and Northern Mariana Islands. SARS-CoV-2 RT-PCR testing data from a subset of public health, commercial, and reference laboratories were used for six states for which data were not directly submitted by state health departments (Maine, Missouri, Ohio, Oklahoma, Washington, and Wyoming), Puerto Rico, and the U.S. Virgin Islands. The data might not include results from all testing sites within a jurisdiction and therefore might reflect the majority of, but not all, SARS-CoV-2 RT-PCR tests in the United States. The data represent laboratory test totals, not individual persons tested, and exclude antibody and antigen tests.

†† 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

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During March 1–December 12, 2020, a total of 2,871,828 laboratory-confirmed cases of COVID-19 in children, adolescents, and young adults aged 0–24 years were reported in the United States. Among these cases, the majority (57.4%) occurred among young adults aged 18–24 years; children and adolescents aged 14–17 years accounted for 16.3% of cases, those 11–13 years for 7.9%, those 5–10 years for 10.9%, and those 0–4 years for 7.4% (Table). Overall, 51.8% of cases occurred in females. Among the 1,504,165 (52.4%) children, adolescents, and young adults with COVID-19 with complete information on race/ethnicity, 50.2% were non-Hispanic White, 27.4% were Hispanic/Latino (Hispanic), and 11.7% were non-Hispanic Black. The proportion of cases among Hispanic persons decreased with increasing age from 34.4% among those aged 0–4 years to 24.6% among those aged 18–24 years.[§§]

Among persons aged 0–24 years, weekly incidence was higher in each successively increasing age group; weekly incidence among adults aged 25–64 years and ≥65 years exceeded that among children and adolescents aged 0–13 years throughout the review period (Figure 1). Weekly incidence was highest during the final week of the review period (the week of December 6) in all age groups: 99.9 per 100,000 (0–4 years), 131.4 (5–10 years), 180.6 (11–13 years), 255.6 (14–17 years), and 379.3 (18–24 years). Trends in weekly incidence for all age groups aged 0–17 years paralleled those observed among adults since June. The trend in incidence among young adults aged 18–24 years had a distinct and more prominent peak during the week of September 6.

Weekly SARS-CoV-2 laboratory testing among children, adolescents, and young adults increased 423.3% from 435,434 tests during the week beginning May 31 to 2,278,688 tests during the week beginning December 6 (Figure 2).[¶¶] At their peak during the week of November 15, tests conducted among children and adolescents aged 0–17 years represented 9.5% of all tests performed, and tests among young adults aged 18–24 years represented 15.3% (Supplementary Figure 1, URL https://stacks.cdc.gov/view/cdc/100246). As observed in trends in incidence, weekly percentage of positive test results among children and adolescents paralleled those of adults, declining between July and September, and then increasing through December (Supplementary Figure 2, URL https://stacks.cdc.gov/view/cdc/100246). Percentage of positive test results among young adults aged 18–24 years peaked earlier in June and increased slightly in late August; this was not observed among other age groups. In contrast to incidence, percentage of positive test results among children and adolescents aged 11–17 years exceeded that among younger children for all weeks and that of all age groups since the week beginning September 6; test volumes over time were lowest among children and adolescents aged 11–13 years, suggesting incidence among these age groups might be underestimated.

Among cases reviewed, data were available for 41.9%, 8.9%, and 49.1% of cases for hospitalizations, intensive care unit (ICU) admissions, and deaths, respectively. Among children, adolescents, and young adults with available data for these outcomes, 30,229 (2.5%) were hospitalized, 1,973 (0.8%) required ICU admission, and 654 (<0.1%) died (Table), compared with 16.6%, 8.6%, and 5.0% among adults aged ≥25 years, respectively. Among children, adolescents, and young adults, the largest percentage of hospitalizations (4.6%) and ICU admissions (1.8%) occurred among children aged 0–4 years. Among 379,247 (13.2%) children, adolescents, and young adults with COVID-19 and available data on underlying conditions, at least one underlying condition or underlying health condition was reported for 114,934 (30.3%), compared with 836,774 (60.4%) among adults aged ≥25 years.

Discussion

Reported weekly incidence of COVID-19 and percentage of positive test results among children, adolescents, and young adults increased during the review period, with spikes in early summer, followed by a decline and then steeply increased in October through December. In general, trends in incidence and percentage of positive test results among preschool-aged children (0–4 years) and school-aged children and adolescents (5–17 years) paralleled those among adults throughout the summer and fall, including during the months that some schools were reopening or open for in-person education. In addition, reported incidence among children, adolescents, and young adults increased with age; among children aged 0–10 years, incidence and percentage of positive test results were consistently lower than they were among older age groups. Case data do not indicate that increases in incidence or percentage of positive test results among adults were preceded by increases among preschool- and school-aged children and adolescents. In contrast, incidence among young adults (aged 18–24 years) was higher than that in other age groups throughout the summer and fall, with peaks in mid-July and early September that preceded increases among other age groups, suggesting that young adults might contribute more to community transmission than do younger children.

Findings from national case and laboratory surveillance data complement available evidence regarding risk for transmission in school settings. As of December 7, nearly two thirds

[§§] In 2019, children and adolescents of Hispanic/Latino ethnicity accounted for 26% of children aged 0–17 years; children and adolescents of non-Hispanic Black race accounted for 14% of children aged 0–17 years; and children and adolescents of non-Hispanic White race accounted for 50% of children and adolescents aged 0–17 years in the United States. https://datacenter.kidscount.org/data/customreports/1/103/compared,single#ind103.

[¶¶] The percentage increase in test volume between the weeks beginning May 31 and December 6 by age group were 328.0% (0–4 years), 644.1% (5–10 years), 669.2% (11–13 years), 536.3% (14–17 years), and 368.1% (18–24 years).

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TABLE. Demographic characteristics and underlying conditions among persons aged 0–24 years with positive test results for SARS-CoV-2 — United States, March 1–December 12, 2020

Characteristic	Age group, yrs, no. (%)						
	0–24	0–17	0–4	5–10	11–13	14–17	18–24
Total	**2,871,828 (100)**	**1,222,023 (42.6)**	**212,879 (7.4)**	**313,913 (10.9)**	**227,238 (7.9)**	**467,993 (16.3)**	**1,649,805 (57.4)**
Sex							
Female	1,469,744 (51.8)	603,948 (50.0)	100,935 (48.2)	152,494 (49.1)	111,683 (49.7)	238,836 (51.6)	865,796 (53.1)
Male	1,367,271 (48.2)	603,029 (50.0)	108,457 (51.8)	157,769 (50.8)	112,930 (50.3)	223,873 (48.4)	764,242 (46.9)
Other	53 (<0.1)	18 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	11 (<0.1)	35 (<0.1)
Missing/Unknown	34,760 (N/A)	15,028 (N/A)	3,485 (N/A)	3,647 (N/A)	2,623 (N/A)	5,273 (N/A)	19,732 (N/A)
Median age (years)	**19**	**9**	**2**	**8**	**12**	**16**	**21**
Symptom Status							
Yes	1,247,552 (94.1)	524,390 (91.9)	87,646 (90.4)	126,010 (88.9)	97,831 (91.8)	212,903 (94.5)	723,162 (95.8)
No	77,899 (5.9)	46,166 (8.1)	9,281 (9.6)	15,720 (11.1)	8,736 (8.2)	12,429 (5.5)	31,733 (4.2)
Missing/Unknown*	1,546,377 (N/A)	651,467 (N/A)	115,952 (N/A)	172,183 (N/A)	120,671 (N/A)	242,661 (N/A)	894,910 (N/A)
Race/Ethnicity†							
Hispanic/Latino	411,775 (27.4)	200,397 (31.0)	38,553 (34.4)	54,457 (33.0)	38,094 (32.0)	69,293 (27.8)	211,378 (24.6)
White, non-Hispanic	754,801 (50.2)	292,930 (45.4)	42,384 (37.8)	68,887 (41.8)	53,772 (45.1)	127,887 (51.3)	461,871 (53.8)
Black, non-Hispanic	176,059 (11.7)	79,291 (12.3)	16,355 (14.6)	21,308 (12.9)	14,228 (11.9)	27,400 (11.0)	96,768 (11.3)
Asian/Pacific Islander, non-Hispanic	50,224 (3.3)	21,243 (3.3)	4,716 (4.2)	6,109 (3.7)	3,556 (3.0)	6,862 (2.8)	28,981 (3.4)
American Indian/Alaska Native, non-Hispanic	23,396 (1.6)	12,887 (2.0)	2,249 (2.0)	3,653 (2.2)	2,610 (2.2)	4,375 (1.8)	10,509 (1.2)
Multiracial/Other race	87,910 (5.8)	38,923 (6.0)	7,860 (7.0)	10,490 (6.4)	6,911 (5.8)	13,662 (5.5)	48,987 (5.7)
Missing/Unknown*	1,367,663 (N/A)	576,352 (N/A)	100,762 (N/A)	149,009 (N/A)	108,067 (N/A)	218,514 (N/A)	791,311 (N/A)
Underlying condition§							
Any	114,934 (30.3)	43,388 (27.6)	6,334 (23.7)	10,203 (26.4)	8,206 (28.8)	18,645 (29.5)	71,546 (32.2)
None	264,313 (69.7)	113,621 (72.4)	20,426 (76.3)	28,386 (73.6)	20,280 (71.2)	44,529 (70.5)	150,692 (67.8)
Missing/Unknown*	2,492,581 (N/A)	1,065,014 (N/A)	186,119 (N/A)	275,324 (N/A)	198,752 (N/A)	404,819 (N/A)	1,427,567 (N/A)
Known condition¶	421,078 (14.7)	176,766 (14.5)	30,665 (14.4)	43,765 (13.9)	32,122 (14.1)	70,214 (15.0)	244,312 (14.8)
Chronic lung disease	26,937 (6.4)	10,521 (6.0)	786 (2.6)	2,495 (5.7)	2,316 (7.2)	4,924 (7.0)	16,416 (6.7)
Disability**	4,162 (1.0)	1,992 (1.1)	243 (0.8)	497 (1.1)	411 (1.3)	841 (1.2)	2,170 (0.9)
Immunosuppression	3,495 (0.8)	1,373 (0.8)	196 (0.6)	323 (0.7)	237 (0.7)	617 (0.9)	2,122 (0.9)
Diabetes mellitus	4,030 (1.0)	1,104 (0.6)	63 (0.2)	133 (0.3)	237 (0.7)	671 (1.0)	2,926 (1.2)
Psychological	3,055 (0.7)	1,176 (0.7)	23 (0.1)	153 (0.3)	231 (0.7)	769 (1.1)	1,879 (0.8)
Cardiovascular disease	3,103 (0.7)	1,133 (0.6)	266 (0.9)	239 (0.5)	163 (0.5)	465 (0.7)	1,970 (0.8)
Current/Former smoker	15,362 (3.6)	798 (0.5)	37 (0.1)	42 (0.1)	39 (0.1)	680 (1.0)	14,564 (6.0)
Severe obesity††	1,865 (0.4)	566 (0.3)	32 (0.1)	109 (0.2)	121 (0.4)	304 (0.4)	1,299 (0.5)
Chronic kidney disease	796 (0.2)	336 (0.2)	80 (0.3)	77 (0.2)	44 (0.1)	135 (0.2)	460 (0.2)
Hypertension	1,788 (0.4)	272 (0.2)	43 (0.1)	20 (0)	29 (0.1)	180 (0.3)	1,516 (0.6)
Autoimmune disease	919 (0.2)	305 (0.2)	17 (0.1)	45 (0.1)	56 (0.2)	187 (0.3)	614 (0.3)
Chronic liver disease	407 (0.1)	137 (0.1)	22 (0.1)	24 (0.1)	22 (0.1)	69 (0.1)	270 (0.1)
Substance abuse/use	355 (0.1)	72 (<0.1)	1 (<0.1)	1 (<0.1)	6 (<0.1)	64 (0.1)	283 (0.1)
Other	10,100 (2.4)	3,511 (2.0)	665 (2.2)	725 (1.7)	581 (1.8)	1,540 (2.2)	6,589 (2.7)

See table footnotes on the next page.

(62.0%) of U.S. kindergarten through grade 12 (K–12) school districts offered either full or partial (hybrid with virtual) in-person learning.*** Despite this level of in-person learning, reports to CDC of outbreaks within K–12 schools have been limited,††† and as of the week beginning December 6, aggregate COVID-19 incidence among the general population in counties where K–12 schools offer in-person education (401.2 per 100,000) was similar to that in counties offering only virtual/online education (418.2 per 100,000).§§§ Several U.S. school districts with routine surveillance of in-school cases report lower incidence among students than in the

*** https://www.mchdata.com/covid19/schoolclosings.

††† In addition to routine case surveillance reports, CDC receives regular updates from state, local, and tribal health departments, as well as various school districts. School-based outbreaks have been periodically reported to CDC at the time jurisdictions request technical assistance. In the context of childcare and K–12 schools, requests for assistance have more frequently been in response to a single case or small clusters of cases. Reports of large outbreaks in these settings have been rare.

§§§ Data presented are for the week beginning December 6, 2020. Aggregate case incidence is the rate derived after summing the case and population values for counties that currently have that K–12 teaching plans. Among the 2,717 counties having school districts with currently known teaching plans, 1,696 had school districts with differing methods. For these counties, case incidence and positive test result data are proportionately allocated into a specific plan based on the ratio of total enrollment for school districts that currently have that plan type to the total enrollment for all school districts in that county. Population estimates were obtained from the Vintage 2019 Bridged-Race Postcensal Population Estimates for Calculating Vital Rates (https://www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm). County-level case counts were obtained from CDC County Aggregate figures (extracted December 28, 2020). School enrollment data and school reopening plans were obtained from MCH Strategic Data (https://www.mchdata.com/covid19/schoolclosings, extracted December 28, 2020). Data were extracted and analyzed by the Johns Hopkins University Applied Physics Laboratory.

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TABLE. (*Continued*) Demographic characteristics and underlying conditions among persons aged 0–24 years with positive test results for SARS-CoV-2 — United States, March 1–December 12, 2020

Characteristic	Age group, yrs, no. (%)						
	0–24	0–17	0–4	5–10	11–13	14–17	18–24
Outcome							
Hospitalized							
Yes	30,229 (2.5)	11,882 (2.3)	4,294 (4.6)	1,983 (1.5)	1,598 (1.6)	4,007 (2.0)	18,347 (2.7)
No	1,172,310 (97.5)	514,834 (97.7)	88,786 (95.4)	132,108 (98.5)	96,021 (98.4)	197,919 (98.0)	657,476 (97.3)
Missing/Unknown*	1,669,289 (N/A)	695,307 (N/A)	119,799 (N/A)	179,822 (N/A)	129,619 (N/A)	266,067 (N/A)	973,982 (N/A)
ICU admission							
Yes	1,973 (0.8)	866 (0.8)	288 (1.8)	168 (0.6)	131 (0.6)	279 (0.6)	1,107 (0.8)
No	252,961 (99.2)	109,234 (99.2)	16,091 (98.2)	25,968 (99.4)	20,574 (99.4)	46,601 (99.4)	143,727 (99.2)
Missing/Unknown*	2,616,894 (N/A)	1,111,923 (N/A)	196,500 (N/A)	287,777 (N/A)	206,533 (N/A)	421,113 (N/A)	1,504,971 (N/A)
Died							
Yes	654 (<0.1)	178 (<0.1)	52 (<0.1)	30 (<0.1)	27 (<0.1)	69 (<0.1)	476 (0.1)
No	1,409,626 (100)	620,989 (100)	111,437 (100)	162,971 (100)	115,664 (100)	230,917 (100)	788,637 (99.9)
Missing/Unknown*	1,461,548 (N/A)	600,856 (N/A)	101,390 (N/A)	150,912 (N/A)	111,547 (N/A)	237,007 (N/A)	860,692 (N/A)

Abbreviations: ICU = intensive care unit; N/A = not available.

* Data are missing for more than 47% of cases. Percentages are calculated from among those with available information only.

† Cases reported as Hispanic or Latino were categorized as "Hispanic/Latino" regardless of availability of race data.

§ Underlying conditions were defined based on the categories included in the COVID-19 Case Report Form including diabetes mellitus, hypertension, severe obesity, cardiovascular disease, chronic renal disease, chronic liver disease, chronic lung disease (asthma, emphysema, and chronic obstructive pulmonary disease [COPD]), other (specified) chronic diseases, other (specified) underlying condition or risk behavior, immunosuppressive conditions, autoimmune conditions, being a current or former smoker, substance abuse or misuse, disability, and psychological/psychiatric condition. Although obesity in children is defined using body mass index percentile, these data are drawn from the COVID-19 Case Report Form, in which severe obesity is defined as noted.

¶ Status of underlying health conditions were known for 421,078 persons aged 0–24 years. Condition status was classified as "known" if any of the conditions included in the COVID-19 Case Report Form were reported as present or absent. Proportion of cases with each individual condition were calculated among persons with known condition status.

** Disability included neurologic or neurodevelopmental disorders, intellectual or physical disability, and vision or hearing impairment.

†† Body mass index ≥40 kg/m2. Although obesity in children is defined using body mass index percentile, these data are drawn from the COVID-19 Case Report Form, in which severe obesity is defined as noted.

surrounding communities¶¶¶ (*2*), and a recent study found no increase in COVID-19 hospitalization rates associated with in-person education (*3*). In contrast to the evidence regarding K–12 school reopenings, previous studies provide evidence for increased community incidence in counties where institutions of higher education reopened for in-person instruction (*4*), and presented case surveillance data showed unique trends.

Success in preventing introduction and transmission of SARS-CoV-2 in schools depends upon both adherence to mitigation strategies in schools and controlling transmission in communities (*5*). In settings with low community incidence, where testing and effective mitigation strategies were in place, studies of in-school transmission have provided preliminary evidence of success in controlling secondary transmission in child care centers and schools (*6–8*). Schools provide a structured environment that can support adherence to critical mitigation measures to help prevent and slow the spread of COVID-19. When community transmission is high, cases in schools should be expected, and as with any group setting, schools can contribute to COVID-19 transmission (*5–7*), especially when mitigation measures, such as universal and proper masking, are not implemented or followed.

The findings in this report are subject to at least four limitations. First, COVID-19 incidence is likely underestimated among children and adolescents because testing volume among these age groups was lower than that for adults, the rate of

Summary

What is already known about this topic?

Studies have consistently shown that children, adolescents, and young adults are susceptible to SARS-CoV-2 infections. Children and adolescents have had lower incidence and fewer severe COVID-19 outcomes than adults.

What is added by this report?

COVID-19 cases in children, adolescents, and young adults have increased since summer 2020, with weekly incidence higher in each successively increasing age group. Trends among children and adolescents aged 0–17 years paralleled those among adults.

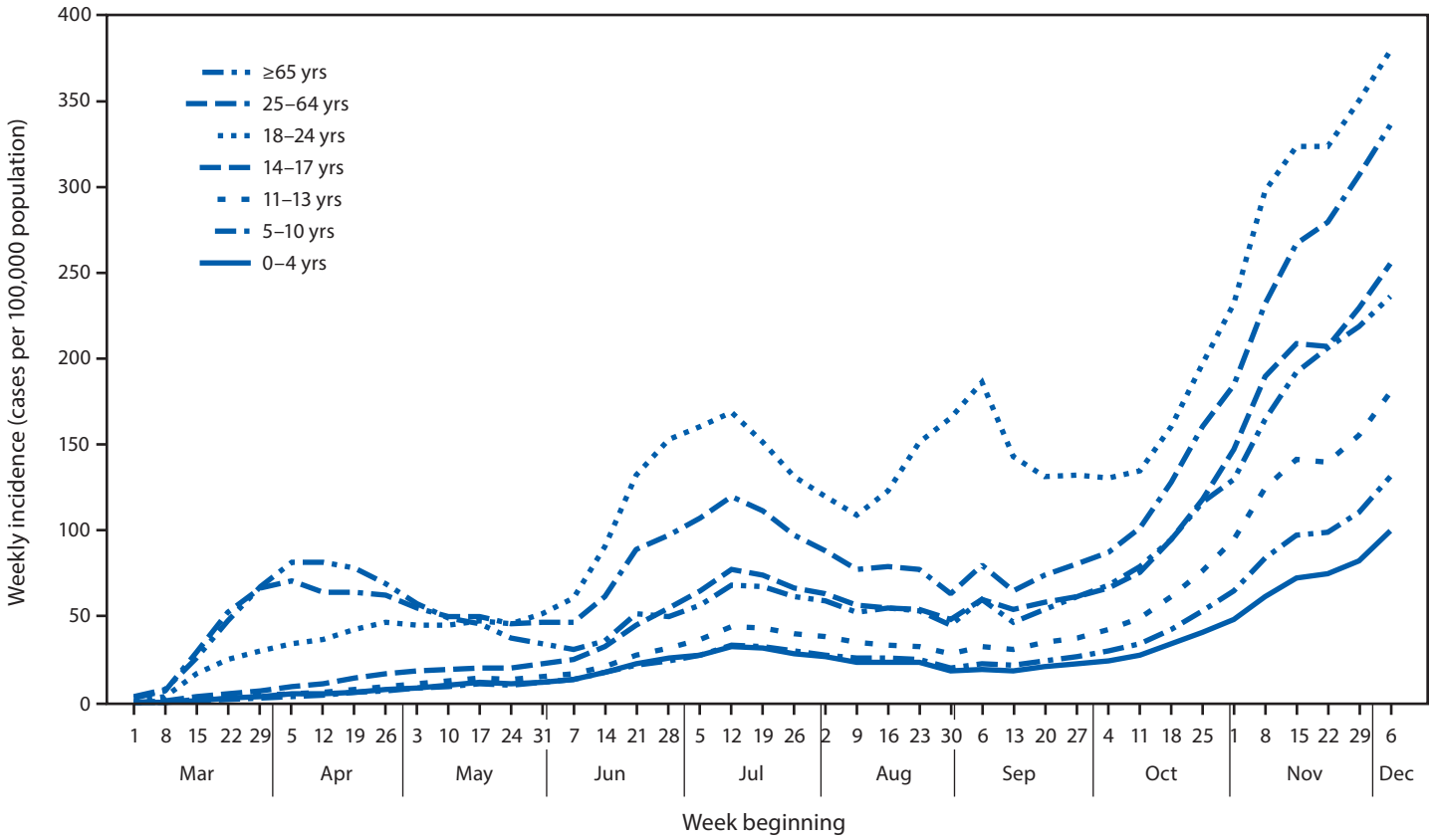
What are the implications for public health practice?

To enable safer in-person learning, schools and communities should fully implement and strictly adhere to multiple mitigation strategies, especially universal and proper mask wearing, to reduce both school and community COVID-19 incidence to help protect students, teachers, and staff members from COVID-19.

¶¶¶ Cases and enrollment reported by the New York Department of Health (https://schoolcovidreportcard.health.ny.gov/#/summary) since October 12, 2020, are analyzed on the National COVID-19 School Response Dashboard (https://covidschooldashboard.com) which presents case and infection rates.

MS-DOH-21-1816-A-002110

FIGURE 1. COVID-19 weekly incidence,*,† by age group — United States, March 1–December 12, 2020§



Abbreviation: COVID-19 = coronavirus disease 2019.
* The 7-day moving average of new cases (current day + 6 preceding days/7) was calculated to smooth expected variation in daily case counts.
† Incidence was calculated per 100,000 population using 2019 U.S. Census population estimates obtained from Kids Count Data Center (https://datacenter.kidscount.org/data).
§ Data included through December 12, 2020, so that each week has a full 7 days of data.

positive test results was generally higher among children and adolescents (particularly those aged 11–17 years) than that among adults, and testing frequently prioritized persons with symptoms; asymptomatic infection in children and adolescents occurs frequently (*9*). Second, data on race/ethnicity, symptom status, underlying conditions, and outcomes are incomplete, and completeness varied by jurisdiction; therefore, results for these variables might be subject to reporting biases and should be interpreted with caution. Future reporting would be enhanced by prioritizing completeness of these indicators for all case surveillance efforts. Third, the reporting of laboratory data differs by jurisdiction and might underrepresent the actual volume of laboratory tests performed; as well, reporting of laboratory and case data are not uniform.**** Finally, the presented analysis explores case surveillance data for children, adolescents, and young adults; trends in cases among teachers and school staff members are not available because cases are not routinely reported nationally by occupations other than health care workers.

Lower incidence among younger children and evidence from available studies (*2*–*8*) suggest that the risk for COVID-19 introduction and transmission among children associated with reopening child care centers and elementary schools might be lower than that for reopening high schools and institutions of higher education. However, for schools to operate safely to accommodate in-person learning, communities should fully implement and strictly adhere to multiple mitigation strategies, especially universal and proper masking, to reduce COVID-19 incidence within the community as well as within schools to protect students, teachers, and staff members. CDC recommends that K–12 schools be the last settings to close after all other mitigation measures have been employed and the first to reopen when they can do so safely (*10*). CDC offers tools†††† to help child care programs, schools, colleges and universities, parents, and caregivers plan, prepare, and respond to

**** Percentage positive for laboratory data for some states relied on data reported directly to CDC from public health laboratories and a sample of six large commercial laboratories.

†††† https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/index.html.

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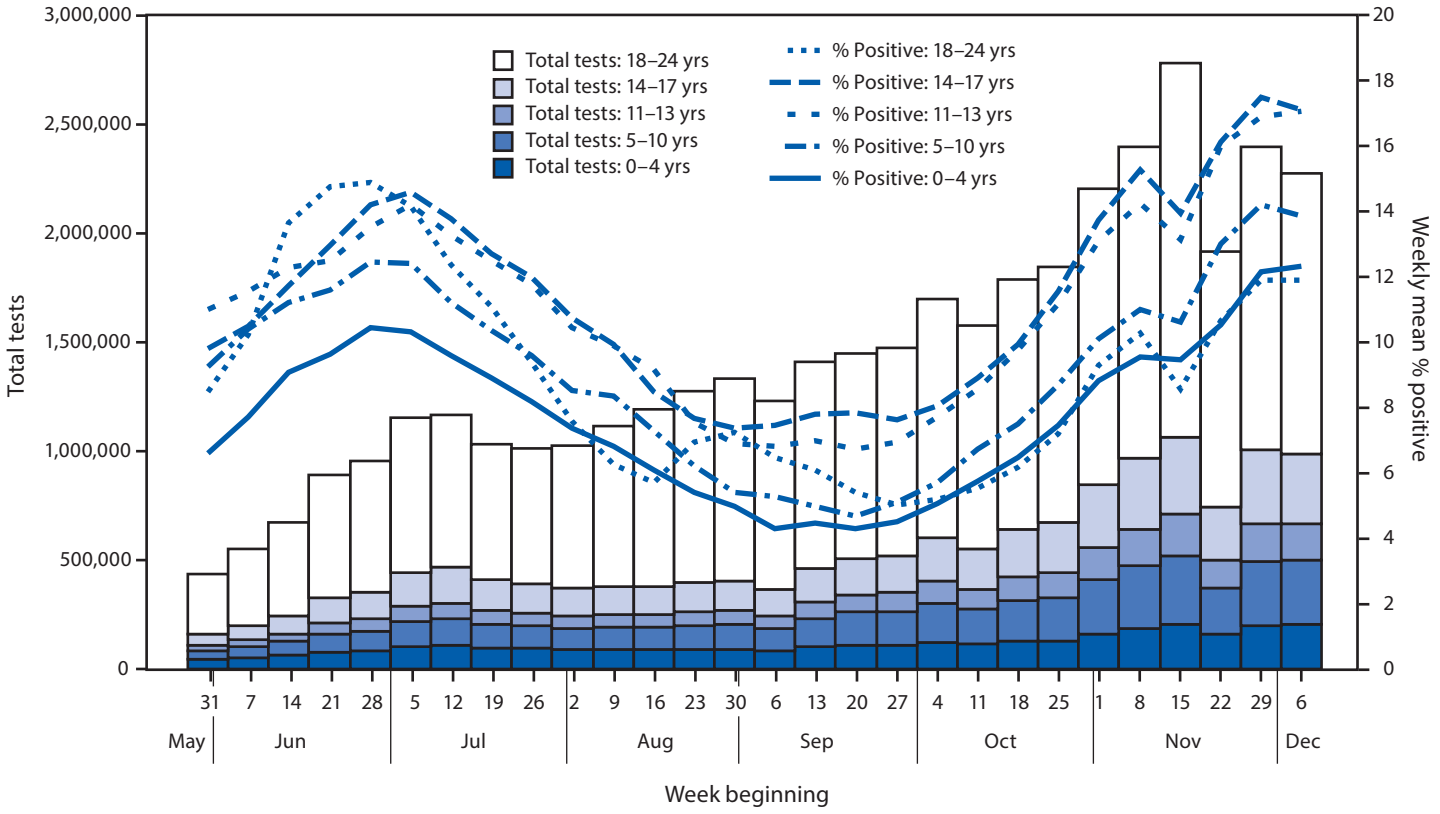
FIGURE 2. Weekly test volume and percentage of SARS-CoV-2-positive test results* among persons aged 0–24 years, by age group — United States, May 31–December 12, 2020†



* By reverse transcription–polymerase chain reaction testing.
† Data included through December 12, 2020, so that each week has a full 7 days of data.

COVID-19, thereby helping to protect students, teachers, and staff members and slowing community spread of COVID-19.

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Emergence of SARS-CoV-2 B.1.1.7 Lineage — United States, December 29, 2020–January 12, 2021

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On December 14, 2020, the United Kingdom reported a SARS-CoV-2 variant of concern (VOC), lineage B.1.1.7, also referred to as VOC 202012/01 or 20I/501Y.V1.* The B.1.1.7 variant is estimated to have emerged in September 2020 and has quickly become the dominant circulating SARS-CoV-2 variant in England (*1*). B.1.1.7 has been detected in over 30 countries, including the United States. As of January 13, 2021, approximately 76 cases of B.1.1.7 have been detected in 12 U.S. states.† Multiple lines of evidence indicate that B.1.1.7 is more efficiently transmitted than are other SARS-CoV-2 variants (*1*–*3*). The modeled trajectory of this variant in the U.S. exhibits rapid growth in early 2021, becoming the predominant variant in March. Increased SARS-CoV-2 transmission might threaten strained health care resources, require extended and more rigorous implementation of public health strategies (*4*), and increase the percentage of population immunity required for pandemic control. Taking measures to reduce transmission now can lessen the potential impact of B.1.1.7 and allow critical time to increase vaccination coverage. Collectively, enhanced genomic surveillance combined with continued compliance with effective public health measures, including vaccination, physical distancing, use of masks, hand hygiene, and isolation and quarantine, will be essential to limiting the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19). Strategic testing of persons without symptoms but at higher risk of infection, such as those exposed to SARS-CoV-2 or who have frequent unavoidable contact with the public, provides another opportunity to limit ongoing spread.

Global genomic surveillance and rapid open-source sharing of viral genome sequences have facilitated near real-time detection, comparison, and tracking of evolving SARS-CoV-2 variants that can inform public health efforts to control the pandemic. Whereas some mutations in the viral genome emerge and then recede, others might confer a selective advantage to the variant, including enhanced transmissibility, so that such a variant can rapidly dominate other circulating variants. Early in the pandemic, variants of SARS-CoV-2 containing the D614G mutation in the spike (S) protein that increases receptor binding avidity rapidly became dominant in many geographic regions (*5*,*6*).

In late fall 2020, multiple countries reported detecting SARS-CoV-2 variants that spread more efficiently. In addition to the B.1.1.7 variant, notable variants include the B.1.351 lineage first detected in South Africa and the recently identified B.1.1.28 subclade (renamed "P.1") detected in four travelers from Brazil during routine screening at the Haneda (Tokyo) airport.§ These variants carry a constellation of genetic mutations, including in the S protein receptor-binding domain, which is essential for binding to the host cell angiotensin-converting enzyme-2 (ACE-2) receptor to facilitate virus entry. Evidence suggests that other mutations found in these variants might confer not only increased transmissibility but might also affect the performance of some diagnostic real-time reverse transcription–polymerase chain reaction (RT-PCR) assays¶ and reduce susceptibility to neutralizing antibodies (*2*,*3*,*5*–*10*). A recent case report documented the first case of SARS-CoV-2 reinfection in Brazil with a SARS-CoV-2 variant that contained the E484K mutation,** which has been shown to reduce neutralization by convalescent sera and monoclonal antibodies (*9*,*10*).

This report focuses on the emergence of the B.1.1.7 variant in the United States. As of January 12, 2021, neither the B.1.351 nor the P.1 variants have been detected in the United States. For information about emerging SARS-CoV-2 variants of concern, CDC maintains a webpage dedicated to providing information on emerging SARS-CoV-2 variants.††

B.1.1.7 lineage (20I/501Y.V1)

The B.1.1.7 variant carries a mutation in the S protein (N501Y) that affects the conformation of receptor-binding domain. This variant has 13 other B.1.1.7 lineage-defining

* https://www.gov.uk/government/news/phe-investigating-a-novel-variant-of-covid-19.

† https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html.

§ https://www.japantimes.co.jp/news/2021/01/11/national/science-health/new-coronavirus-variant-japan/.

¶ https://www.fda.gov/news-events/press-announcements/fda-issues-alert-regarding-sars-cov-2-viral-mutation-health-care-providers-and-clinical-laboratory?utm_medium.

** https://virological.org/t/spike-e484k-mutation-in-the-first-sars-cov-2-reinfection-case-confirmed-in-brazil-2020/584.

†† https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html.

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Summary

What is already known about this topic?

A more highly transmissible variant of SARS-CoV-2, B.1.1.7, has been detected in 12 U.S. states.

What is added by this report?

Modeling data indicate that B.1.1.7 has the potential to increase the U.S. pandemic trajectory in the coming months. CDC's system for genomic surveillance and the effort to expand sequencing will increase the availability of timely U.S. genomic surveillance data.

What are the implications for public health practice?

The increased transmissibility of the B.1.1.7 variant warrants universal and increased compliance with mitigation strategies, including distancing and masking. Higher vaccination coverage might need to be achieved to protect the public. Genomic sequence analysis through the National SARS-CoV-2 Strain Surveillance program will enable a targeted approach to identifying variants of concern in the United States.

mutations (Table), several of which are in the S protein, including a deletion at positions 69 and 70 (del69–70) that evolved spontaneously in other SARS-CoV-2 variants and is hypothesized to increase transmissibility (*2*,*7*). The deletion at positions 69 and 70 causes S-gene target failure (SGTF) in at least one RT-PCR–based diagnostic assay (i.e., with the ThermoFisher TaqPath COVID-19 assay, the B.1.1.7 variant and other variants with the del69–70 produce a negative result for S-gene target and a positive result for the other two targets); SGTF has served as a proxy in the United Kingdom for identifying B.1.1.7 cases (*1*).

Multiple lines of evidence indicate that B.1.1.7 is more efficiently transmitted compared with other SARS-CoV-2 variants circulating in the United Kingdom. U.K. regions with a higher proportion of B.1.1.7 sequences had faster epidemic growth than did other areas, diagnoses with SGTF increased faster than did non-SGTF diagnoses in the same areas, and a higher proportion of contacts were infected by index patients with B.1.1.7 infections than by index patients infected with other variants (*1*,*3*).

Variant B.1.1.7 has the potential to increase the U.S. pandemic trajectory in the coming months. To illustrate this effect, a simple, two-variant compartmental model was developed. The current U.S. prevalence of B.1.1.7 among all circulating viruses is unknown but is thought to be <0.5% based on the limited number of cases detected and SGTF data (*8*). For the model, initial assumptions included a B.1.1.7 prevalence of 0.5% among all infections, SARS-CoV-2 immunity from previous infection of 10%–30%, a time-varying reproductive number (R_t) of 1.1 (mitigated but increasing transmission) or 0.9 (decreasing transmission) for current variants, and a reported incidence of 60 cases per 100,000 persons per day on January 1, 2021. These assumptions do not precisely represent any single U.S. location, but rather, indicate a generalization of conditions common across the country. The change in R_t over time resulting from acquired immunity and increasing prevalence of B.1.1.7, was modeled, with the B.1.1.7 R_t assumed to be a constant 1.5 times the R_t of current variants, based on initial estimates from the United Kingdom (*1*,*3*).

Next, the potential impact of vaccination was modeled assuming that 1 million vaccine doses were administered per day beginning January 1, 2021, and that 95% immunity was achieved 14 days after receipt of 2 doses. Specifically, immunity against infection with either current variants or the B.1.1.7 variant was assumed, although the effectiveness and duration of protection against infection remains uncertain, because these were not the primary endpoint of clinical trials for initial vaccines.

In this model, B.1.1.7 prevalence is initially low, yet because it is more transmissible than are current variants, it exhibits rapid growth in early 2021, becoming the predominant variant in March (Figure 1). Whether transmission of current variants is increasing (initial R_t = 1.1) or slowly decreasing (initial R_t = 0.9) in January, B.1.1.7 drives a substantial change in the transmission trajectory and a new phase of exponential growth. With vaccination that protects against infection, the early epidemic trajectories do not change and B.1.1.7 spread still occurs (Figure 2). However, after B.1.1.7 becomes the dominant variant, its transmission was substantially reduced. The effect of vaccination on reducing transmission in the near term was greatest in the scenario in which transmission was already decreasing (initial R_t = 0.9) (Figure 2). Early efforts that can limit the spread of the B.1.1.7 variant, such as universal and increased compliance with public health mitigation strategies, will allow more time for ongoing vaccination to achieve higher population-level immunity.

Discussion

Currently, there is no known difference in clinical outcomes associated with the described SARS-CoV-2 variants; however, a higher rate of transmission will lead to more cases, increasing the number of persons overall who need clinical care, exacerbating the burden on an already strained health care system, and resulting in more deaths. Continued genomic surveillance to identify B.1.1.7 cases, as well as the emergence of other variants of concern in the United States, is important for the COVID-19 public health response. Whereas the SGTF results can help identify potential B.1.1.7 cases that can be confirmed by sequencing, identifying priority variants that do not exhibit SGTF relies exclusively on sequence-based surveillance.

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TABLE. Characteristics of SARS-CoV-2 variants of concern — worldwide, September 2020–January 2021

Variant designation	First identification		Characteristic mutations (protein: mutation)	No. of current sequence-confirmed cases		No. of countries with sequences
	Location	Date		United States	Worldwide	
B.1.1.7 (20I/501Y.V1)	United Kingdom	Sep 2020	ORF1ab: T1001I, A1708D, I2230T, del3675–3677 SGF S: del69–70 HV, del144 Y, N501Y, A570D, D614G, P681H, T761I, S982A, D1118H ORF8: Q27stop, R52I, Y73C N: D3L, S235F	76	15,369	36
B.1.351 (20H/501Y.V2)	South Africa	Oct 2020	ORF1ab: K1655N E: P71L N: T205I S:K417N, E484K, N501Y, D614G, A701V	0	415	13
P.1 (20J/501Y.V3)	Brazil and Japan	Jan 2021	ORF1ab: F681L, I760T, S1188L, K1795Q, del3675–3677 SGF, E5662D S: L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I ORF3a: C174G ORF8: E92K ORF9: Q77E ORF14: V49L N: P80R	0	35	2

Abbreviations: del = deletion; E = envelope protein; N = nucleocapsid protein; ORF = open reading frame; S = spike protein.

The experience in the United Kingdom and the B.1.1.7 models presented in this report illustrate the impact a more contagious variant can have on the number of cases in a population. The increased transmissibility of this variant requires an even more rigorous combined implementation of vaccination and mitigation measures (e.g., distancing, masking, and hand hygiene) to control the spread of SARS-CoV-2. These measures will be more effective if they are instituted sooner rather than later to slow the initial spread of the B.1.1.7 variant. Efforts to prepare the health care system for further surges in cases are warranted. Increased transmissibility also means that higher than anticipated vaccination coverage must be attained to achieve the same level of disease control to protect the public compared with less transmissible variants.

In collaboration with academic, industry, state, territorial, tribal, and local partners, CDC and other federal agencies are coordinating and enhancing genomic surveillance and virus characterization efforts across the United States. CDC coordinates U.S. sequencing efforts through the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES)[§§] consortium, which includes approximately 170 participating institutions and promotes open data-sharing to facilitate the use of SARS-CoV-2 sequence data. To track SARS-CoV-2 viral evolution, CDC is implementing multifaceted genomic surveillance to understand the epidemiologic, immunologic, and evolutionary processes that shape viral phylogenies (phylodynamics); guide outbreak investigations; and facilitate the detection and characterization of possible reinfections, vaccine breakthrough cases, and emerging viral variants. In November 2020, CDC established the National SARS-CoV-2 Strain Surveillance (NS3) program to improve the representativeness of domestic SARS-CoV-2 sequences. The program collaborates with 64 U.S. public health laboratories to support a genomic surveillance system; NS3 is also building a collection of SARS-CoV-2 specimens and sequences to support public health response and scientific research to evaluate the impact of concerning mutations on existing recommended medical countermeasures. CDC has also contracted with several large commercial clinical laboratories to rapidly sequence tens of thousands of SARS-CoV-2–positive specimens each month and has funded seven academic institutions to conduct genomic surveillance in partnership with public health agencies, thereby adding substantially to the availability of timely genomic surveillance data from across the United States. In addition to these national initiatives, many state and local public health agencies are sequencing

[§§] https://www.cdc.gov/coronavirus/2019-ncov/covid-data/spheres.html.

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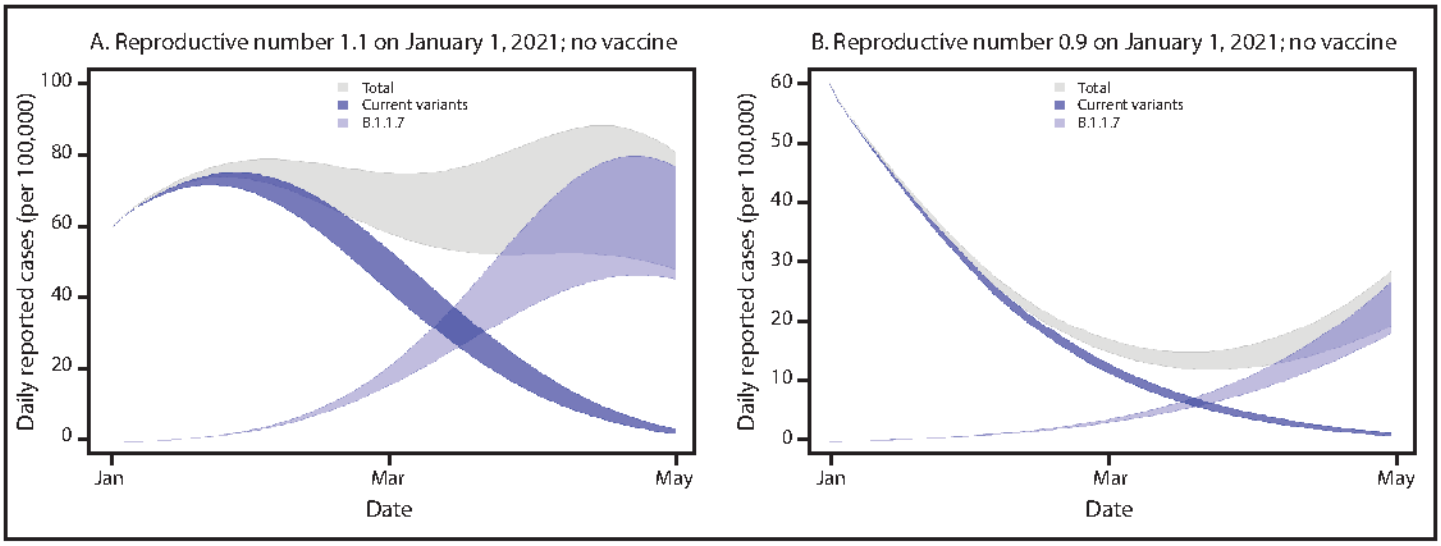
FIGURE 1. Simulated case incidence trajectories* of current SARS-CoV-2 variants and the B.1.1.7 variant,† assuming no community vaccination and either initial R_t = 1.1 (A) or initial R_t = 0.9 (B) for current variants — United States, January–April 2021

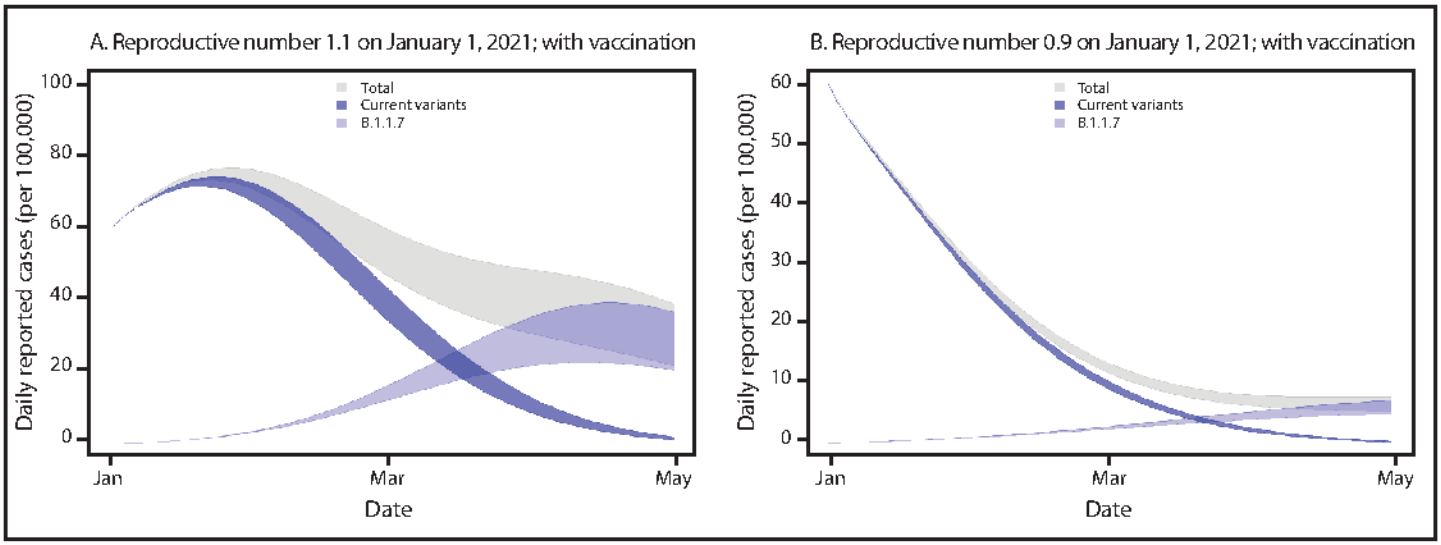


Abbreviation: R_t = time-varying reproductive number.

* For all simulations, it was assumed that the reporting rate was 25% and that persons who were seropositive or infected within the simulation became immune. The simulation was initialized with 60 reported cases of SARS-CoV-2 infection per 100,000 persons (approximately 200,000 cases per day in the U.S. population) on January 1, 2021. Bands represent simulations with 10%–30% population-level immunity as of January 1, 2021.

† Initial B.1.1.7 prevalence is assumed to be 0.5% among all infections and B.1.1.7 is assumed to be 50% more transmissible than current variants.

FIGURE 2. Simulated case incidence trajectories* of current SARS-CoV-2 variants and the B.1.1.7 variant,† assuming community vaccination§ and initial R_t = 1.1 (A) or initial R_t = 0.9 (B) for current variants — United States, January–April 2021



Abbreviation: R_t = time-varying reproductive number.

* For all simulations, it was assumed that the reporting rate was 25% and that persons who were seropositive or infected within the simulation became immune. The simulation was initialized with 60 reported cases of SARS-CoV-2 infection per 100,000 persons (approximately 200,000 cases per day in the U.S. population) on January 1, 2021. Bands represent simulations with 10%–30% population-level immunity as of January 1, 2021.

† Initial B.1.1.7 prevalence is assumed to be 0.5% among all infections and B.1.1.7 is assumed to be 50% more transmissible than current variants.

§ For vaccination, it was assumed that 300 doses were administered per 100,000 persons per day (approximately 1 million doses per day in the U.S. population) beginning January 1, 2021, that 2 doses achieved 95% immunity against infection, and that there was a 14-day delay between vaccination and protection.

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SARS-CoV-2 to better understand local epidemiology and support public health response to the pandemic.

The findings in this report are subject to at least three limitations. First, the magnitude of the increase in transmissibility in the United States compared with that observed in the United Kingdom remains unclear. Second, the prevalence of B.1.1.7 in the United States is also unknown at this time, but detection of variants and estimation of prevalence will improve with enhanced U.S. surveillance efforts. Finally, local mitigation measures are also highly variable, leading to variation in R_t. The specific outcomes presented here are based on simulations and assumed no change in mitigations beyond January 1.

The increased transmissibility of the B.1.1.7 variant warrants rigorous implementation of public health strategies to reduce transmission and lessen the potential impact of B.1.1.7, buying critical time to increase vaccination coverage. CDC's modeling data show that universal use of and increased compliance with mitigation measures and vaccination are crucial to reduce the number of new cases and deaths substantially in the coming months. Further, strategic testing of persons without symptoms of COVID-19, but who are at increased risk for infection with SARS-CoV-2, provides another opportunity to limit ongoing spread. Collectively, enhanced genomic surveillance combined with increased compliance with public health mitigation strategies, including vaccination, physical distancing, use of masks, hand hygiene, and isolation and quarantine, will be essential to limiting the spread of SARS-CoV-2 and protecting public health.

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Evaluation of Abbott BinaxNOW Rapid Antigen Test for SARS-CoV-2 Infection at Two Community-Based Testing Sites — Pima County, Arizona, November 3–17, 2020

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Rapid antigen tests, such as the Abbott BinaxNOW COVID-19 Ag Card (BinaxNOW), offer results more rapidly (approximately 15–30 minutes) and at a lower cost than do highly sensitive nucleic acid amplification tests (NAATs) (*1*). Rapid antigen tests have received Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for use in symptomatic persons (*2*), but data are lacking on test performance in asymptomatic persons to inform expanded screening testing to rapidly identify and isolate infected persons (*3*). To evaluate the performance of the BinaxNOW rapid antigen test, it was used along with real-time reverse transcription–polymerase chain reaction (RT-PCR) testing to analyze 3,419 paired specimens collected from persons aged ≥10 years at two community testing sites in Pima County, Arizona, during November 3–17, 2020. Viral culture was performed on 274 of 303 residual real-time RT-PCR specimens with positive results by either test (29 were not available for culture). Compared with real-time RT-PCR testing, the BinaxNOW antigen test had a sensitivity of 64.2% for specimens from symptomatic persons and 35.8% for specimens from asymptomatic persons, with near 100% specificity in specimens from both groups. Virus was cultured from 96 of 274 (35.0%) specimens, including 85 (57.8%) of 147 with concordant antigen and real-time RT-PCR positive results, 11 (8.9%) of 124 with false-negative antigen test results, and none of three with false-positive antigen test results. Among specimens positive for viral culture, sensitivity was 92.6% for symptomatic and 78.6% for asymptomatic individuals. When the pretest probability for receiving positive test results for SARS-CoV-2 is elevated (e.g., in symptomatic persons or in persons with a known COVID-19 exposure), a negative antigen test result should be confirmed by NAAT (*1*). Despite a lower sensitivity to detect infection, rapid antigen tests can be an important tool for screening because of their quick turnaround time, lower costs and resource needs, high specificity, and high positive predictive value (PPV) in settings of high pretest probability. The faster turnaround time of the antigen test can help limit transmission by more rapidly identifying infectious persons for isolation, particularly when used as a component of serial testing strategies.

Paired upper respiratory swabs were collected at the same timepoint from persons aged ≥10 years receiving testing for SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), at two Pima County Health Department community testing sites during November 3–17 (site A) and November 8–16 (site B). The sites offered SARS-CoV-2 testing to anyone in the community who wanted testing. A questionnaire capturing demographic information and current and past–14-day symptoms was administered to all participants. At both sites, a health care professional first collected a bilateral anterior nasal swab, using a swab provided in the BinaxNOW kit, immediately followed by a bilateral nasopharyngeal (NP) swab for real-time RT-PCR testing. Anterior nasal swabs were immediately tested on-site using the BinaxNOW antigen test according to the manufacturer's instructions (*4*). NP swabs were stored in phosphate buffered saline at 39°F (4°C) and analyzed within 24–48 hours by real-time RT-PCR using either the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for detection of SARS-CoV-2 (*5*) (2,582 swabs) or the Fosun COVID-19 RT-PCR Detection Kit (*6*) (837 swabs). Viral culture[*,†] was attempted on 274 of 303 residual real-time RT-PCR specimens if either the real-time RT-PCR or BinaxNOW antigen test result was positive (the remaining 29 were not available for viral culture). Results from real-time RT-PCR and the BinaxNOW antigen test were compared to evaluate sensitivity, specificity, negative predictive value (NPV), and PPV. Statistical analyses were performed using SAS (version 9.4; SAS Institute). Cycle threshold (Ct) values from real-time RT-PCR were compared using a Mann-Whitney U Test; 95% confidence intervals (CIs)

[*] Specimens were used to perform a limiting-dilution inoculation of Vero CCL-81 cells, and cultures showing evidence of cytopathic effect were tested by real-time RT-PCR for the presence of SARS-CoV-2 RNA. Viral recovery was defined as any culture in which the first passage had an N1 Ct value at least two Ct values lower than the corresponding clinical specimen.

[†] https://www.biorxiv.org/content/10.1101/2020.03.02.972935v1.

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were calculated using the exact binomial method. The investigation protocol was reviewed by CDC and determined to be nonresearch and was conducted consistent with applicable federal law and CDC policy.[§]

Paired upper respiratory swabs were collected from 3,419 persons, including 1,458 (42.6%) from site A and 1,961 (57.4%) from site B (Table 1). Participants ranged in age from 10 to 95 years (median = 41 years) with 236 (6.9%) aged 10–17 years, 1,885 (55.1%) aged 18–49 years, 743 (21.7%) aged 50–64 years, and 555 (16.2%) aged ≥65 years. Approximately one third (31.4%) of participants identified as Hispanic or Latino, and three quarters (75.1%) identified as White.

At the time of testing, 827 (24.2%) participants reported at least one COVID-19–compatible sign or symptom,[¶] and 2,592 (75.8%) were asymptomatic. Among symptomatic participants, 113 (13.7%) received a positive BinaxNOW antigen test result, and 176 (21.3%) received a positive real-time RT-PCR test result. Among asymptomatic participants, 48 (1.9%) received a positive BinaxNOW antigen test result, and 123 (4.7%) received a positive real-time RT-PCR test result.

Testing among symptomatic participants indicated the following for the BinaxNOW antigen test (with real-time RT-PCR as the standard): sensitivity, 64.2%; specificity, 100%; PPV, 100%; and NPV, 91.2% (Table 2); among asymptomatic persons, sensitivity was 35.8%; specificity, 99.8%; PPV, 91.7%; and NPV, 96.9%. For participants who were within 7 days of symptom onset, the BinaxNOW antigen test sensitivity was 71.1% (95% CI = 63.0%–78.4%), specificity was 100% (95% CI = 99.3%–100%), PPV was 100% (95% CI = 96.4%–100%), and NPV was 92.7% (95% CI = 90.2%–94.7%). Using real-time RT-PCR as the standard, four false-positive BinaxNOW antigen test results occurred, all among specimens from asymptomatic participants. Among 299 real-time RT-PCR positive results, 142 (47.5%) were false-negative BinaxNOW antigen test results (63 in specimens from symptomatic persons and 79 in specimens from asymptomatic persons).

Virus was recovered from 96 (35.0%) of 274 analyzed specimens that were positive by either test, including 85 (57.8%) of 147 with concordant positive results and 11 (8.9%) of 124 with false-negative BinaxNOW antigen test results. Virus was not recovered from any of the three available specimens with false-positive BinaxNOW antigen test results. Among the 224 specimens undergoing viral culture that were analyzed with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for detection of SARS-CoV-2, median Ct values[**] were significantly higher for specimens with false-negative BinaxNOW antigen test results, indicating lower viral RNA levels than in those with concordant positive results (33.9 versus 22.0 in specimens from symptomatic persons [p<0.001] and 33.9 versus 22.5 in specimens from asymptomatic persons [p<0.001]) (Figure). Median Ct values for SARS-CoV-2 culture-positive specimens (22.1) were significantly lower than were those for culture-negative specimens (32.8) (p<0.001), indicating higher levels of viral RNA in culture-positive specimens. Among specimens with positive viral culture, the sensitivity of the BinaxNOW antigen test compared with real-time RT-PCR in specimens from symptomatic participants was 92.6% (95% CI = 83.7%–97.6%) and in those from asymptomatic participants was 78.6% (95% CI = 59.1%–91.7%).

Discussion

In this evaluation, using real-time RT-PCR as the standard, the sensitivity of the BinaxNOW antigen test was lower among specimens from asymptomatic persons (35.8%) than among specimens from symptomatic persons (64.2%). Specificity (99.8%–100%) was high in specimens from both asymptomatic and symptomatic groups. The prevalence of having SARS-CoV-2 real-time RT-PCR positive test results in this population was moderate (8.7% overall; 4.7% for asymptomatic participants); administering the test in a lower prevalence setting will likely result in a lower PPV.[††] Among 11 participants with antigen-negative, real-time RT-PCR–positive specimens with positive viral culture, five were symptomatic and six asymptomatic. Some antigen-negative, real-time RT-PCR–positive specimens possibly could represent noninfectious viral particles, but some might also represent infectious virus not detected by the antigen test. In a clinical context, real-time RT-PCR provides the most sensitive assay to detect infection. Viral culture, although more biologically relevant than real-time RT-PCR, is still an artificial system and is subject to limitations. Numerous biological (e.g., individual antibody status and specific sequence of the virus) and environmental (e.g., storage conditions and number of freeze-thaw cycles) variables can affect the sensitivity and

[§] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

[¶] Participants were asked whether they had each sign or symptom from a list based on Council for State and Territorial Epidemiologists clinical criteria for COVID-19 that included fever, cough, shortness of breath, fatigue, sore throat, headache, muscle aches, chills, nasal congestion, difficulty breathing, diarrhea, nausea, vomiting, abdominal pain, rigors, loss of taste, and loss of smell. https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/positionstatement2020/Interim-20-ID-02_COVID-19.pdf.

[**] Ct values from the N1 viral nucleocapsid protein gene region from real-time RT-PCR were compared only for specimens that were analyzed with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for detection of SARS-CoV-2. Lower Ct values represent higher levels of viral RNA in the specimen and higher Ct values represent lower levels of viral RNA.

[††] https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Interpreting-Results-of-Diagnostic-Tests.

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TABLE 1. Characteristics of persons providing paired upper respiratory swabs (N = 3,419)* for the Abbott BinaxNOW COVID-19 Ag Card Point of Care Diagnostic Test and real-time reverse transcription–polymerase chain reation (RT-PCR) testing† for SARS-CoV-2 at two community-based testing sites, by test results — Pima County, Arizona, November 2020

Characteristic	Total no. of persons (column %)	No. of persons (row %)§			
		Antigen-positive	Real-time RT-PCR–positive	Real-time RT-PCR–positive, antigen-negative	Real-time RT-PCR–negative, antigen-positive
Total	**3,419 (100)**	**161 (4.7)**	**299 (8.7)**	**142 (4.2)**	**4 (0.1)**
Testing site					
A	**1,458 (42.6)**	72 (4.9)	145 (9.9)	74 (5.1)	1 (0.1)
B	**1,961 (57.4)**	89 (4.5)	154 (7.9)	68 (3.5)	3 (0.2)
Sex					
Male	**1,290 (37.7)**	74 (5.7)	138 (10.7)	65 (5.0)	1 (0.1)
Female	**1,681 (49.2)**	76 (4.5)	127 (7.6)	54 (3.2)	3 (0.2)
Undisclosed	**448 (13.1)**	11 (2.5)	34 (7.6)	23 (5.1)	0 (—)
Ethnicity					
Hispanic/Latino	**1,075 (31.4)**	86 (8.0)	150 (14.0)	65 (6.0)	1 (0.1)
Not Hispanic or Latino	**1,930 (56.4)**	63 (3.3)	118 (6.1)	58 (3.0)	3 (0.2)
Undisclosed	**414 (12.1)**	12 (2.9)	31 (7.5)	19 (4.6)	0 (—)
Race					
White	**2,567 (75.1)**	110 (4.3)	204 (7.9)	98 (3.8)	4 (0.2)
Black/African American	**83 (2.4)**	3 (3.6)	8 (9.6)	5 (6.0)	0 (—)
American Indian/Alaska Native	**69 (2.0)**	1 (1.4)	2 (2.9)	1 (1.4)	0 (—)
Asian	**84 (2.5)**	4 (4.8)	10 (11.9)	6 (7.1)	0 (—)
Native Hawaiian/Pacific Islander	**24 (0.7)**	1 (4.2)	1 (4.2)	0 (—)	0 (—)
Undisclosed	**592 (17.3)**	42 (7.1)	74 (12.5)	32 (5.4)	0 (—)
Age group, yrs					
10–17	**236 (6.9)**	10 (4.2)	22 (9.3)	13 (5.5)	1 (0.4)
18–49	**1,885 (55.1)**	91 (4.8)	178 (9.4)	89 (4.7)	2 (0.1)
50–64	**743 (21.7)**	41 (5.5)	69 (9.3)	29 (3.9)	1 (0.1)
≥65	**555 (16.2)**	19 (3.4)	30 (5.4)	11 (2.0)	0 (—)
Median age (range)	**41 (10–95)**	40 (13–84)	38 (11–84)	35 (11–83)	27 (16–63)
Current symptoms¶					
≥1	**827 (24.2)**	113 (13.7)	176 (21.3)	63 (7.6)	0 (—)
None	**2,592 (75.8)**	48 (1.9)	123 (4.7)	79 (3.0)	4 (0.2)
Days from symptom onset**					
Median (range)	**4 (0–210)**	3 (0–14)	4 (0–45)	4 (0–45)	2 (0–12)
0–3	**382 (11.2)**	59 (15.4)	84 (22.0)	25 (6.5)	0 (—)
4–7	**280 (8.2)**	42 (15.0)	58 (20.7)	16 (5.7)	0 (—)
8–10	**43 (1.3)**	6 (14.0)	12 (27.9)	6 (14.0)	0 (—)
11–14	**63 (1.8)**	6 (9.5)	16 (25.4)	10 (15.9)	0 (—)
>14	**55 (1.6)**	0 (—)	6 (10.9)	6 (10.9)	0 (—)
≤7	**662 (19.4)**	101 (15.3)	142 (21.5)	41 (6.2)	0 (—)
Exposure to a diagnosed COVID-19 case††					
Yes	**1,138 (33.3)**	93 (8.2)	162 (14.2)	71 (6.2)	2 (0.2)
No/Unknown	**2,281 (66.7)**	68 (3.0)	137 (6.0)	71 (3.1)	2 (0.1)
Days since last exposure, median (range)	**5 (0–14)**	4 (0–14)	3 (0–14)	1 (0–14)	9 (4–14)
Positive test results in past 90 days§§					
Yes	**179 (5.2)**	22 (12.3)	83 (46.4)	62 (34.6)	1 (14.3)
No/Unknown	**3,239 (94.7)**	139 (4.3)	216 (6.7)	80 (2.5)	3 (42.9)

Abbreviation: COVID-19 = coronavirus disease 2019.

* Includes 113 persons who received testing multiple times and were included more than once in the analysis.

† Testing with real-time RT-PCR was performed using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for detection of SARS-CoV-2 (2,582 participants) or Fosun assay (837 participants).

§ Only selected categories shown; therefore, row numbers and percentages do not sum to total or 100%.

¶ Participants were asked whether they had each individual sign or symptom from a list based on the Council of State and Territorial Epidemiologists' clinical criteria for COVID-19 interim case definition, which include fever, cough, shortness of breath, fatigue, sore throat, headache, muscle aches, chills, nasal congestion, difficulty breathing, diarrhea, nausea, vomiting, abdominal pain, rigors, loss of taste, and loss of smell (https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/positionstatement2020/Interim-20-ID-02_COVID-19.pdf).

** Based on one or more symptoms.

†† Exposure was defined as close contact (within 6 ft for ≥15 min) in the 14 days before the day of testing with a person with diagnosed COVID-19.

§§ Received positive real-time RT-PCR or antigen test result.

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TABLE 2. Test results and performance characteristics of the Abbott BinaxNOW COVID-19 Ag Card Point of Care Diagnostic Test (BinaxNOW antigen test) compared with real-time reverse transcription–polymerase chain reaction (RT-PCR) for testing received among asymptomatic and symptomatic persons at two community-based testing sites — Pima County, Arizona, November 2020

	Real-time RT-PCR, no. of tests		
Results and Performance	**Positive**	**Negative**	**Total**
BinaxNOW antigen test result			
All participants (N = 3,419)			
Positive	157	4	**161**
Negative	142	3,116	**3,258**
Total	**299**	**3,120**	**3,419**
Symptomatic (≥1 symptom) (n = 827)			
Positive	113	0	**113**
Negative	63	651	**714**
Total	**176**	**651**	**827**
Asymptomatic (n = 2,592)			
Positive	44	4	**48**
Negative	79	2,465	**2,544**
Total	**123**	**2,469**	**2,592**
BinaxNOW antigen test performance, % (95% CI)			
All participants (N = 3,149)			
Sensitivity		52.5 (46.7–58.3)	
Specificity		99.9 (99.7–100.0)	
PPV		97.5 (93.8–99.3)	
NPV		95.6 (94.9–96.3)	
Symptomatic (n = 827)			
Sensitivity		64.2 (56.7–71.3)	
Specificity		100.0 (99.4–100.0)	
PPV		100.0 (96.8–100.0)	
NPV		91.2 (88.8–93.1)	
Asymptomatic (n = 2,592)			
Sensitivity		35.8 (27.3–44.9)	
Specificity		99.8 (99.6–100.0)	
PPV		91.7 (80–7.7)	
NPV		96.9 (96.1–97.5)	

Abbreviations: CI = confidence interval; COVID-19 = coronavirus disease 2019; NPV = negative predictive value; PPV = positive predictive value.

outcome of viral culture. Despite the limitations of interpreting culture-negative specimens, a positive viral culture is strong evidence for the presence of infectious virus. The performance of the BinaxNOW antigen test compared with real-time RT-PCR was better for those specimens with positive viral culture than for all specimens, with a sensitivity of 92.6% for specimens from symptomatic persons and 78.6% for those from asymptomatic persons. The results of the current evaluation differ from those of an evaluation of the BinaxNOW antigen test in a community screening setting in San Francisco (*7*), which found a BinaxNOW antigen test overall sensitivity of 89.0% among specimens from all 3,302 participants, regardless of the Ct value of the real-time RT-PCR–positive specimens.

The findings in this investigation are subject to at least five limitations. First, anterior nasal swabs were used for BinaxNOW antigen testing, but NP swabs were used for real-time RT-PCR testing, which might have contributed to increased detection for the real-time RT-PCR assay (*8*). Second, participants might have inadvertently reported common nonspecific symptoms as COVID-19–compatible symptoms. Third, this investigation evaluated the BinaxNOW antigen test, and results presented here cannot be generalized to other FDA-authorized SARS-CoV-2 antigen tests. Fourth, the BinaxNOW antigen test characteristics might be different depending on whether an individual had previously tested positive. Finally, many factors might limit the ability to culture virus from a specimen, and the inability to detect culturable virus should not be interpreted to mean that a person is not infectious.

Public health departments are implementing various strategies to reduce or prevent SARS-CoV-2 transmission, including expanded screening testing for asymptomatic persons (*3*). Because estimates suggest that over 50% of transmission occurs from persons who are presymptomatic or asymptomatic (*9*), expanded screening testing, potentially in serial fashion for reducing transmission in specific venues (e.g., institutions of higher education, schools, and congregate housing settings), is essential to interrupting transmission (*3*).

Rapid antigen tests can be an important tool for screening because of their quick turnaround time, lower requirement for resources, high specificity, and high PPV in settings of high pretest probability (e.g., providing testing to symptomatic persons, to persons with a known COVID-19 exposure, or where community transmission is high). Importantly, the faster time from testing to results reporting can speed isolation of infectious persons and will be particularly important in communities with high levels of transmission.

Although the sensitivity of the BinaxNOW antigen test to detect infection was lower compared with real-time RT-PCR, it was relatively high among specimens with positive viral culture, which might reflect better performance for detecting infection in a person with infectious virus present. Community testing strategies focused on preventing transmission using antigen testing should consider serial testing (e.g., in kindergarten through grade 12 schools, institutions of higher education, or congregate housing settings), which might improve test sensitivity in decting infection (*10*). When the pretest probability for receiving positive SARS-CoV-2 test results is elevated (e.g. for symptomatic persons or for persons with a known COVID-19 exposure) a negative antigen test result should be confirmed by NAAT. Asymptomatic persons who receive a positive BinaxNOW antigen test result in a setting with a high risk for adverse consequences resulting from false-positive results (e.g. in long-term care facilities) should also receive confirmatory testing by NAAT (*1*).

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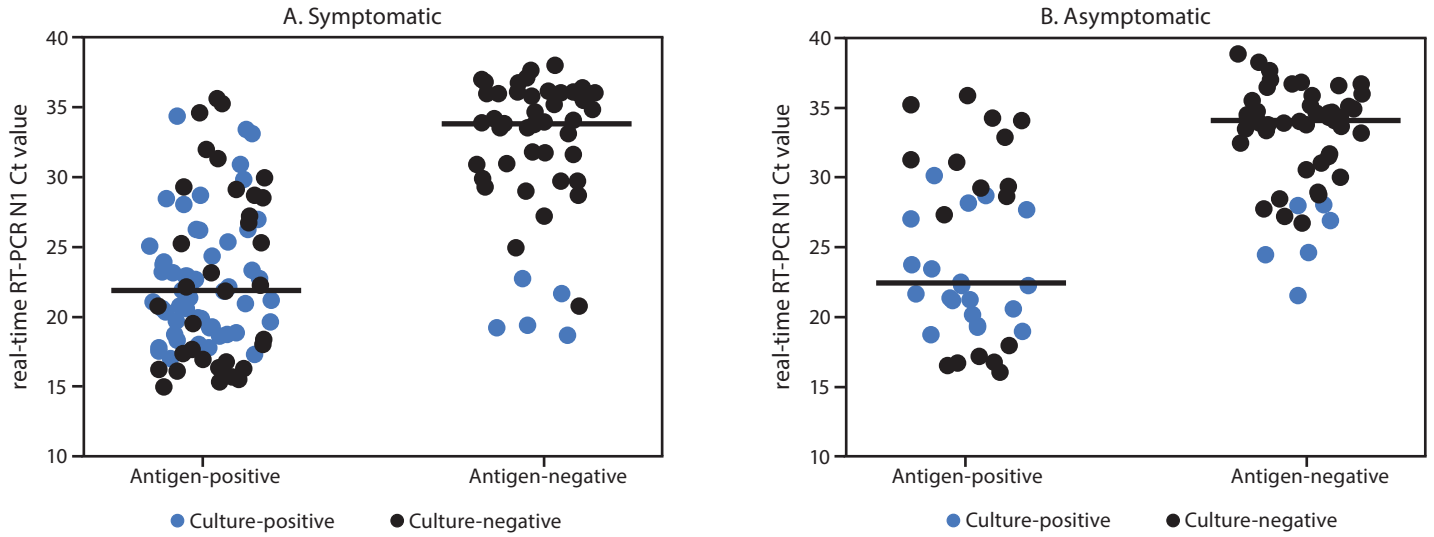
FIGURE. Abbott BinaxNOW COVID-19 Ag Card Point of Care Diagnostic Test (antigen test) results, N1 cycle threshold (Ct) values,* and viral culture results† among A) symptomatic (N = 136)§ and B) asymptomatic (N = 88)¶ participants receiving positive SARS-CoV-2 real-time reverse transcription–polymerase chain reaction (RT-PCR) test results at two community-based testing sites — Pima County, Arizona, November 2020



* Only those specimens that were analyzed using the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for detection of SARS-CoV-2 and that were analyzed using viral culture are included in the graph.

† Twenty specimens with Ct values <18 had positive antigen and real-time RT-PCR results but were culture negative. The culture showed evidence of cytopathic effects and had presence of SARS-CoV-2 RNA as detected by real-time RT-PCR in the first passage culture, but viral recovery was not two Ct values lower than the corresponding clinical specimen Ct.

§ Antigen test results: 88 positive and 48 negative; median Ct values indicated with black line: 22.0 for antigen-positive specimens and 33.9 for antigen-negative specimens.

¶ Antigen test results: 37 positive and 51 negative; median Ct values indicated with black line: 22.5 for antigen-positive specimens and 33.9 for antigen-negative specimens.

Summary

What is already known about this topic?

The BinaxNOW rapid antigen test received Emergency Use Authorization by the Food and Drug Administration for testing specimens from symptomatic persons; performance among asymptomatic persons is not well characterized.

What is added by this report?

Sensitivity of the BinaxNOW antigen test, compared with polymerase chain reaction testing, was lower when used to test specimens from asymptomatic (35.8%) than from symptomatic (64.2%) persons, but specificity was high. Sensitivity was higher for culture-positive specimens (92.6% and 78.6% for those from symptomatic and asymptomatic persons, respectively); however, some antigen test-negative specimens had culturable virus.

What are the implications for public health practice?

The high specificity and rapid BinaxNOW antigen test turnaround time facilitate earlier isolation of infectious persons. Antigen tests can be an important tool in an overall community testing strategy to reduce transmission.

Despite their reduced sensitivity to detect infection compared with real-time RT-PCR, antigen tests might be particularly useful when real-time RT-PCR tests are not readily available or have prolonged turnaround times. Persons who know their positive test result within 15–30 minutes can isolate sooner, and contact tracing can be initiated sooner and be more effective than if a test result is returned days later. Serial antigen testing can improve detection, but consideration should be given to the logistical and personnel resources needed. All persons receiving negative test results (NAAT or antigen) should be counseled that wearing a mask, avoiding close contact with persons outside their household, and washing hands frequently remain critical to preventing the spread of COVID-19.§§

§§ https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.

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[1]CDC COVID-19 Response Team; [2]Arizona Department of Health Services; [3]Epidemic Intelligence Service, CDC; [4]Pima County Health Department, Tucson, Arizona.

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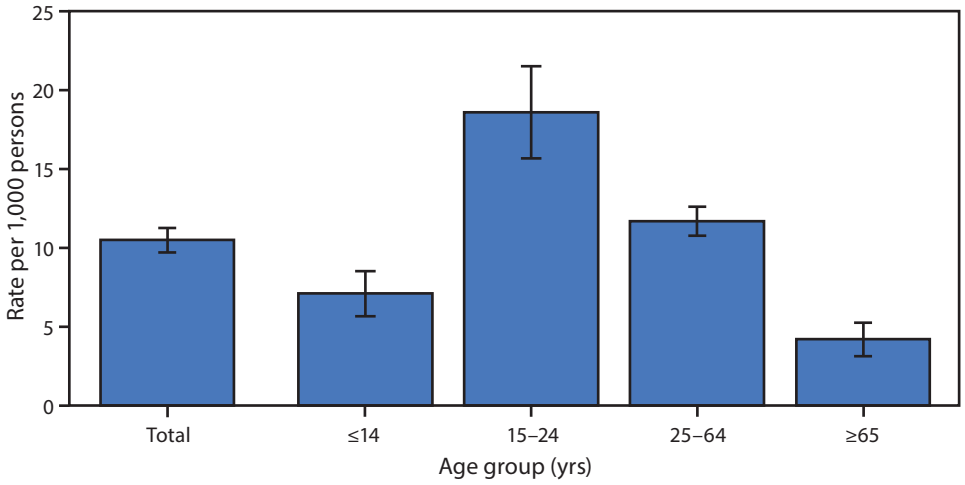
QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Emergency Department Visit Rates* for Motor Vehicle Crashes,† by Age Group — United States, 2018§



* Visit rates are based on the July 1, 2018, set of estimates of the U.S. civilian noninstitutionalized population as developed by the U.S. Census Bureau, Population Division. 95% confidence intervals indicated with error bars.

† Motor vehicle crashes defined as a visit with *International Classification of Diseases, Tenth Revision, Clinical Modification* codes: [V02–V04] (with fourth character = 1, 9), V09.2, V09.3, [V12–V14, V20–V28] (with fourth character = 3, 4, 5, 9), V19.4–V19.6, V19.9, V29.4–V29.9, [V30–V79] (with fourth character = 4, 5, 6, 7, 8, 9), [V83–V86] (with fourth character = 0, 1, 2, 3), V80.3–V80.5, V81.1, V82.1, V87.0–V87.8, V89.2, X81.0, X82, Y02.0, Y03, Y32. Injured persons included motor vehicle occupants, motorcyclists, pedal cyclists, and pedestrians.

§ Based on a sample of visits to emergency departments in noninstitutional general and short-stay hospitals, exclusive of federal, military, and Veterans Administration hospitals, located in the 50 U.S. states and the District of Columbia.

In 2018, the U.S. emergency department (ED) visit rate for motor vehicle crashes was 10.5 visits per 1,000 persons. The ED visit rate for motor vehicle crashes among persons aged 0–14 years was 7.1 ED visits per 1,000 persons. The visit rate for motor vehicle crashes was highest for persons aged 15–24 years (18.6) and declined with age to 11.7 for those aged 25–64 years and to 4.2 for those aged ≥65 years.

Source: National Center for Health Statistics. National Hospital Ambulatory Medical Care Survey, 2018. https://www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm.

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For more information on this topic, CDC recommends the following link: https://www.cdc.gov/transportationsafety.

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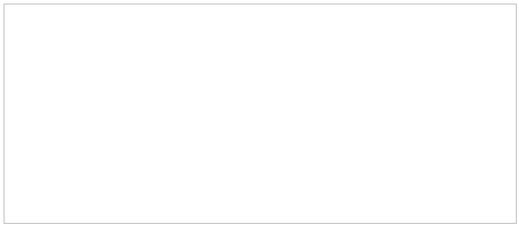
Sent: Friday, January 22, 2021 11:40 AM EST
To: CSTE Emergency Response <Preparedness@cste.org>
Subject: National Strategy for the COVID-19 Response and Pandemic Preparedness

From: White House Press Office <whopress@who.eop.gov>
Sent: Thursday, January 21, 2021 5:56 AM
To: Cisneros, Eduardo EOP/WHO <Eduardo.Cisneros@who.eop.gov>
Subject: National Strategy for the COVID-19 Response and Pandemic Preparedness



National Strategy for the COVID-19 Response and Pandemic Preparedness
January 21, 2021
Executive Summary

We can and will beat COVID-19. America deserves a response to the COVID-19 pandemic that is driven by science, data, and public health — not politics. Through the release of the National Strategy for the COVID-19 Response and Pandemic Preparedness, the United States is initiating a coordinated pandemic response that not only improves the effectiveness of our fight against COVID-19, but also helps restore trust, accountability and a sense of common purpose in our government.

On January 9, 2020, the World Health Organization announced that there were 59 cases of coronavirus-related pneumonia. Just one year later, the United States has experienced over 24 million confirmed COVID-19 cases and over 400,000 COVID-19 deaths. America has just 4% of the world's population, but 25% of the world's COVID-19 cases and 20% of all COVID-19 deaths. And our nation continues to experience the darkest days of the pandemic, with record numbers of cases, hospitalizations and deaths. Over 77,000 Americans lost their lives to COVID-19 in December, and across our nation businesses are closing, hospitals are full, and families are saying goodbye to their loved ones remotely.

The National Strategy provides a roadmap to guide America out of the worst public health crisis in a century. It outlines an actionable plan across the federal government to address the COVID-19 pandemic, including twelve initial executive actions that will be issued by President Biden during his first two days in office:

The National Strategy is organized around seven goals:

1. Restore trust with the American people.
2. Mount a safe, effective, and comprehensive vaccination campaign.
3. Mitigate spread through expanding masking, testing, treatments, data, health care workforce, and clear public health standards.
4. Immediately expand emergency relief and exercise the Defense Production Act.
5. Safely reopen schools, businesses, and travel while protecting workers.
6. Protect those most at risk and advance equity, including across racial, ethnic and rural/urban lines.
7. Restore U.S. leadership globally and build better preparedness for future threats.

To execute on the National Strategy, the White House will establish a COVID-19 Response Office responsible for coordinating the pandemic response across

all federal departments and agencies. Through implementation of the National Strategy, the United States will make immediate progress on the seven goals. To monitor outcomes, the National Strategy will establish a data-driven, evidence-based approach to evaluating America's progress in the fight against COVID-19.

The federal government cannot solve this crisis alone. Full implementation of the National Strategy for COVID-19 will require sustained, coordinated, and complementary efforts of the American people, as well as groups across the country, including State, local, territorial, and Tribal governments; health care providers; businesses; manufacturers critical to the supply chain; civic, religious and civil rights organizations; and unions. It will also require a global effort to contain the virus and advance health security.

America has always risen to the challenge and we will do so now. In collaboration with the people of this country, the United States government will lead an effective COVID-19 response that gets us back to our lives and loved ones. As we've seen during this pandemic, we can't solve our problems as a divided nation. The only way we come through this is together as fellow Americans and as the United States of America.

Goal 1: Restore trust with the American people.

The federal government should be the source of truth for the public to get clear, accessible, and scientifically accurate information about COVID-19. To rebuild the trust of the American people, the National Strategy will signal clear public leadership and a commitment to a robust whole-of-government response that puts science first. The federal government will be transparent with the American people, maintaining an open line of communication with the public and all stakeholders. To continue to restore trust, the United States will:

Establish a national COVID-19 response structure where decision-making is driven by science and equity. The Biden-Harris Administration has developed a unified plan to rebuild expert leadership across the government and regain the trust of the American public. As part of the strategy, on his first day in office, President Biden issued Executive Order *Organizing and Mobilizing the U.S. Government to Provide a Unified And Effective Response to Combat COVID-19 and to Provide United States Leadership on Global Health and Security* establishing a White House COVID-19 national response structure to coordinate across the U.S. Government and restoring the White House Directorate on Global Health Security and Biodefense established by the Obama-Biden Administration. The COVID-19 Response office will establish clear lines of communications with all governors, state public health officials and immunization managers, and local leaders.

Conduct regular expert-led, science-based public briefings. The federal government will conduct regular, expert-led, science-based public briefings and release regular reports on the state of the pandemic. Experts and scientists at the U.S. Centers for Disease Control and Prevention (CDC) will also develop clear, evidence-based, metric-driven public health guidance and effectively and frequently communicate and distribute guidance and updates to the American people.

Publicly share data around key response indicators. Metrics and metric-driven public health guidance will be essential to controlling the pandemic. President Biden will issue Executive Order *Ensuring a Data-Driven Response to COVID-19 and Future High Consequence Public Health Threats* directing steps to enhance federal agencies' collection, production sharing, and analysis of, and collaboration with respect to, data to support an equitable COVID-19 response and recovery. As further detailed in National Strategy Goals Two, Three, and Six, the federal government will track a range of performance measures and data including cases, testing, vaccinations, and hospital admissions, and will make real-time information readily available to the public and to policymakers at the federal, state, and local level. The CDC will also maintain a public dashboard tracking COVID-19 cases at the county

level, so that Americans can gauge the level of transmission in their own communities to make their own informed choices.

Engage the American people. The federal government cannot solve this crisis alone. It will take regular engagement with the public, state and local leaders, the private sector, unions, community volunteers, and health care providers to guide policy and implementation. The Administration will prioritize outreach to state and local governments, the public and private sectors, vulnerable communities, students, workers, and community leaders, using input from these stakeholders to drive the government's COVID-19 response.

Lead science-first public health campaigns. The Administration will lead world-class public education campaigns — covering topics like masking, testing, vaccinations and vaccine hesitancy — designed with diversity and inclusivity in mind, including communications in multiple languages, to maximize reach and effectiveness. The campaigns will be coordinated, across national, state, and local levels, and engage with the private and public sector. They will be anchored by science and fact-based public health guidance. The Administration will work to counter misinformation and disinformation by ensuring that Americans are obtaining science-based information.

Goal 2: Mount a safe, effective, comprehensive vaccination campaign.

The United States will spare no effort to ensure Americans can get vaccinated quickly, effectively, and equitably. The federal government will execute an aggressive vaccination strategy, focusing on the immediate actions necessary to convert vaccines into vaccinations, including improving allocation, distribution, administration, and tracking. Central to this effort will be additional support and funding for state, local, Tribal, and territorial governments -- and improved line of sight into supply -- to ensure that they are best prepared to mount local vaccination programs. At the same time, the federal government will mount an unprecedented public campaign that builds trust around vaccination and communicates the importance of maintaining public health measures such as masking, physical distancing, testing, and contact tracing even as people receive safe and effective vaccinations. To mount a safe, effective, comprehensive vaccination campaign, the United States will:

Ensure the availability of safe, effective vaccines for the American public. The national vaccination effort will be one of the greatest operational challenges America has ever faced. To ensure all Americans can be vaccinated quickly, the President has developed a plan for expanding vaccine manufacturing and purchasing COVID-19 vaccine doses for the U.S. population by fully leveraging contract authorities, including the Defense Production Act; deploying onsite support to monitor contract manufacturing operations; and purchasing additional FDA-authorized vaccines to deliver as quickly as possible. The effort includes prioritizing supplies that could cause bottlenecks, including glass vials, stoppers, syringes, needles, and the "fill and finish" capacity to package vaccine into vials.

Accelerate getting shots into arms and get vaccines to the communities that need them most. The success of the national vaccination effort will depend on reaching communities across the United States. To achieve this, the federal government will take a series of steps to simplify and strengthen the allocation and distribution process. In order to expand the supply available to states, the Administration will end the policy of holding back significant levels of doses, instead holding back a small reserve and monitoring supply to ensure that everyone receives the full regimen as recommended by the FDA. The United States will accelerate the pace of vaccinations by encouraging states and localities to move through the priority groups more quickly -- expanding access to frontline essential workers and individuals over the age of 65, while staying laser-focused on working to ensure that the highest-risk members of the public, including those in congregate facilities, can access the vaccine where and when they need it. The

Administration will also improve the allocation process by providing states and localities with clear, consistent projections to inform their planning. Through it all, the United States will work to ensure that the vaccine is distributed quickly, effectively and equitably, with a focus on making sure that high-risk and hard-to-reach communities are not left behind.

Create as many venues as needed for people to be vaccinated. The federal government -- in partnership with state and local governments -- will create as many venues for vaccination as needed in communities and settings that people trust. This includes, but is not limited to federally run community vaccination centers, in places like stadiums and conference centers, federally-supported state and locally operated vaccination sites in all 50 states and 14 territories, pharmacies and retail stores, federal facilities like Veterans Affairs hospitals, community health centers, rural health clinics, critical access hospitals, physician offices, health systems, urgent care centers, and mobile and on-site occupational clinics**.**

Focus on hard-to-reach and high-risk populations. As the United States accelerates the pace of vaccinations nationwide, we remain focused on building programs to meet the needs of hard-to-reach and high-risk populations, and meeting communities where they are to make vaccinations as accessible and equitable as possible. The federal government will deploy targeted strategies to meet the needs of individuals at increased risk and others who need to take extra precautions, according to the CDC, as well as the communities hardest hit by this pandemic. Local public health officials will play a critical role.

Fairly compensate providers, and states and local governments for the cost of administering vaccinations. Fairly compensating providers, and state and local governments for the costs of vaccine administration will be critical to expanding vaccination participation. President Biden will work with Congress to expand the Federal Medicaid Assistance Percentage (FMAP) to 100 percent for vaccinations of Medicaid enrollees—with the goal of alleviating state costs for administration of these vaccines and supporting states in their work to meet the needs of their communities. The Department of Health and Human Services will ask the Centers for Medicare & Medicaid Services to consider whether current payment rates for vaccine administration are appropriate or whether a higher rate may more accurately compensate providers. The federal government will fund vaccine supply and will greatly expand funding for vaccine administration by allowing state and local governments to reimburse vaccination administration expenses through the FEMA Disaster Relief Fund and by ensuring that workforce and equipment expenses for state and local-run sites are also eligible.

Drive equity throughout the vaccination campaign and broader pandemic response. The federal government will drive equity in vaccinations by using demographic data to identify communities hit hardest by the virus and supporting them, ensuring no out-of-pocket costs for vaccinations, and making sure vaccines reach those communities. Working with state, local, and community-based organizations and trusted health care providers, like community health centers, will be central to this effort.

Launch a national vaccinations public education campaign. The United States will build public trust through an unprecedented vaccination public health campaign at the federal, State, Tribal, territorial, local and community level. The public education campaign will support vaccination programs, address vaccine hesitancy, help simplify the vaccination process for Americans, and educate the public on effective prevention measures. The campaign will be tailored to meet the needs of diverse communities, get information to trusted, local messengers, and outline efforts to deliver a safe and effective vaccine as part of a national strategy for beating COVID-19.

Bolster data systems and transparency for vaccinations. The operational complexity of vaccinating the public will make robust data and its use in decision-making related to vaccinations more important than ever. The

federal government, with CDC, will track distribution and vaccination progress, working hand-in-hand with states and localities to support their efforts. The Administration will build on and strengthen the federal government's approach to data collection related to vaccination efforts, removing impediments and developing communication and technical assistance plans for jurisdictions and providers. The Administration, through HHS and other federal partners, will rely on data to drive decision-making and the national vaccinations program.

Monitor vaccine safety and efficacy. The Administration will ensure that scientists are in charge of all decisions related to vaccine safety and efficacy. The FDA will also continue to honor its commitment to make relevant data on vaccine safety and efficacy publicly available and to provide opportunities for public, non-governmental expert input. Through expanded and existing systems, the CDC and FDA will ensure ongoing, real-time safety monitoring. Through it all, the Administration will communicate clearly with the American public to continue to build trust around the vaccine and its benefits for individuals, their families and communities.

Surge the health care workforce to support the vaccination effort. A diverse, community-based health care workforce is essential to an effective vaccination program. The United States will address workforce needs by taking steps to allow qualified professionals to administer vaccines and encourage states to leverage their flexibility fully to surge their workforce, including by expanding scope of practice laws and waiving licensing requirements as appropriate.

Goal 3: Mitigate spread through expanding masking, testing, treatment, data, workforce, and clear public health standards.

A comprehensive national public health effort to control the virus — even after the vaccination program ramps up — will be critical to saving lives and restoring economic activity. The federal government will partner with state, local, Tribal, and territorial leaders to implement a cohesive strategy to significantly reduce the spread of COVID-19 and release clear public health guidance to the public about what to do and when, including implementing mask mandates; expanding testing; strengthening the public health workforce; modernizing data collection and reporting capabilities for COVID-19 and future epidemics; and providing equitable access to treatment and clinical care. To mitigate the spread of COVID-19 through clear public health standards, the United States will:

Implement masking nationwide by working with governors, mayors, and the American people. The President has asked the American people to do what they do best: step up in a time of crisis and wear masks. He has issued Executive Order *Protecting the Federal Workforce and Requiring Mask-Wearing* which directs compliance with CDC guidance on masking and physical distancing in federal buildings, on federal lands, and by federal employees and contractors. Additionally, the President will issue Executive Order *Promoting COVID-19 Safety in Domestic and International Travel* which directs applicable agencies to take immediate action to require mask-wearing on some airplanes, trains, and certain other forms of public transportation in the United States. He has called on governors, public health officials, mayors, business leaders, and others to implement masking, physical distancing, and other CDC public measures to control COVID-19.

Scale and expand testing. To control the COVID-19 pandemic and safely reopen schools and businesses, America must have wide-spread testing. A national testing strategy is a cornerstone to reducing the spread of COVID-19 and controlling outbreaks, and clear federal guidance and a unified national approach to implementation are essential. The President will issue Executive Order *Establishing the National Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID-19 and Other Biological Threats* which establishes the COVID-19 Pandemic Testing Board to oversee implementation of a clear, unified approach to testing. The federal government will expand the rapid testing supply and double test supplies and increase testing capacity. The Administration will also increase onshore test

manufacturing, fill testing supply shortfalls, enhance laboratory capacity to conduct testing over the short- and long-term, and expand surveillance for hotspots and variants.

Effectively distribute tests and expand access to testing. The federal government will support school screening testing programs to help schools reopen. The Administration will also stand up a dedicated CDC Testing Support Team, fund rapid test acquisition and distribution for priority populations, work to spur development and manufacturing of at-home tests and work to ensure that tests are widely available. Through Executive Order *Establishing the National Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID-19 and Other Biological Threats* the President will direct agencies to facilitate testing free of charge for those who lack health insurance and to clarify insurers' obligation to cover testing. The federal government will also provide testing protocols to inform the use of testing in congregate settings, schools, and other critical areas and among asymptomatic individuals. Further, technical assistance will support more widespread adoption of testing to improve timely diagnosis and public confidence in the safety of settings like schools.

Prioritize therapeutics and establish a comprehensive, integrated COVID-19 treatment discovery and development program. Effective treatments for COVID-19 are critical to saving lives. The federal government will establish a comprehensive, integrated, and coordinated preclinical drug discovery and development program, with diverse clinical trials, to allow therapeutics to be evaluated and developed rapidly in response to COVID-19 and other pandemic threats. This includes promoting the immediate and rapid development of therapeutics that respond to COVID-19 by developing new antivirals directed against the coronavirus family, accelerating research and support for clinical trials for therapeutics in response to COVID-19 with a focus on those that can be readily scaled and administered, and developing broad-spectrum antivirals to prevent future viral pandemics. President Biden will issue Executive Order *Improving and Expanding Access to Care and Treatment for COVID-19* which also outlines steps to bolster clinical care capacity, provide assistance to long-term care facilities and intermediate care facilities for people with disabilities, increase health care workforce capacity, expand access to programs designed to meet long-term health needs of patients recovering from COVID-19, and support access to safe and effective COVID-19 therapies for those without coverage.

Develop actionable, evidence-based public health guidance. CDC will develop and update public health guidance on containment and mitigation that provides metrics for measuring and monitoring the incidence and prevalence of COVID-19 in health care facilities, schools, workplaces, and the general public, including metric-driven reopening guidance that the federal government communicates widely. Informed by up-to-date national and state data, the CDC will provide and update guidance on key issues such as physical distancing protocols, testing, contact tracing, reopening schools and businesses, and masking. The CDC also will provide focused guidance for older Americans and others at higher risk, including people with disabilities.

Expand the U.S. public health workforce and increase clinical care capacity for COVID-19.
In addition to supporting the surge in health care workers for vaccination efforts detailed in Goal Two, the federal government will also build and support an effective public health workforce to fight COVID-19 and the next public health threat. As part of the President's commitment to provide 100,000 COVID-19 contact tracers, community health workers, and public health nurses, the Administration will establish a U.S. Public Health Jobs Corps, provide support for community health workers, and mobilize Americans to support communities most at-risk. The United States will also provide technical support for testing, contact tracing, and other urgent public health workforce needs to better prepare for public health crises.

Improve data to guide the response to COVID-19. Federal agencies will

make increased use of data to guide the public health response against COVID-19. To that end, Agencies will collect, aggregate, share, and analyze non-personally identifiable data, and take steps to make it publicly available and in a machine-readable form to enhance COVID-19 response efforts. And the federal government will facilitate evidence-based decision-making through focused data-based projects. These efforts will require collaboration with state, local, Tribal, and territorial governments to aggregate and analyze data for critical decisions to track access to vaccines and testing, reopen schools and businesses, address disparities in COVID-19 infections and health outcomes, and enhance critical monitoring capacity where needed. In addition, critical response activities such as workforce mobilization and vaccination appointment scheduling may require new technology solutions. The federal government will provide technical support to ensure that these systems meet mission critical requirements to support a robust response.

Goal 4: Immediately expand emergency relief and exercise the Defense Production Act.

It's past time to fix America's COVID-response supply shortage problems for good. The United States will immediately address urgent supply gaps, which will require monitoring and strengthening supply chains, while also steering the distribution of supplies to areas with the greatest need. As new vaccines, testing protocols, and treatments are developed, they will also need to be manufactured in sufficient supply. To respond to this unprecedented operational challenge, the President is immediately expanding emergency relief by giving state and local governments the support they need. To make vaccines, tests, Personal Protective Equipment (PPE), and other critical supplies available for the duration of the pandemic, the President has directed the use of all available legal authorities, including the Defense Production Act (DPA), instructing departments and agencies to expand the availability of critical supplies, to increase stockpiles so that PPE is available to be used in the recommended safe manner, and to start to fill all supply shortfalls immediately. To expand emergency relief and strengthen the supply chain, the government will:

Increase emergency funding to states and bolster the Federal Emergency Management Agency (FEMA) response. The President will issue a Presidential Memorandum entitled *Extend Federal Support to Governors' Use of National Guard to Respond to COVID-19 and to Increase Reimbursement and other Assistance Provided to States,* directing FEMA to fully reimburse states for the cost of National Guard personnel and emergency supplies, including emergency supplies like PPE for schools and child care providers.

Fill supply shortfalls by invoking the Defense Production Act (DPA). The United States is taking immediate action to fill supply shortfalls for vaccination supplies, testing supplies, and PPE. The President will issue Executive Order *A Sustainable Public Health Supply Chain* which directs agencies to fill supply shortfalls using all available legal authorities, including the DPA, and the United States has identified twelve immediate supply shortfalls that will be critical to the pandemic response, including shortages in the dead-space needle syringes available to administer the vaccine. The President has directed relevant agencies to exercise all appropriate authorities, including the DPA, to accelerate manufacturing, delivery, and administration to meet shortfalls in these twelve categories of critical supplies, including taking action to increase the availability of supplies like N95 masks, isolation gowns, nitrile gloves, polymerase chain reaction **(**PCR) sample collection swabs, test reagents, pipette tips, laboratory analysis machines for PCR tests, high-absorbency foam swabs, nitrocellulose material for rapid antigen tests, rapid test kits, low dead-space needles and syringes, and all the necessary equipment and material to accelerate the manufacture, delivery, and administration of COVID-19 vaccine.

Identify and solve urgent COVID-19 related supply gaps and strengthen the supply chain. The *A Sustainable Public Health Supply Chain* executive order will also direct federal agencies to fill supply shortfalls

using all available legal authorities.The federal government will focus on the near-term goal of building a stable, secure, and resilient supply chain with increased domestic manufacturing in four key critical sectors:

- Antigen and molecular-based testing;
- PPE and durable medical equipment;
- Vaccine development and manufacturing; and
- Therapeutics and key drugs.

The federal government will immediately focus on procuring supplies that will be critical to control the spread of COVID-19 by initiating contracts, entering into purchase commitments, making investments to produce supplies and expanding manufacturing capacity.

Secure the pandemic supply chain and create a manufacturing base in the United States. To respond more effectively to this crisis, and ensure that the United States is able to respond more quickly and efficiently to the next pandemic, we need a resilient, domestic public health industrial base. The U.S. Government will not only secure supplies for fighting the COVID-19 pandemic, but also build toward a future, flexible supply chain and expand an American manufacturing capability where the United States is not dependent on other countries in a crisis. To this end, *A Sustainable Public Health Supply Chain* will direct the development of a new Pandemic Supply Chain Resilience Strategy.

Improve distribution and expand availability of critical materials. After conducting a review of existing COVID-19 and related pandemic supply chain distribution plans and working in consultation with state and regional compacts, the United States will coordinate distribution plans, prioritizing areas of highest-risk and highest need, and set up a structure to improve the distribution of critical materials. To work toward expanding the affordability and accessibility of supplies, *A Sustainable Public Health Supply Chain* will direct the Department of Defense (DOD), HHS, and Department of Homeland Security (DHS) to develop recommendations to address the pricing of COVID-19 supplies. The federal government will also reduce the opacity of the market for critical supplies and supply chains by clearly and rapidly communicating with states, health care providers, and manufacturers about federal interventions.

Goal 5: Safely reopen schools, businesses, and travel, while protecting workers.

Reopening schools, businesses, travel, and our economy will require major, unified federal investments in rapid testing, an expanded rapid response public health workforce, clear guidance and protections, and support for people to stay home when they are infected to stop the spread of COVID-19. At the same time that the United States takes immediate steps to achieve an overall decrease in COVID-19 spread, it will also support the safe operation of schools, businesses, and travel. To protect workers and safely reopen, schools, businesses, and travel, the United States will:

Implement a national strategy to support safely reopening schools. The United States is committed to ensuring that students and educators are able to resume safe, in-person learning as quickly as possible, with the goal of getting a majority of K-8 schools safely open in 100 days. The President will issue Executive Order *Supporting the Reopening and Continuing Operation of Schools and Early Childhood Education Providers* which directs a national strategy for safely reopening schools, including requiring the Departments of Education and HHS to provide guidance on safe reopening and operating, and to develop a Safer Schools and Campuses Best Practices Clearinghouse to share lessons learned and best practices from across the country. Presidential Memorandum *Extend Federal Support to Governors' Use of National Guard to Respond to COVID-19 and to Increase Reimbursement and other Assistance Provided to States* will restore full reimbursement for eligible costs necessary to support safe school reopening through the FEMA Disaster Relief Fund and the President has called on Congress to provide at least $130 billion

in dedicated funding to schools, $350 billion in flexible state and local relief funds that will help districts avoid lay-offs and close budget gaps, and additional resources so that schools can safely reopen, including funds to implement screening testing. The Administration will release a handbook that helps schools and local leaders implement the precautions and strategies necessary for safe reopening. It will also work with states and local school districts to support screening testing in schools, including working with states to ensure an adequate supply of test kits.

Support safe operations at child care centers and at-home providers. With enrollments down and costs up due to COVID-19 precautions, child care providers are struggling to stay afloat while providing vital services to their communities. Due to increased costs and lower enrollment, a recent survey of child care providers showed that most child care providers expect that they will close within a few months without relief, or are uncertain how long they can stay open.[1] If not addressed, child care providers will close and millions of parents will be left to make devastating choices between caring for their children and working to put food on the table. President Biden has called on Congress to provide $25 billion in emergency stabilization to support hard-hit child care providers through the pandemic. These funds would help providers pay rent, utilities, and payroll, as well as cover pandemic-related costs like personal protective equipment, ventilation supplies, smaller group sizes, and alterations to physical spaces that improve safety. The President has also called on Congress to provide $15 billion to help families struggling to afford child care.

Support equitable reopening and operation in higher education. College enrollment for high school graduates was down more than 20% in 2020 compared to 2019, and students from low-income families are nearly twice as likely to report canceling their plans to attend college. Reopening and keeping colleges open is critical to ensuring that all Americans have a shot at a college credential -- but it must be done safely, to protect the health of students, faculty, staff, and the broader community. To support colleges through the pandemic, President Biden has requested that Congress provide an additional $35 billion in emergency stabilization funds for higher education.

Protect workers and issue stronger worker safety guidance. It is critical that the federal government protect the health and safety of America's workers and take swift action to prevent workers from contracting COVID-19 in the workplace. The President will issue Executive Order *Protecting Worker Health and Safety* which directs the Occupational Safety and Health Administration (OSHA) to issue updated guidance on COVID-19 worker protections. It also directs OSHA and the Mine Safety and Health Administration (MSHA) to consider whether emergency temporary standards, including with respect to mask-wearing, are necessary. President Biden is taking steps to cover workers not typically covered by OSHA or MSHA by directing agencies like the Department of Transportation to keep workers safe. He has also called on Congress to extend and expand emergency paid leave; to allow OSHA to issue standards covering a broad set of workers, like many public workers on the frontlines; to provide additional funding for worker health and safety enforcement, and to provide grant funding for organizations to help keep vulnerable workers healthy and safe from COVID-19.

Provide guidance and support to safely open businesses. To maintain safe operations during the pandemic, businesses need to know how to change their practices to protect employees and customers. As the conditions of the pandemic continue to evolve and more Americans get vaccinated, the business community needs clear information from the federal government on what to expect and how to adapt their operations. Many businesses affected by the pandemic–particularly the smallest ones–need additional support to adjust their physical spaces and purchase PPE and supplies. The United States will immediately work to prioritize funds under the recent COVID relief package to the companies hardest hit by COVID-19 and in compliance with public health restrictions, ensuring that small businesses have the funds they need to operate safely. Further, the Small Business Administration will work with the

Department of Labor to disseminate updated OSHA guidance on worker safety and support businesses in implementing the updated guidance.

Promote Safe Travel. Ensuring that people can safely travel will be critical for families and to jumpstarting the economy, which is why the President will issue an executive order that requires mask-wearing on certain public modes of transportation and at ports of entry to the United States. For international air travel, Executive Order *Promoting COVID-19 Safety in Domestic and International Travel* will require a recent negative COVID-19 test result prior to departure and quarantine on arrival, consistent with CDC guidelines. The Executive Order will also direct agencies to develop options for expanding public health measures for domestic travel and cross-border land and sea travel and calls for incentives to support and encourage compliance with CDC guidelines on public transportation.

Goal 6: Protect those most at risk and advance equity, including across racial, ethnic and rural/urban lines.

The COVID-19 pandemic has exposed and exacerbated severe and pervasive health inequities among communities defined by race, ethnicity, geography, disability, sexual orientation/gender identity, and other factors. Addressing this pandemic's devastating toll is both a moral imperative and pragmatic policy. The federal government will address disparities in rates of infection, illness and death. Each of the goals of this National Strategy include comprehensive actions that will address these disparities and advance equity. In addition, the United States will:

Establish the COVID-19 Health Equity Task Force. The President will issue Executive Order *Ensuring an Equitable Pandemic Response and Recovery* which establishes a high-level task force to address COVID-19 related health and social inequities and help coordinate an equitable pandemic response and recovery. The Task Force will convene national experts on health equity and provide recommendations on how to mitigate COVID-19 health inequities.

Increase data collection and reporting for high risk groups. The fragmented and limited availability of data by race, ethnicity, geography, disability and other demographic variables delays recognition of risk and a targeted response. President Biden will issue the Executive Order *Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats* directing federal agencies to expand their data infrastructure to increase collection and reporting of health data for high risk populations, while reaffirming data privacy. Using these data, the federal government will identify high-risk communities, track resource distribution and evaluate the effectiveness of the response. Finally, HHS will optimize data collection from public and private entities to increase the availability of data by race, ethnicity, geography, disability, and other demographic variables, as feasible.

Ensure equitable access to critical COVID-19 PPE, tests, therapies and vaccines. The continued surge of COVID-19 highlights the critical importance of meaningful access to PPE, tests, therapies, and vaccines to prevent spread and reduce illness and death in high-risk populations and settings. The federal government will center equity in its COVID-19 response, providing PPE, tests, vaccines, therapeutics and other resources in a fair and transparent way. A targeted, stakeholder- and data-informed vaccination communication campaign will be launched to encourage vaccination in all communities. Additionally, the CDC will work with states and localities to update their pandemic plans. Finally, through prioritizing diverse and inclusive representation in clinical research and strengthening enforcement of anti-discrimination requirements, the federal government will increase access to effective COVID-19 care and treatment.

Expand access to high quality health care. The federal government will work to expand affordable coverage to increase access to care during this pandemic, and the Task Force will provide recommendations to align federal incentives with improved clinical outcomes. Specific actions include efforts to

increase funding for community health centers, provide greater assistance to safety net institutions, strengthen home- and community-based services, expand mental health care, and support care and research on the effects of long COVID.

Expand the clinical and public health workforce, including community-based workers. In order to assure equitable PPE distribution, testing, contact tracing, social support for quarantine and isolation and vaccination, there must be sufficient workforce to serve the communities in greatest need. The federal government will augment the health workforce, including with community based workers, as outlined in Goal Three above, to help fill this critical gap. The federal government will create a United States Public Health Workforce Program of new community based workers to assist with testing, tracing and vaccination. Additionally, it will deploy federal workers to assist with the COVID-19 response in under-resourced areas.

Strengthen the social service safety net to address unmet basic needs. With millions of families already struggling pre-pandemic to meet basic needs, including food, housing and transportation, COVID-19 has exacerbated these challenges. These challenges contribute to difficulties by many to adhere to public health guidance regarding social distancing and quarantine/isolation. This Administration is committed to addressing these needs in multiple ways, including providing paid sick leave, child care support, and rental assistance, with requested Congressional appropriations. Additionally, it will undertake agency actions to designate COVID-19 health equity leads and extend eligibility and enrollment flexibilities for select programs during the pandemic, as well work with community-based, multi-sector organizations to align health and social interventions.

Support communities most at-risk for COVID-19. The federal government is committed to supporting populations that are most vulnerable to COVID-19. Whether residing in congregate settings (such as prisons, nursing and group homes, and homeless shelters), serving as essential workers, living as a person with a disability, or bearing the burden of chronic medical conditions, these vulnerable populations are disproportionately composed of people of color. The CDC will develop and update clear public health guidance for such high-risk populations and settings to further minimize the risk of COVID infection, and work with states to update their pandemic plans to incorporate such guidance as necessary.

Goal 7: Restore U.S. leadership globally and build better preparedness for future threats.

U.S. international engagement to combat COVID-19, promote health, and advance global health security is urgent to save lives, promote economic recovery, and develop resilience against future biological catastrophes. America's withdrawal from the world stage has impeded progress on a global COVID-19 response and left the U.S. more vulnerable to future pandemics. The Biden-Harris Administration will restore America's role in leading the world through global crises, advancing global health security and the Global Health Security Agenda, including by supporting the international pandemic response effort, providing humanitarian relief and global health assistance, and building resilience for future epidemics and pandemics. The President will issue a National Security Directive that directs steps to restore U.S. leadership globally and build better preparedness. In addition, the United States of America will:

Restore the U.S. relationship with the World Health Organization and seek to strengthen and reform it. The World Health Organization (WHO) is essential to coordinating the international response to COVID-19 and improving the health of all people**.** On his first day in office, the President sent letters informing the UN Secretary-General and the WHO Director General of his decision to cease the previous Administration's process of withdrawal from the WHO and meet its financial obligations. The United States is participating in the WHO Executive Board meeting this month, and will take actions to strengthen and reform the WHO.

Surge the international COVID-19 public health & humanitarian response. The United States will commit to multilateralism in the international COVID-19 public health and humanitarian response. The President will restore U.S. leadership on the global COVID-19 response and health security, laying out an active role for the United States in surging the health and humanitarian response to COVID-19, and supporting global vaccine distribution and research and development for treatments, tests, and vaccines. The United States will support the Access to COVID-19 Tools (ACT) Accelerator, join the COVID-19 Vaccines Global Access (COVAX) Facility, and seek to strengthen other existing multilateral initiatives, such as the Coalition for Epidemic Preparedness Innovations; Gavi, the Vaccine Alliance; and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The United States will also take steps to enhance humanitarian relief and support for the capacity of the most vulnerable communities to prevent, detect, respond to, mitigate, and recover from impacts of COVID-19, such as food insecurity and gender-based violence.

Restore U.S. leadership to the international COVID-19 response and advance global health security and diplomacy. The United States will promote sustainable global health and global health security, rebuild health security alliances, elevate U.S. efforts to support the Global Health Security Agenda, and revitalize U.S. leadership. The United States will advance global health security financing, promote efforts to harmonize crisis response and early warning for public health emergencies, and strengthen global pandemic supply chains. The United States will also work within the UN Security Council and with partners to strengthen multilateral public health and humanitarian cooperation on the COVID-19 response, global institutions to combat disease, and a global health security architecture to prevent, detect, and respond to future biological threats.

Build better biopreparedness and expand resilience for biological threats. The United States is committed to strengthening U.S. biopreparedness and capacity to counter COVID-19 and future biological threats. The President has immediately restored the White House National Security Council Directorate for Global Health Security and Biodefense, originally established by the Obama-Biden administration. He has reconstituted White House and Administration-wide infrastructure for monitoring and responding to emerging biological risks. And to improve the United States' preparedness, the Administration will work to secure funding and Congressional support to establish an integrated, National Center for Epidemic Forecasting and Outbreak Analytics to modernize global early warning and trigger systems to prevent, detect, and respond to biological threats. The United States will also review and seek to strengthen our pandemic supply chain, public health workforce, medical countermeasure development and distribution, bioeconomic investment and technology-related risks.

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[1] https://www.naeyc.org/sites/default/files/globally-shared/downloads/PDFs/our-work/public-policy-advocacy/naeyc_policy_crisis_coronavirus_december_survey_data.pdf

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From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Mar. 23 (incl. DOE Resources, CDC Lab Update, CSTE Webinar, CDC Call to Action, Priority Science Questions, and more)
Date:	Tuesday, March 23, 2021 4:14:59 PM
Attachments:	image001.png image002.png Laboratory Update CMS Posts FAQ for Reporting Sequencing Results for SARS-CoV-2 Variants.msg HHS COVID-19 Update - 322.msg COVID-19 Partner Updates March 22.msg CLIA SARS-CoV-2 Variant FAQ_updated 3.19.21.pdf Department of Education Resources for Reopening Schools.pdf Back to School Call to Action_Final.pdf Partner Update - Priority Science Questions.pdf

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- Department of Education Resources for Reopening Schools [Attachment]
    - Please see attached for information regarding:
        - The Department of Education's virtual National Safe School Reopening Summit occurring **tomorrow**, Wednesday, **March 24** (registration is available here)
        - Details on a "Safer Schools and Campuses Best Practices Clearinghouse," which includes a "Lessons from the Field" webinar series that will begin **Wednesday, March 31** (information is available here)
        - The upcoming release of Volume 2 of the K-12 COVID-19 Handbook for districts, schools, and educators
- CDC Lab Update: CMS Posts FAQ for Reporting Sequencing Results for SARS-CoV-2 Variants [Attachment, Link]
    - Please see the following message from CDC's Laboratory Outreach Communication System (LOCS):
        - *On March 19, 2021, the U.S. Centers for Medicare & Medicaid Services (CMS) posted the "CLIA SARS-CoV-2 Variant Testing Frequently Asked Question" document to provide information for facilities that perform sequencing to identify SARS- CoV-2 genetic variants. CMS will not cite CLIA-certified laboratories that perform SARS-CoV-2 genetic variant testing on identified specimens and report*

patient-specific variant results to state or local public health departments without establishing performance specifications as required by §493.1253(b)(2), provided that the laboratory only reports patient-specific results to a public health department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment. If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA-certified laboratory and in compliance with all applicable CLIA regulations."

- The FAQ document is available on CMS' website here.

- CSTE Webinar: "Unpacking the COVID-19 Genomic Epidemiology Toolkit" [Link]
  - The next installment of CSTE's membership webinar series will take place **Thursday, March 25** at **3:00 pm EDT**. The webinar, co-hosted by CSTE and CDC's Office of Advanced Molecular Detection (AMD), will cover the recently released COVID-19 Genomic Epidemiology Toolkit. This toolkit is designed to help epidemiologists use genomic data to track and investigate SARS-CoV-2 in their jurisdictions, and consists of brief, modular video presentations with audio transcripts. During the webinar, featured presenters will showcase toolkit features and answer questions.
  - Call capacity is limited to 1,000 participants, and is first-come, first-served. Call information is below:
    - Weblink: https://webinar.ringcentral.com/j/1466093845
      Telephone: (470) 860-2200 *[East]* | (773) 231-9226 *[North]* | (469) 445-0100 *[South]* | (623) 404-9000 *[West]* | (720) 902-7700 *[Central]*
      Meeting ID: 146 609 3845
      One-Tap Mobile: +1(470)8692200,,1466093845# *[East]* |
      +1(773)2319226,,1466093845# *[North]* |
      +1(469)4450100,,1466093845# *[South]* |
      +1(623)4049000,,1466093845# *[West]* |
      +1(720)9027700,,1466093845# *[Central]*

- CDC Call to Action: "Help Kids' Safe Return to School - Get Caught Up on Recommended Vaccines" [Attachment]
  - Please see below for a message from CDC's COVID-19 Vaccine Task Force Partnership Team:
    - *"COVID-19 disrupted both in-person learning and routine well-child visits for many children over the last year. As a result, too many children have fallen behind on receiving recommended vaccines. We all want our kids to be back in school safely, and that means getting caught up on vaccines that were missed over the last year. Please find attached a Call to Action, which outlines efforts needed to get children caught up on vaccinations. This letter will be posted on the CDC website soon and we will be hosting a partner webinar in the near future to discuss this important topic. Thank you for your continued partnership and attention to this critical issue."*
  - The referenced Call to Action is attached to this email.

- CDC Priority Science Questions [Attachment, Link]
  - Please see attached for a message from CDC's State, Tribal, Local and Territorial

Support Task Force, regarding the release of a new set of *Priority Science Questions* intended to guide prioritization of CDC's scientific research portfolio related to COVID-19, including articles published in *MMWR* and other scientific journals. These questions are in response to the objectives in CDC's *Science Agenda for COVID-19*.
    - The new set of Priority Science Questions is now available on CDC's website here.

Standing Updates

- CDC Partner Update Call: "Understanding the Role of Telehealth Usage During the COVID-19 Pandemic" [Link]
    - CDC will host the next installment of its weekly partner call **Monday, March 29** at **3:00 pm EDT**. Dr. Cynthia Ogden will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Drs Hanna B Demeke, Paramjit Sandhu, and Antoni Neri will discuss highlights on the usage of telehealth systems during the COVID-19 Response.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 3/29" in the subject line. The call will be recorded and posted to CDC's website here.
- CDC Partner Update – March 22 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – March 22 [Attachment]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
    - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

Help Kids' Safe Return to School - Get Caught Up on Recommended Vaccines

COVID-19 disrupted both in-person learning and routine well-child visits for many children over the last year. As a result, too many children have fallen behind on receiving recommended vaccines[1]. We all want our kids to be back in school safely, and that means getting caught up on vaccines that were missed over the last year. CDC's public sector vaccine ordering data show a 14% drop in 2020-2021 compared to 2019, and measles vaccine is down by more than 20%. Kids need to get caught up now so that they are protected as they go back to in-person learning. Catch-up vaccination will require efforts from healthcare systems, health care providers, schools, state and local governments, and families.

Healthcare systems and healthcare providers should:

- Identify families whose children have missed doses and contact them to schedule appointments
- Prompt clinicians when these children are seen to deliver vaccines that are due or overdue
- Let families know what precautions are in place for safe delivery of in-person services

Healthcare provider organizations should:

- Encourage members to identify and follow up with families whose children have missed doses to get appointments scheduled

Schools and state and local governments agencies should:

- Send reminders to families about school immunization requirements
- Follow-up with families of children who are not in compliance with requirements to encourage compliance
- Use the state's immunization information system's reminder-recall capacity to notify families whose children have fallen behind on vaccines

We all should:

- Communicate directly to families the importance of well-child visits and getting caught up on any recommended vaccines that were missed

Help us protect children by doing what you can to get kids caught up on recommended vaccines.

Sincerely,

Nancy Messonnier, MD
Senior Official, CDC COVID-19 Vaccine Task Force
Director, National Center for Immunization and Respiratory Diseases

[1] Centers for Disease Control and Prevention. General Best Practice Guidelines for Immunization: Vaccination Programs. ACIP Vaccination Programs Guidelines for Immunization | Recommendations | CDC. Accessed March 21, 2021.

CLIA SARS-CoV-2 Variant Testing Frequently Asked Question
Date: 3/19/2021

Does a facility that performs surveillance testing to identify SARS- CoV-2 genetic variants need a CLIA certificate?

CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 genetic variant testing on identified specimens in which patient-specific results are reported to State or local Public Health Departments. As defined by Centers for Disease Control and Prevention (CDC), public health surveillance testing for SARS-CoV-2 is intended to monitor community- or population-level outbreaks of disease, or to characterize the incidence and prevalence of disease. Public health surveillance testing is performed on de-identified specimens, and thus results are not linked to individuals. Public health surveillance testing cannot be used for individual decision-making. See CDC's Testing Strategies for SARS-CoV-2 (Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories).

Generally, surveillance testing using sequencing technology to identify SARS-CoV-2 genetic variants can be performed in a facility that is NOT CLIA certified, provided that patient-specific results are **not** reported to (1) the individual who was tested or (2) their health care provider. If at any time a facility intends to perform testing on identified specimens and report a patient-specific SARS-CoV-2 genetic variant test result to the individual who was tested or to their health care provider, the facility must comply with CLIA and is thereby required to obtain the appropriate CLIA certificate in accordance with 42 CFR Part 493, laboratory requirements.

However, as indicated above, CMS will not take action against non-CLIA certified facilities that perform SARS-CoV-2 genetic variant testing on identified specimens and report patient-specific results to State or local Public Health Departments, provided that the facility only reports patient-specific results to a Public Health Department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment. The Public Health Departments should only use these results for public health purposes, such as contact tracing, outbreak detection, etc. If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA certified laboratory and in compliance with all applicable CLIA regulations (42 CFR part 493).

CLIA-certified laboratories continue to be permitted to report patient-specific results to authorized persons, which may include the individual who was tested, their health care provider, or a Public Health Department[1], as applicable, for SARS-CoV-2 genetic variant testing and other tests. If a CLIA certified laboratory performing SARS-CoV-2 genetic variant testing decides to report patient-specific results to an individual or their healthcare provider, then the laboratory must establish performance specifications for their assay. See 42 CFR §493.1253(b)(2). CLIA regulations are not prescriptive as to the number of samples required to establish performance specifications. When a genetic variant is discovered during a public health emergency, there may be very limited number of samples available for the establishment of performance specifications. This does not necessarily prevent laboratories from utilizing assays testing for the novel variant. When the number of samples that a laboratory would normally run for the establishment of performance specifications are not available, it is the responsibility of the laboratory director (LD) to ensure that procedures used are adequate to establish the accuracy, precision, and other pertinent performance characteristics of the method. While initially there may not be many samples to establish performance specifications, as time goes on, and as more samples become

[1] While most if not all public health departments would likely meet the CLIA definition of an "authorized person", see 42 CFR §493.2 ("Authorized person means an individual authorized under State law to order tests or receive test results, or both."), this would technically be determined on a case-by-case basis.

available, the LD may choose to enhance their assay to the level of other tests in their laboratory. *However, CMS will not cite CLIA certified laboratories that perform SARS-CoV-2 genetic variant testing on identified specimens and report patient-specific variant results to* State or local *Public Health Departments without establishing performance specifications as required by §493.1253(b)(2), provided that the laboratory only reports patient-specific results to a Public Health Department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment. If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA-certified laboratory and in compliance with all applicable CLIA regulations.*

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Monday, March 22, 2021 1:00 PM EDT
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Mueller, Trisha (CDC/DDNID/NCCDPHP/DRH) <czj5@cdc.gov>; CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Subject: COVID-19 Partner Updates: March 22

Good afternoon partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov.

Thank you for your partnership.

Best,
Jordan Moody

STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

Monday, March 22, 2021

CDC All-State, Tribal, Local, and Territorial (STLT) Update Call

- **CDC All-STLT Update Call (Formerly All-State Update Call):** We are excited to announce that on Monday, March 22, the All-STLT Update Call transitioned to a Zoom webinar format. Click here to register for the Zoom webinar. Once you register you will receive a confirmation link. **Please save this link,** it will work for the entire series. The weekly call series will continue to be held each Monday from 2:00-2:45 PM EST. If you have any questions about this transition or would like to join our distribution list, please email eocevent424@cdc.gov.

CDC Resources

- **COVID Data Tracker**: Provides maps and charts tracking cases, deaths, and trends of COVID-19 in the United States, updated daily by 8:00 PM EST.
- **COVID Data Tracker Weekly Review:** This webpage and newsletter highlights key data from COVID Data Tracker, CDC's home for COVID-19 data, along with high priority supplemental information, narrative interpretations of the data, and visualizations from the week. The *Weekly Review* also summarizes important trends in the pandemic and provides CDC data and reporting in a centralized location. Sign up to have the COVID Data Tracker Weekly Review delivered to your inbox every Friday.
- **COVID-19 Science Update**: Released March 19, 2021, this Science Update provides summaries of detection, burden, and impact of SARS—CoV-2; transmission among primary and secondary students and staff; natural history of SARS-CoV-2 infection; and prevention, mitigation, and intervention strategies.

Upcoming Meetings

- **NAACHO's Nursing Home TeleICAR Training**: Thursday, March 25, 3:00-4:00 PM EST. This webinar covers a high-level overview of the TeleICAR process, including scheduling and outreach, conducting the ICAR, providing feedback, documenting observations, and follow-up. This training is recommended for jurisdictions that are new to the TeleICAR process or are onboarding new staff that will be tasked with conducting ICARs in nursing home settings.
- **Precision Public Health in the Pandemic:** Wednesday, May 26, 1:00-2:00 PM EST. MicrobeTrace is a secure, local, and user-friendly data visualization tool developed by the CDC, initially for HIV cluster detection and response, that has been rapidly retooled and adopted for the COVID-19 response. MicrobeTrace allows users to map transmission networks based on person-to-person contacts, pathogen-to-pathogen genetic distance, or person-to-place exposures. This webinar will provide an overview of how MicrobeTrace can be used in the COVID-19 response and will present examples of how MicrobeTrace has been used in investigations of COVID-19 outbreaks in poultry facilities, K-12 schools, institutes of higher education, and nursing homes.

The Department of Education will convene a virtual National Safe School Reopening Summit 3/24/2021 to share best practices, discuss successful prevention and reopening strategies, and learn from students, educators, and other experts. The Summit will offer a forum for researchers and practitioners to discuss strategies for addressing the social, emotional, and academic needs of students—with a focus on those students most underserved—as many schools across the country continue their work to safely reopen. It will also feature experts from Centers for Disease Control and Prevention (CDC) and the U.S. Department of Education who will discuss how schools can safely reopen and how the Biden Administration is providing support and resources to schools, educators, and students as they work to reopen safely and address student needs. Agenda and registration can be found at Agenda - National Safe School Reopening Summit (cvent.com)

The Department is launching the "Safer Schools and Campuses Best Practices Clearinghouse" called for in President Biden's Executive Order, starting with the "Lessons from the Field" webinar series. The Clearinghouse will highlight lessons learned and best practices that can help schools and districts identify opportunities to best utilize American Rescue Plan funds to meet their unique needs. The Clearinghouse will include resources that target the needs of students and teachers, faculty and staff in early childhood programs, K-12 schools, and colleges and universities in three main areas:

- **Safe and Healthy Environments:** School and campus approaches to implementing the Centers for Disease Control and Prevention's (CDC) recommended prevention strategies and preparing for and sustaining in-person operations safely.
- **Providing Supports to Students:** School and campus strategies to meet student social, emotional, mental health, academic, financial, and other needs, including access to food and other basic needs.
- **Teacher, Faculty, and Staff Well-Being, Professional Development, and Supports:** School and campus strategies to address the social, emotional, health, and other needs of teachers, faculty, and staff.

The Clearinghouse's "Lessons from the Field" webinar series will begin on March 31. The Department welcomes lessons learned and best practices from the field for consideration for the Clearinghouse, including those with an educational equity focus. Submissions should be sent via email to: Bestpracticesclearinghouse@ed.gov. Please visit https://bestpracticesclearinghouse.ed.gov/ for more information about the Clearinghouse.

The Department will release Volume 2 of the K-12 COVID-19 Handbook for districts, schools, and educators in early April. This volume will provide research-based strategies to address the impact of COVID-19 on students, educators, and staff, especially for historically underserved students and communities that have been hit hardest by the pandemic. In February, the Department released the first volume of the COVID-19 Handbook, which provided educators and staff with practical examples, roadmaps, and tools to implement CDC's K-12 operational strategy for in-person learning, including the recommended five key prevention measures. Since the release of Volume 1, the Department and CDC have transmitted the handbook and offered technical assistance to educators; state and local elected officials in every state and

territory, including governors, chief state school officers, state boards of education, state legislative leaders and staff, mayors, and superintendents; and thousands of stakeholder organizations across the country.

From: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Sent: Monday, March 22, 2021 8:20 PM EDT
To: Baker, Michael (OS/IEA) <Michael.Baker@hhs.gov>
Subject: HHS COVID-19 Update - 3/22

Dear Partner—

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 22, 2021:

Highlights from Friday and Monday's White House COVID-19 Response Team briefings:

Jeff Zients:

- **Increasing Vaccine Supply:** The President has taken aggressive action to move up the production timelines for all three vaccines — Pfizer, Moderna, and Johnson & Johnson. As a result, by the end of May, we will have enough vaccine for every adult in the United States. This week, about 22 million doses went out to states, Tribes, and territories, and through the federal channels, including pharmacies and community health centers.
- **Increasing the Number of Vaccinators:** The Administration has deployed nearly 6,000 federal personnel to serve as vaccinators and support vaccinations, including over 2,000 active-duty military men and women. At the President's direction, that number will grow to more than 6,000 active-duty troops over the coming weeks.
- **Increasing the Number of Places to get Vaccinated**: The Administration has provided federal support for more than 600 community vaccination sites and more than 1 million shots have been administered at federally run community vaccination sites across the country with more than 60 percent of those vaccinations administered to minority populations. The American Rescue Plan will allow the Administration to continue to increase the number of community vaccination centers. The Administration is already sending vaccines directly to 250 community health centers and by the end of April, vaccines will be delivered to an additional 700 community health centers.
- **Global Efforts to Address the Pandemic**: Under the President's direction, the U.S. reengaged with the World Health Organization on day one of his presidency and the Administration is committed to providing the most funding to COVAX than any country in the world: $4 billion. We are also announcing that we are loaning about 4 million doses of our releasable AstraZeneca vaccines to Mexico and to Canada. This loan will not reduce the available supply of vaccines to Americans. The doses we are loaning are not approved for use in the United States. No American will be without a vaccine because of this action.

Andy Slavitt

- **Number of People Vaccinated:** This weekend was the first time that the U.S. reported vaccinating more than 3 million people on consecutive days. There are now a total of 81 million people — or nearly 1 in 3 adults — with at least one vaccine dose in the U.S., and 44 million who are fully vaccinated. Nearly 69 percent of seniors have now received their first vaccination, and 42 percent are fully vaccinated.
- **Federal Vaccination Sites:** Today, the state of Washington will receive its first federally-supported community vaccination site. The Yakima County CVC will be able to offer up to 1,200 shots per day. Local residents will be able to drive through the Central Washington State Fair Park and get a shot. This is the 22nd federally run vaccination site opened. Combined, they deliver nearly 100,000 shots per day.

Dr. Walensky:

- **Case Update:** The most recent seven-day average is about 53,800 cases per day, which is a slight increase from the previous seven-day period. And over the past two weeks, cases have continued to fluctuate somewhere between 50,000 and 60,000 daily cases. Hospital admissions have been relatively stable over the last two weeks, hovering around 4,500 to 5,000 admissions per day and deaths continue to decline with slightly under 1,000 deaths per day, but the rate of decline in deaths has slowed which is concerning.
- **Variant Spread:** Increasingly, states are seeing a growing proportion of their COVID-19 cases attributed to variants. The newly identified variant, B1427/B1429, is estimated to account for 52 percent of cases in California, 41 percent in Nevada, and 25 percent in Arizona. And the B117 variant is estimated to be responsible for 9 percent of cases in New Jersey and 8 percent in Florida.
- **Avoiding a Surge:** Taken together, these statistics should serve as a warning sign for the American people. As I've stated before, the continued relaxation of prevention measures while cases are still high, and while concerning variants are spreading rapidly throughout the United States, is a serious threat to the progress we have made as a nation. I'm calling the American people to action, whether vaccinated or not, to recommit to doing the right thing. Take the steps we know work to stop COVID-19: Wear a well-fitted mask, socially distant, avoid crowds and travel, and be ready to roll up your sleeve to get vaccinated when the vaccine is available to you.
- **Science on Safe Reopening of Schools:** Safe in-person instruction gives our children access to the critical, social, and mental health services that prepare them for the future, in addition to the vital educational needs that they need to succeed. Last week, the Journal of Clinical Infectious Diseases published a study that looked at COVID-19 in 251 Massachusetts school districts over a four-month period of time. It found that physical distancing of at least three feet between students could safely be adopted in school settings when everyone — students and staff — wore a mask at all times. CDC published additional studies that add to this evidence base (see below). Overall, all of the studies found that layered mitigation strategies, including strict use of masks among students and a distance of at least three feet between students, were common factors among the schools in these studies that demonstrated decreased transmission from COVID-19. This additional evidence continues to underscore why it is so important for schools to use layered prevention strategies to provide the greatest level of protection.
- **Updated CDC Guidance on School Reopening:** CDC updated their recommendations for physical distancing between students and classrooms in our K-12 operational strategy. Specifically, in elementary schools, CDC is now recommending that all students remain at least three feet apart in classrooms where everyone is wearing a mask, regardless of whether community COVID-19 risk is low, moderate, substantial, or high. In middle and high schools, CDC is also recommending that students be at least three feet apart in classrooms where everyone is wearing a mask and the community level of risk is low, moderate, or substantial. CDC recommends that middle and high school students should be at least six feet apart in communities where COVID 19 risk is high, unless cohorting (when groups of students are kept together with the same peers and staff, without close interaction with other groups or cohorts) is possible.

Dr. Fauci:

- **B.1.1.7 Variant (UK Variant):** The UK variant likely accounts now for about 20 to 30 percent of the infections in this country, and that number is growing. Of concern is that there are about 50 percent increase in transmission with this particular variant that has been documented in the UK, and there's likely an increase in severity of disease if infected with this variant. The way we can counter 117,

which is a growing threat in our country, is to do two things: to get as many people vaccinated as quickly and as expeditiously as possible with the vaccine that we know works against this variant; and finally, to implement the public health measures: masking, physical distancing, and avoiding congregate settings, particularly indoors.

- **Results from AstraZeneca Trial:** The vector that is used in this platform is a chimp adenovirus in which the SARs-CoV spike protein DNA was inserted (similar to Johnson & Johnson vaccine). Their efficacy data showed: 78.9 percent vaccine efficacy of preventing symptomatic disease; importantly, with regard to severe or critical disease requiring hospitalization, there was zero in the vaccine arm and five in the placebo arm. The good news is also that there was comparable efficacy across ethnicity and age; namely, a very good efficacy — 79.9 percent — in participants who are 65 years of age or older. The vaccine was well-tolerated, and the Data and Safety Monitoring Board identified no specific safety concerns related to the vaccines. Importantly, and this is a quote from the DSMB, "No evidence of disproportionate risk of thrombosis or events characterized by thrombosis among the 21,583 participants who received at least one dose. An in-depth search of the database for venous thrombosis revealed no events in this study." Importantly, this vaccine can be stored, transported, and handled at refrigerator temperatures for at least six months. And also, importantly, conditional marketing authorization or emergency use is already in play in more than 70 countries across six continents, and it has been given emergency use listing by the WHO.

Vaccine Updates

Investigational AstraZeneca Vaccine Prevents COVID-19: Results from a large clinical trial in the United States and South America indicate that AstraZeneca's COVID-19 vaccine, AZD1222, is well-tolerated and protects against symptomatic COVID-19 disease, including severe disease or hospitalization. The independent Data and Safety Monitoring Board (DSMB) overseeing the trial identified no safety concerns related to the vaccine. The United Kingdom-based global biopharmaceutical company AstraZeneca developed the vaccine and led the trial as regulatory sponsor.

Vaccines and Health Departments. This page provides states, tribes, localities, and territories health facilities with key resources on COVID-19 vaccination information including operational guidance, funding, reporting, training and more. As the COVID-19 vaccination program is implemented across the United States, jurisdictions and organizations confront this historic and challenging undertaking, tailoring programs to their population's needs. Learn about their unique approaches to distributing the COVID-19 vaccine and educating their populations.

Use of Social Media to Engage Long-Term Care Residents: As COVID-19 vaccines roll out across the country, states continue to find ways to communicate with their communities and citizens about COVID-19, including the importance of getting vaccinated. The need to keep physically distant from one another has presented unique challenges for talking with people about the importance of vaccination. The Connecticut Long Term Care Ombudsman Program (LTCOP) turned to social media to educate and answer questions about the COVID-19 vaccine.

Vaccination for Communities: CDC updated their resources and information on COVID-19 vaccinations for communities.

Vaccines for Disproportionally Affected Communities: CDC updated their resources for disproportionately affected communities. View vaccination FAQs for people experiencing homelessness.

Vaccines for Long-Term Care Facilities: CDC updated their resources and information on COVID-19 vaccinations for long-term care facilities. View information for long-term care facilities (LTCFs) to prepare staff, residents, and their families for COVID-19 vaccination.

Testing

Machine Learning-Based Screening Device to Identify Certain Biomarkers: The FDA issued an emergency use authorization (EUA) for the first machine learning-based Coronavirus Disease 2019 (COVID-19) non-diagnostic screening device that identifies certain biomarkers that are indicative of some types of conditions, such as hypercoagulation (a condition causing blood to clot more easily than normal). The Tiger Tech COVID Plus Monitor is intended for use by trained personnel to help prevent exposure to and spread of SARS-CoV-2, the virus that causes COVID-19. The device identifies certain biomarkers that may be indicative of SARS-CoV-2 infection as well as other hypercoagulable conditions (such as sepsis or cancer) or hyper-inflammatory states (such as severe allergic reactions), in asymptomatic individuals over the age of 5. The Tiger Tech COVID Plus Monitor is designed for use following a temperature reading that does not meet criteria for fever in settings where temperature check is being conducted in accordance with Centers for Disease Control and Prevention (CDC) and local institutional infection prevention and control guidelines. This device is not a substitute for a COVID-19 diagnostic test and is not intended for use in individuals with symptoms of COVID-19.

Screening for COVID-19: The FDA posted a new web page on FDA.gov, screening for COVID-19: deciding which test to use when establishing testing programs. This resource is intended for schools, workplaces, communities and others looking to establish testing programs to screen people without symptoms and with no known or suspected exposure to COVID-19. The FDA also posted a new template for test developers to help facilitate submission of an emergency use authorization (EUA) request for certain COVID-19 tests for screening using a serial testing approach.

Testing updates: As of Friday, 341 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 254 molecular tests and sample collection devices, 72 antibody and other immune response tests, and 15 antigen tests. There are 38 molecular authorizations that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home test, one over-the-counter (OTC) at-home antigen test, and one OTC molecular test.

Treatment

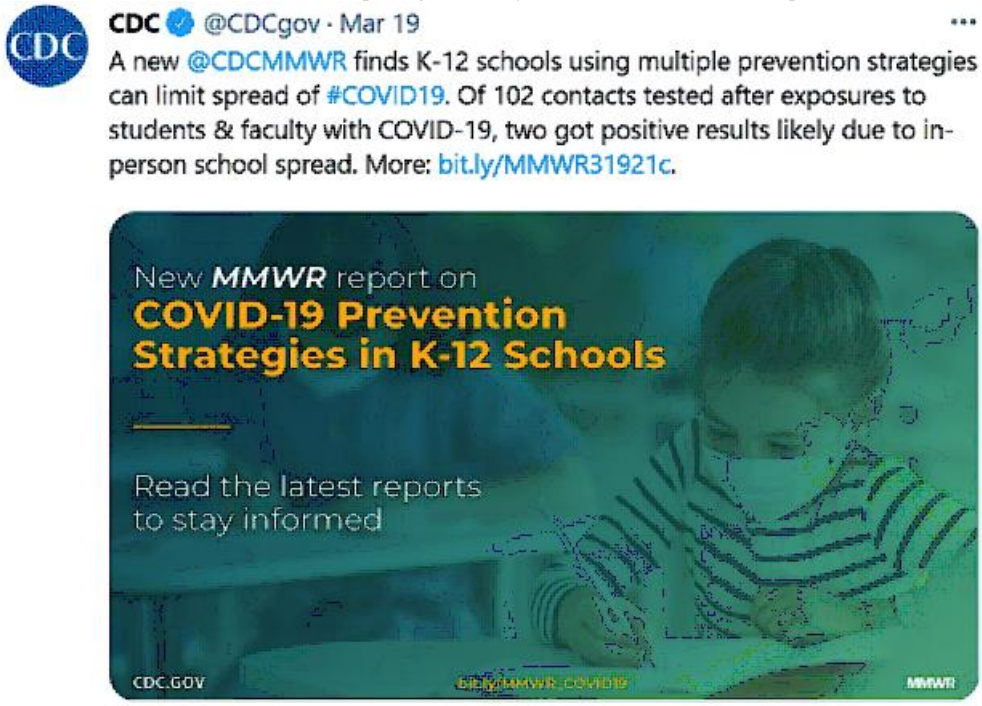
Monoclonal Antibodies' Responses to Variants: The FDA authorized revised fact sheets for health providers on March 18. The fact sheets now include additional information on susceptibility of specific SARS-CoV-2 variants to each of the three monoclonal antibody (mAb) therapies authorized for treating mild-to-moderate COVID-19 in at-risk patients: bamlanivimab, bamlanivimab with etesevimab, and casirivimab with imdevimab. Resistance by a variant may make a therapy less effective.

- The authorized mAb therapies continue to be available for direct ordering, except where contraindicated.
- Given concerns that the clinical activity of bamlanivimab is impacted by variants B.1.429 and B.1.427, ASPR is limiting distribution of

bamlanivimab to California, Arizona, and Nevada, where these variants are circulating in high numbers.

Reopening Schools Research and Updated Guidance

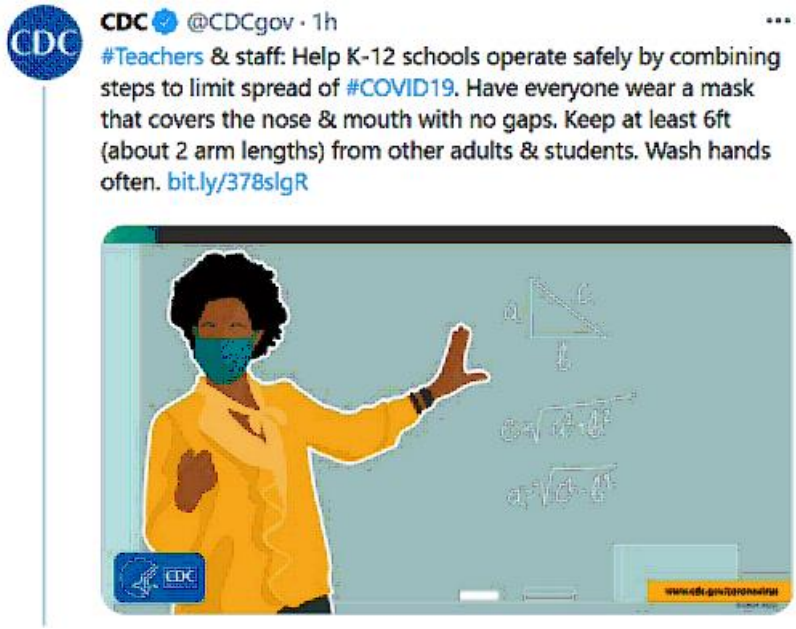
COVID-19 in Primary and Secondary School Settings: CDC released an MMWR on COVID-19 in primary and secondary school settings during the first semester of school reopening. COVID-19 school-related disease incidence among Florida students was correlated with community incidence in the counties observed and was highest in smaller counties, districts without mask requirements, and those that reopened earliest after closure in March 2020. Incidence increased with the proportion of students receiving in-person instruction. Fewer than 1% of registered students were identified as having school-related COVID-19. Both community-level and school-based mitigation measures are important in limiting transmission of COVID-19; school reopening can likely be achieved without widespread student illness in K–12 settings.



Low SARS-CoV-2 Transmission in Elementary Schools: CDC released an MMWR on low SARS-CoV-2 transmission in elementary schools in Salt Lake Country, Utah. SARS-CoV-2 testing was offered to 1,041 school contacts of 51 index patients across 20 elementary schools in Salt Lake County, Utah. In a high community transmission setting, low school-associated transmission was observed with a 0.7% secondary attack rate. Mask adherence was high, but students' classroom seats were <6 ft apart and a median of 3 ft apart. These findings add to evidence that in-person elementary schools can be opened safely with minimal in-school transmission when critical prevention strategies including mask use are implemented, even though maintaining ≥6 ft between students' seats might not be possible.

Investigation of SARS-CoV-2 Secondary Transmission in K-12 Schools: CDC released an MMWR on the pilot investigation of SARS-CoV-2 secondary transmission in Kindergarten through Grade 12 Schools implementing mitigation strategies in St. Louis County and City of Springfield, Missouri. In 22 participating K–12 schools implementing multiple COVID-19 mitigation strategies, school-based SARS-CoV-2 secondary transmission was detected in two of 102 tested close contacts of 37 persons with COVID-19. Among 21 tested student contacts participating in a modified quarantine, all SARS-CoV-2 test results were negative. Schools implementing strategies including mask mandates, physical distancing, and increased ventilation had much lower SARS-CoV-2 transmission than in the community. K–12 schools should continue implementing these measures and following CDC isolation and quarantine guidance to minimize secondary transmission in schools.

K-12 School Operational Strategy: CDC updated their K-12 school operational strategy. These changes include: revised physical distancing recommendations to reflect at least 3 feet between students in classrooms and provide clearer guidance when a greater distance (such as 6 feet) is recommended, clarified that ventilation is a component of strategies to clean and maintain healthy facilities, removed recommendation for physical barriers, clarified the role of community transmission levels in decision-making, and added guidance on interventions when clusters occur. View CDC's guidance and considerations for operating schools during COVID-19.



Transmission of SARS-CoV-2 in K-12 Schools: In the spring of 2020, all public kindergarten to grade 12 (K-12) schools in the United States closed for in-person instruction as a strategy to slow the spread of SARS-CoV-2. With the beginning of the fall term 2020, K-12 schools have variably used several models of instruction, including in-person, virtual, and hybrid models of instruction. Other countries have opened schools at varying points in the pandemic. Their experiences have contributed to our knowledge of the nature of SARS-CoV-2 transmission in schools and their surrounding communities.

Vaccines for Teachers, School Staff, and Childcare Workers: CDC updated their recommendations and information on COVID-19 vaccinations for school staff and childcare workers. On March 2, the U.S. Department of Health and Human Services issued a directive that all states immediately make teachers, school staff, and childcare workers eligible for COVID-19 vaccination across all vaccination providers.

Information for Specific Populations

Alcohol & Substance Use: CDC updated their resources for alcohol and substance use. Increased stress can lead to increases in alcohol and substance use. You may experience increased stress during this pandemic.

Pandemic Planning Scenarios: CDC and the Office of the Assistant Secretary for Preparedness and Response (ASPR) have developed five COVID-19 Pandemic Planning Scenarios that are designed to advance public health preparedness and planning and help inform decisions by public health officials who use mathematical modeling and by mathematical modelers throughout the federal government. A summary of these recent changes include: the Infection Fatality Ratio (IFR) parameter has been updated to reflect recently published estimates, the healthcare utilization statistics in Table 2 have been updated to include a 0–17-years-old age group, and this will be the final update to the COVID-19 Pandemic Planning Scenarios, as there is now a substantial body of published literature that modelers can draw on to inform parameter estimates and assumptions for their models for the general population and for sub-populations of interest.

Handlers of Service & Therapy Animals: CDC updated their guidance for handlers of service and therapy animals. These updates include vaccination and prevention information was added for service animal handlers and their household members.

Animal Testing Guidance: CDC updated their guidance for testing of animals for SARS-CoV-2. This guidance was developed for use by state public health veterinarians, state animal health officials, veterinarians, biologists, and wildlife health specialists.

Use of Inspectional Tools for Ensuring Access to Safe, Quality Food and Medical Products: In a March 18 FDA Voices, FDA leaders explain that over the past year, the agency's approach to foreign and domestic inspections for food and medical products has been both risk-based and deliberate. The COVID-19 pandemic required us to rework our business operations so that we could carry out our public health mission while protecting our workforce, and the workforces of those we regulate.

Non COVID-19 News

HHS Secretary Sworn In: On March 19, Xavier Becerra was sworn in as the 25th Secretary of the Department of Health and Human Services. Follow the Secretary on Twitter at @SecBecerra.

11th Anniversary of the Affordable Care Act: Today, HHS Secretary Xavier Becerra released the following statement on the eve of 11th anniversary of the Affordable Care Act: "In the eleven years since it became law, the Affordable Care Act has saved lives, brought down health care costs, and expanded Medicaid to our most vulnerable neighbors. The lifesaving law has been a game changer, protecting roughly 133 million people with pre-existing conditions and extending quality, affordable health care to millions more… Beginning on April 1, millions of Americans will be eligible for even more affordable options on HealthCare.gov. Because of the American Rescue Plan, four out of five enrollees will be able to qualify for coverage for as little as $10 per month."

Marvin Figueroa, Director
Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services

Washington, D.C.

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

From: Centers for Disease Control and Prevention <no-reply@emailupdates.cdc.gov>
Sent: Monday, March 22, 2021 2:00 PM EDT
To: commandcenter@cste.org <commandcenter@cste.org>
Subject: Laboratory Update: CMS Posts FAQ for Reporting Sequencing Results for SARS-CoV-2 Variants

Audience: Facilities Performing Whole Genome Sequencing to Identify SARS- CoV-2 Genetic Variants
Level: Laboratory Update

On March 19, 2021, the U.S. Centers for Medicare & Medicaid Services (CMS) posted the "CLIA SARS-CoV-2 Variant Testing Frequently Asked Question" document to provide information for facilities that perform sequencing to identify SARS- CoV-2 genetic variants.

CMS will not cite CLIA-certified laboratories that perform SARS-CoV-2 genetic variant testing on identified specimens and report patient-specific variant results to state or local public health departments without establishing performance specifications as required by §493.1253(b)(2), provided that the laboratory only reports patient-specific results to a public health department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment.

If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA-certified laboratory and in compliance with all applicable CLIA regulations.

Please share this message with your networks and invite them to opt in to LOCS to receive future updates.

Online resources:

- Information for Laboratories about Coronavirus (COVID-19)
- Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories
- CDC Coronavirus (COVID-19) Website
- CDC Laboratory Outreach Communication System (LOCS)
- Clinical Laboratory COVID-19 Response Calls

If you have any questions, please contact us at LOCS@cdc.gov.

Thank you,
The Laboratory Outreach Communication System

Laboratory Outreach Communication System (LOCS) | Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Centers for Disease Control and Prevention (CDC)
LOCS@cdc.gov
www.cdc.gov/csels/dls/locs

Dear Partners,

In late 2020, CDC released a *Science Agenda for COVID-19*, which articulates key areas of scientific inquiry and opportunities to guide the development of actionable, evidence-based public health guidance to limit the spread and impact of SARS-CoV-2 and ultimately end the COVID-19 pandemic. As the evidence base and public health response to the COVID-19 pandemic continues to evolve, this *Science Agenda* has helped promote efforts to fill critical, time-sensitive scientific gaps and to inform evidence-based decision making.

To help achieve the objectives outlined in the *Science Agenda for COVID-19,* CDC initiated an effort during February-March 2021 to systematically identify *Priority Science Questions* that are relevant, actionable near-term, and reflect the evolving needs of the ongoing public health response. On Friday, March 19th, a new set of 19 *Priority Science Questions* will be released, which comprise of content from six major topic areas:

- Variants
- Prevention Strategies and Non-Pharmaceutical Interventions
- Vaccines
- Testing
- Natural History, Reinfection, Health Impacts
- Transmission Risk, Dynamics

Moving forward, these *Priority Science Questions* will be used to help guide prioritization of CDC's scientific research portfolio related to COVID-19, including articles published in *MMWR* and other scientific journals. To that end, these new questions reflect the broad scope of CDC and other public health partner's scientific work related to COVID-19, including surveillance, research, implementation science, and evaluation. Importantly, these questions also serve to expand the evidence base to accelerate progress towards reducing COVID-19 disparities and achieving health equity.

The new set of *Priority Science Questions* will be available on Friday, March 19th, 2021 at 1pm ET at the following link:
https://www.cdc.gov/coronavirus/2019-ncov/more/science-agenda-covid19.html

We hope you will find these questions informative for building the evidence base necessary to further drive public health action and help end the COVID-19 pandemic. If you have any questions related to the *Science Agenda* or the new *Priority Science Questions,* they can be directed to the Strategic Science Unit (SSU) of the CDC COVID-19 Response at: EOCevent538@cdc.gov.

Best regards,
Aliki

Aliki Pappas Weakland, MPH MSW (she/her/hers)

Lead, Policy & Public Health Partnerships
State, Tribal, Local and Territorial Support Task Force
Coronavirus Disease-2019 (COVID-19) Response
Centers for Disease Control and Prevention (CDC)

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Nov. 23 (incl. CDC Travel Planner Launch, CDC Recs and Guidance, WH STLT Call, COCA Call, MMWR Early Releases, and more)
Date:	Monday, November 23, 2020 2:02:37 PM
Attachments:	image001.png image002.png Travel Planner Live to Public.pdf MMWR ER - Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020.pdf MMWR ER - COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State — Minnesota, August–September 2020 - November 20, 2020.pdf MMWR ER - Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020 - November 20, 2020.pdf CDC Response Website Updates (Nov 13–20).docx 2020_11_17_Science-Update_Final-Public.pdf

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[PureMessage: Suspect .eml attachment quarantined.]

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of recent Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

- CDC Travel Planner Public Launch [Attachment]
  - Please see attached for a letter from CDC's Global Migration Task Force announcing the public-facing launch of **CDC Travel Planner**. This web portal serves as a centralized communication platform for COVID-19 travel restrictions and policies enacted by STLT governments. If you have not done so already, add your jurisdiction's information using the instructions listed in the attached letter. You can also promote the Travel Planner using marketing materials linked within.
- CDC Recommendations: "Prioritizing Case Investigations and Contact Tracing for COVID-19 in High Burden Jurisdictions" [Link]
  - Today, CDC released new recommendations for prioritizing case investigations and contact tracing to assist health departments experiencing escalating COVID-19 cases. These new recommendations further refine existing prioritization recommendations and presents new modeling data regarding timeframes to maximize the effectiveness of contact tracing activities.

CDC Guidance: "Considerations for Restaurant and Bar Operators" [Link]

- Released Wednesday, November 18

- White House National State, Local, Tribal COVID-19 Briefing Call [Link]
  - The White House Office of Intergovernmental Affairs (IGA) will host its next weekly briefing call for STLT leaders **Wednesday, December 2** at **1:00 pm EST**. RSVPs will be allocated in the order they are received. To register, click here.
- CDC COCA Call: The Impact of Telehealth on Health Equity from the Perspective of Large Healthcare Systems during the COVID-19 Pandemic [Attachment]
  - CDC Clinician Outreach and Community Activity (COCA) will host a webinar **Tuesday, December 8** at **2:00 pm EST** to discuss how telehealth has affected health equity in their patient populations before and during the COVID-19 pandemic. Presenters from Kaiser Permanente and the Veteran's Health Administration will share strategies to expand access that can reduce disparities and improve culturally responsive care to help achieve health equity within each organization. Call information is below:
    - Weblink: https://www.zoomgov.com/j/1600369650
      Telephone: (669) 254 5252 or (646) 828 7666
      Webinar ID: 160 036 9650
      Post-Event
      Recording: https://emergency.cdc.gov/coca/calls/2020/callinfo_120820.asp
- MMWR Early Release: "The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020" [Attachment, Link]
  - From the summary: *"In addition to scientific data and implementation feasibility, four ethical principles will assist ACIP in formulating recommendations for the initial allocation of COVID-19 vaccine: 1) maximizing benefits and minimizing harms; 2) promoting justice; 3) mitigating health inequities; and 4) promoting transparency."*
- MMWR Early Release: "COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State — Minnesota, August–September 2020" [Attachment, Link]
  - From the summary: *"Following a 10-day motorcycle rally in South Dakota attended by approximately 460,000 persons, 51 confirmed primary event-associated cases, 21 secondary cases, and five tertiary cases were identified in Minnesota residents. An additional nine likely rally-associated secondary or tertiary cases occurred. Four patients were hospitalized, and one died. Genomic sequencing supported the associations with the motorcycle rally."*
- MMWR Early Release: "Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020" [Attachment, Link]
  - From the summary: *"The governor of Kansas issued an executive order requiring wearing masks in public spaces, effective July 3, 2020, which was subject to county authority to opt out. After July 3, COVID-19 incidence decreased in 24 counties with mask mandates but continued to increase in 81 counties without mask mandates."*
- Reminder: CDC Partner Update Call: Resilience and Mental Health for the Holidays [Link]
  - CDC will host a webinar **Monday, November 30** at **3:00 pm EST** focusing on the

upcoming holiday season. Dr. Cliff McDonald will share updates on CDC's COVID-19 response, including the latest scientific information and what everyone should know about protecting themselves and others. Additionally, Dr. Kathleen Ethier will discuss strategies for building resilience and mental health during the COVID-19 pandemic and the holiday season.
    - Registration is available here. Please email questions in advance to eocevent337@cdc.gov with "Partner Call 11/30" in the subject line. The call will be recorded and posted to CDC's website here.
- CDC Response Website Updates [Attachment]
    - for November 13–20
- CDC COVID-19 Science Update [Attachment, Link]
    - Published November 17
- Reminder: Request Form for CSTE COVID-19 Call Topics [Link]

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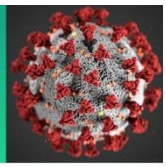
CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
Business Hours Line: 770.458.3811
After-Hours Line: 678.256.3945
preparedness.cste.org

COVID-19 Science Update



From the Office of the Chief Medical Officer, CDC COVID-19 Response, and the CDC Library, Atlanta, GA.
Intended for use by public health professionals responding to the COVID-19 pandemic.

***** Available on-line at https://www.cdc.gov/library/covid19 *****

*****This week and next week the CDC COVID-19 Science Update will only be produced on Tuesday, 11/17 and Tuesday, 11/24. The CDC COVID-19 Science Update will not be produced on Friday, 11/20, or Friday, 11/27.*****

COVID-19 and Return to College

The increase in COVID-19 cases among younger persons points to a need to implement effective mitigation strategies to protect college students returning to campus, as well as the neighboring communities. Six out of 10 colleges and universities re-opened in the fall with in-person classes, either full-time or combined with online classes. Safely bringing students and faculty back to campus will require testing and mitigation measures to prevent SARS-CoV-2 transmission. Optimal testing strategies for in-person classes and variables associated with likelihood of holding in-person classes at colleges and universities are discussed in the following papers.

PEER-REVIEWED

Evaluation of COVID-19 testing strategies for repopulating college and university campuses: A decision tree analysis. Van Pelt *et al.* Journal of Adolescent Health (November 3, 2020).

Key findings:

- Strategies that included RT-PCR testing of in-coming students identified more cases than symptom-based screening alone; however, all strategies failed to detect a portion of the cases.
    - Using only symptom-based screening, less than 50% of true positive cases will be detected.
    - Testing all students on arrival, and again 7 days later, will detect the greatest number of cases.
- At higher prevalence of infection, repeat testing will detect more true positives per test, but will cost more.

Methods: A decision tree analysis was used to evaluate testing strategies for safely repopulating a university with 20,000 students. The analysis evaluated five strategies: (1) classifying students with symptoms as having COVID-19 (no testing); 2) testing done on symptomatic students, (3) testing all students, (4) testing all students and retesting *symptomatic* students with a negative first test, and (5) testing all students and retesting *all* students with a negative first test. Costs estimates for given strategies were estimated. *Limitations:* Disease prevalence was based on national estimates; no analyses of testing strategies later in the semester.

MS-DOH-21-1816-A-002163

PREPRINTS (NOT PEER-REVIEWED)

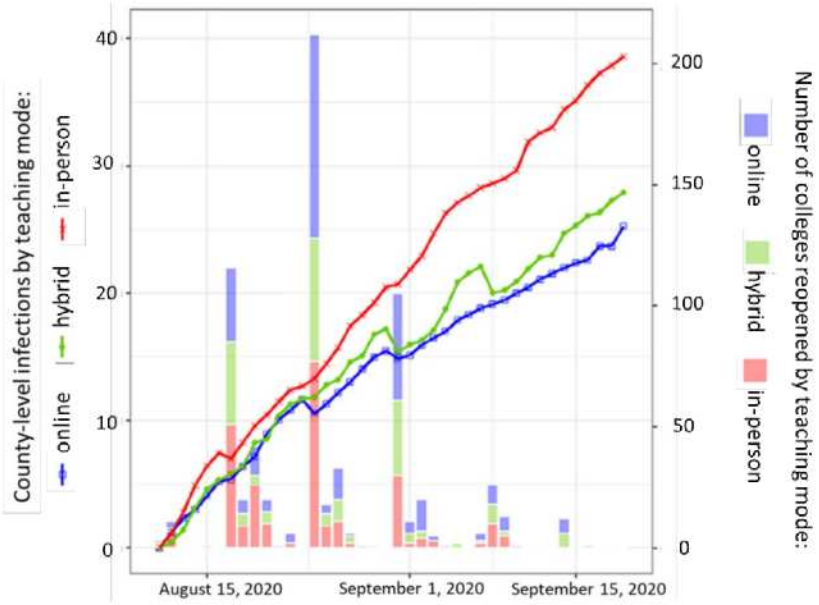
Causal impacts of teaching modality on U.S. COVID-19 spread in fall 2020 semester. Badruddoza & Amin. MedRxiv. (November 3, 2020).

Key findings:

- Reopening colleges was associated with increased COVID-19 cases and deaths.
- Colleges with in-person classes are in counties with rapidly increasing COVID-19 cases (Figure).
    - Daily new COVID-19 cases increased in the fall 2020 semester by 1.87 cases per 100,000 population.
- The variables most strongly associated ($p < 0.05$) with adopting online teaching modes vs in-person enrollment were higher student enrollments, larger endowments per student, being a public (vs private) institution, individual mask policies, and prevalence of specific political party affiliation in the community.
- There was a negative association between the percentage of county residents staying home and disease spread.

Methods: Use of metrics of new daily COVID-19 cases and COVID-19-related deaths in the county to describe the effects of college teaching modality on spread of disease for 745 US institutions and surrounding communities. The probability of choosing each teaching mode was calculated with multinomial logistic regression. *Limitations:* Student-specific infections are not addressed; method for classifying counties with multiple colleges with different teaching modes not explained.

Figure:



Note: From Badruddoza *et al*. County-level growth of COVID-19 cases in counties by teaching modality for in-person, online, or hybrid classes. Opening date for colleges by teaching modality shown in bars from August 10 to September 19, 2020. Licensed under CC-BY-ND 4.0.

Implications for 2 studies (Van Pelt *et al.* and Badurddoza & Amin) These two articles highlight measures that colleges and universities can use to mitigate COVID-19. As discussed in Walke *et al.*, institutional resources, cost of testing, and the possibility of distance learning need to be considered when re-opening schools. These articles show that decisions regarding type of teaching are also influenced by the surrounding communities, such as locally enacted preventative measures and the local political environment. Being aware of these influences may guide administrators in decision-making regarding re-opening campuses.

Immunity

Antibodies to SARS-CoV-2, particularly neutralizing antibodies, appear to wane over time. Long-term protection against SARS-CoV-2 may rely on the maintenance of memory immune cells that quickly re-activate upon secondary infection, primarily B cells that produce antibodies and T cells that help B cells and kill virus-infected cells. The duration of SARS-CoV-2-specific cell-mediated immunity – i.e. immunity not mediated by antibody – is not well understood. Following are two recent pre-print studies examining the longevity of memory B and T cell responses against SARS-CoV-2.

PREPRINTS (NOT PEER-REVIEWED)

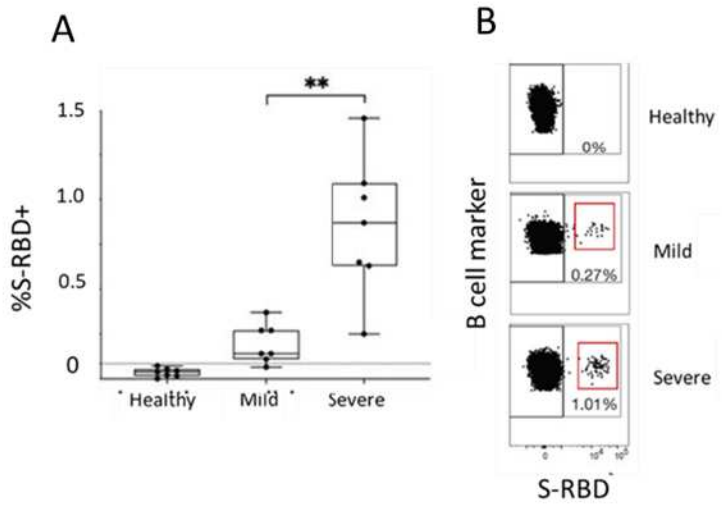
Durable SARS-CoV-2 B cell immunity after mild or severe disease. Ogega *et al.* MedRxiv (October 30, 2020).

Key findings:

- B cells recognizing SARS-CoV-2 spike protein receptor binding domain (S-RBD) were detected in 13 of 14 participants with COVID-19 (Figure, A).
    - Four (57%) of seven patients with mild COVID-19 had S-RBD-specific immature B cells and antibody-secreting cells (ASC) and six (86%) had detectable memory B cells (MBC).
    - 100% of moderate-to-severe COVID-19 patients had S-RBD-specific B cells of all types (immature, ASC, and MBC).
- The frequency of S-RBD specific MBC was significantly higher in patients with moderate-to-severe COVID-19 compared with mild COVID-19 (mean S-RBD+ frequency 0.85% vs. 0.20%, p = 0.004) (Figure, B).
    - The single individual with SARS-CoV-2 infection but without detectable S-RBD-specific MBC was asymptomatic.

Methods: S-RBD-specific B cells from seven ambulatory patients with mild COVID-19 and seven hospitalized patients with moderate-to-severe COVID-19, and cryopreserved cells from healthy blood donors collected prior to the COVID-19 pandemic were evaluated. *Limitations*: Maximum time from symptom onset to B cell sampling was 104 days (median 54 days); small sample size.

Figure:



Note: Adapted from Ogega *et al.* The percent of S-RBD-specific memory B cells from healthy participants, participants with mild-COVID-19, or participants with severe COVID-19. A. Box and whiskers plots show summary of participants (whiskers are minimum to maximum). B. dot plot shows representative data from each group, with **the population of B cells binding to S-RBD highlighted in the box**. ** Indicates p ≤0.01. Licensed under CC-BY-ND 4.0.

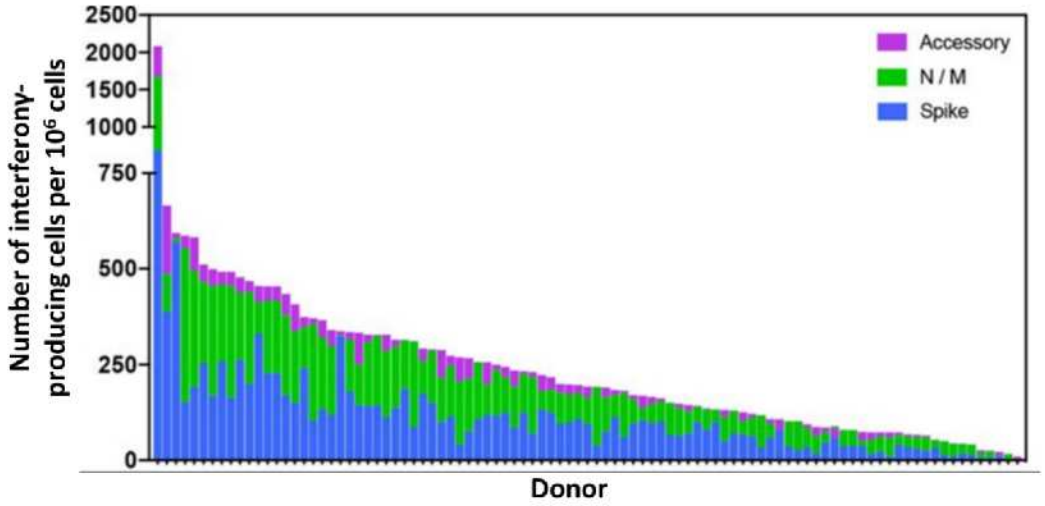
Robust SARS-CoV-2-specific T cell immunity is maintained at 6 months following primary infection. Zuo *et al.* BioRxiv (November 2, 2020).

Key findings:

- Evidence of SARS-CoV-2-specific T cell responses was found in all donors at 6 months (Figure).
- Median T cell responses were 50% higher in donors who had symptomatic infection compared with asymptomatic infection.
- T cell responses at six months correlated with peak antibody levels against the SARS-CoV-2 nucleoprotein, receptor binding domain (RBD), and spike proteins.

Methods: Blood samples from 100 convalescent plasma donors were analyzed to characterize the cellular immune response measured by production of interferon-γ six months after SARS-CoV-2 infection, and to measure peak antibody levels against SARS-CoV-2 nucleoprotein, RBD, and spike proteins. *Limitations*: No assessment of immune responses beyond six months.

Figure:



Note: Adapted from Zuo *et al.* Cellular response against SARS-CoV-2 proteins (spike, nucleoprotein/membrane proteins [N/M], and a pool of other SARS-CoV-2 peptides [accessory]) at six months following primary infection. Licensed under CC-BY-ND 4.0.

Implications for 2 studies (Ogega *et al.* & Zuo *et al.*): Memory B and T cells could provide durable immunity to SARS-CoV-2 even after serum antibodies decline, particularly in symptomatic individuals. A commentary from Wise, J. highlights that durable T cell responses against a range of SARS-CoV-2 proteins might point to potential new vaccine targets.

Epidemiology

PEER-REVIEWED

Transmission of SARS-CoV-2 on mink farms between humans and mink and back to humans. Munnink *et al.* Science (November 10, 2020).

Key findings:

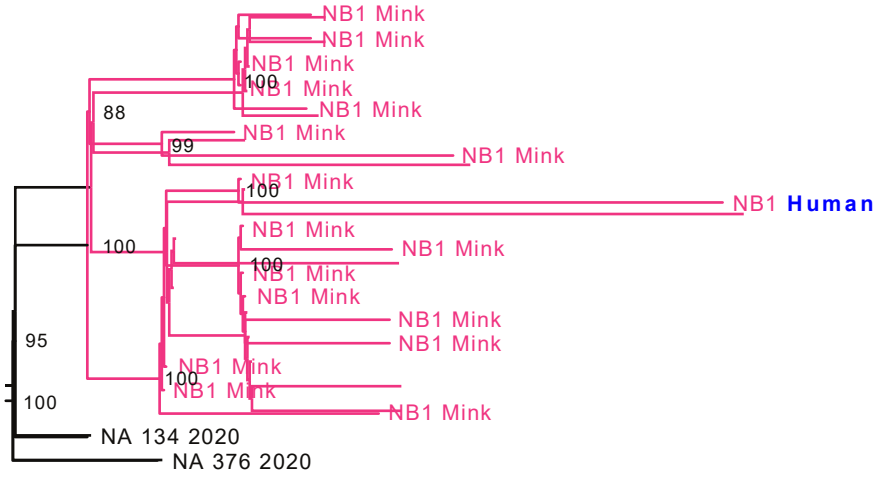
- Of 97 mink farm employees tested, 43/88 (49%) were positive by RT-PCR, 38/75 (51%) had detectable antibodies, and 66/97 (67%) had evidence of SARS-CoV-2 infection by RT-PCR or serology.
- The mink and human strains clustered closely together (Figure).

    - There was greater phylogenetic relatedness between farm-related human and mink cases than between farm-related human and community cases within the same postal code.
- Potential mink-to-human transmitted SARS-CoV-2 infections did not have differences in signs, duration, or severity compared with human-to-human transmitted infections.

Methods: Outbreak investigations were performed when respiratory signs and increased mortality for minks were reported to the Dutch Agriculture authorities. Investigations at 16 mink farms sought to identify the source of the outbreak, trace contacts and track movement of animals, vehicles, and people. SARS-CoV-2 diagnostic testing for mink and human samples was performed using RT-PCR and by antibody testing. Viral genomes were sequenced for PCR-positive samples with Ct values ≤32. *Limitations*: The investigation could not exclude the role that exposures from untested animals or humans might have played in transmission; temporary farm workers not tested.

Implications: SARS-CoV-2 outbreaks in mink farms are well-documented and resulted in recently-abandoned plans to cull Denmark's 17 million minks. This paper provides phylogenetic data suggestive of mink-to-human SARS-CoV-2 transmission; however, directionality of transmission is challenging to definitively demonstrate using phylogenetics. Concerns about potential mutations in SARS-CoV-2 from animal-to-human transmission that may lead to more rapid spread or jeopardize vaccine efficacy may be premature.

Figure:



Note: Adapted from Munnink *et al*. Phylogenetic tree of **mink** and **human** sequences found in a single farm (NB1) and the closest matching human sequences from the **national SARS-CoV-2 database** (NA 134 2020, and NA 376 2020). Numbers in black represent the bootstrapping values using all Dutch SARS-CoV-2 sequences. Permission request in process.

Repeated cross-sectional sero-monitoring of SARS-CoV-2 in New York City. Stadlbauer *et al.* Nature (November 3, 2020).

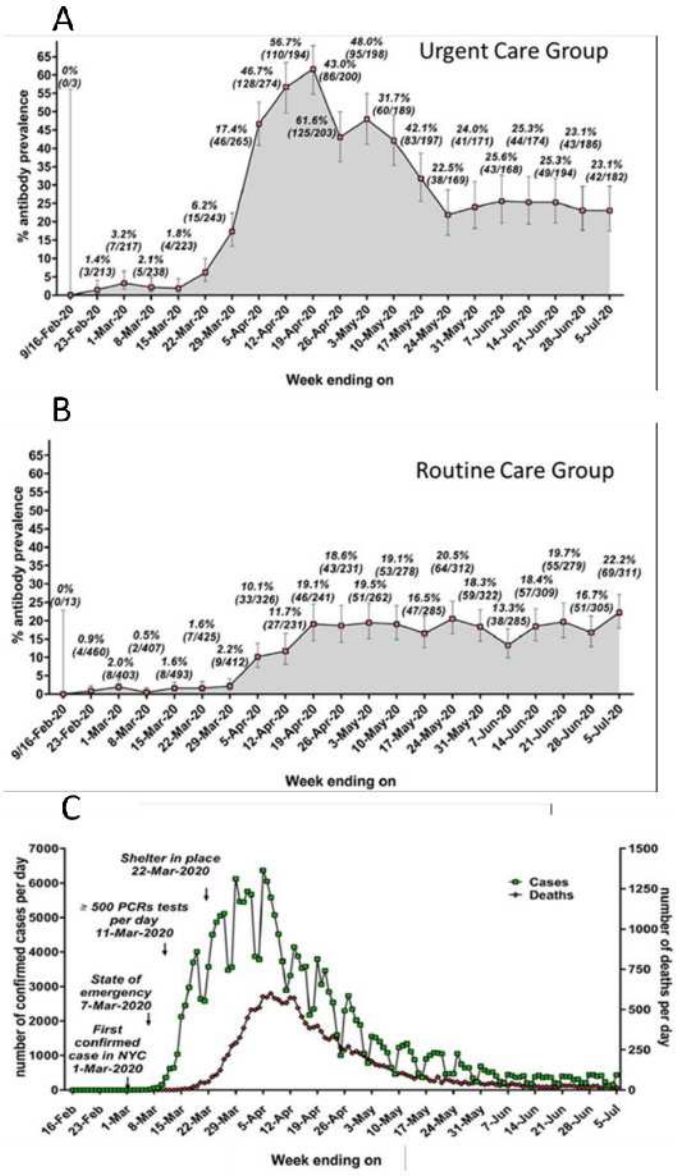
Key findings:

- A rapid rise in SARS-CoV-2 seroprevalence (6.2%) was detected in the urgent care (UC) group (Figure, A) compared with the routine care (RC) group, coinciding with the surge of new confirmed SARS-CoV-2 infections and related hospitalizations in New York City.
    - The uptick in seropositivity lagged approximately 1–2 weeks behind the increase in new cases (Figure A, C).
- There was a longer delay between the increase in confirmed cases and the increase in seroprevalence in the RC group (Figure B, C).
- Seroprevalence in the UC group declined to levels seen in the RC group coinciding with a drop in incidence of SARS-CoV-2 cases between May and July 2020 (Figures A, C).

Methods: Weekly cross-sectional analysis of anti-SARS-CoV-2 spike antibodies on 10,691 plasma samples randomly collected from patients at Mount Sinai Hospital in New York City from February 9 to July 5, 2020. Seroprevalence was compared between an UC group (meant to capture seropositive individuals) and a RC group (meant to capture visits unrelated to COVID-19 and resemble the general population). ***Limitations***: Non-random, non-representative sampling.

Implications: This will be the first of a series of repeated cross-sectional seroprevalence studies to understand the dynamics of SARS-CoV-2 transmission, seroconversion, and the stability of antibody responses over the course of a COVID-19 outbreak.

Figure:



Note: Adapted from Stadlbauer *et al.* Serum antibody prevalence in the UC group **(A)** and in the RC group **(B)**, and **number of confirmed cases/day** and **number of deaths per day,** February–July 2020 **(C)**. Permission request in process.

Outcomes of contact tracing in San Francisco, California—test and trace during shelter-in-place. Sachdev *et al.* JAMA Internal Medicine (November 2, 2020).

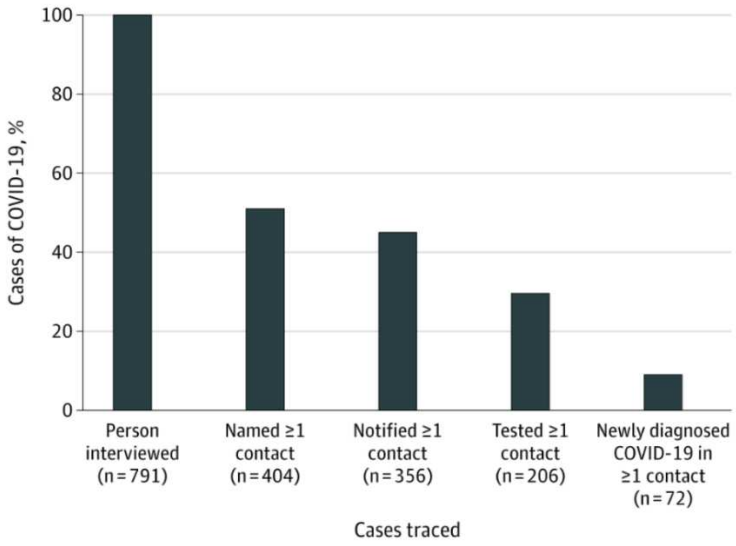
Key findings:

- COVID-19 contact tracing program reached more than 85.4% of cases (Figure) and 83.8% of contacts.
- The secondary attack rate was higher among household compared with non-household contacts (111 of 983 [11.3%] and 9 of 231 [3.9%], respectively; p <0.001).
- Median time from symptom onset for a case to notifying and testing the contact was 6 days.
    - The median time from symptom onset to receipt of test results was 5 days.
    - Case interviews occurred on average 1 day after the test result and the first contact was notified on average 1 day after that.

Methods: Case investigation and contact tracing for 1,394 COVID-19 cases identified in San Francisco, California between April 13 and June 8, 2020. The study period included dates after which universal testing for COVID-19 contacts, regardless of symptoms, was recommended. The proportion of people who were interviewed and for whom close contacts were identified, with at least 1 contact being notified, was calculated. Median number of days (with IQR) taken to process each step was reported. *Limitations*: Underreporting of close contacts.

Implications: In order to maximize the impact of contact tracing on mitigating the spread of COVID-19, metrics such as these are needed, and efforts must be made to address testing delays and to improve contact identification.

Figure:



Note: Adapted from Sachdev *et al*. Percentages for people with COVID-19 at selected stages of contact tracing implementation. Reproduced with permission from JAMA Internal Medicine. Sachdev *et al.*, Outcomes of contact tracing in San Francisco, California—test and trace during shelter-in-place. DOI:10.1001/jamainternmed.2020.5670. Copyright© 2020 American Medical Association. All rights reserved.

Proportion of asymptomatic infection among COVID-19 positive persons and their transmission potential: A systematic review and meta-analysis. Yanes-Lane *et al.* PLOS One (November 7, 2020).

Key findings:

- 24 studies report that the proportion of asymptomatic individuals among individuals testing positive for SARS-CoV-2 ranged from:
  - 20%–75% for the general population.
  - 8.2%–50% for contacts of known cases.
  - 45%–100% of obstetric patients presenting to hospitals.
  - 42%–66.7% of nursing home residents; 0%–50% of nursing home staff.
  - 50%–87.8% in congregate settings such as temporary homeless shelter.
  - 76.2% of retail workers (single study).
- 18.8% (18/96) of contacts of asymptomatic index patients were SARS-CoV-2 positive in pooled analysis of 5 transmission studies.

Methods: Review of 28 moderate or high-quality studies systematically testing for COVID-19 through June 22, 2020, assessing the proportion of infections occurring in asymptomatic individuals and transmission. *Limitations*: Included mainly small studies of people with COVID-19 (n <100), limiting estimate precision; contact tracing in studies was limited which may bias the results; study heterogeneity limited ability to analyze by age group or sex.

Implications: The proportion of asymptomatic infections appears high in many groups. As asymptomatic individuals may have considerable transmission potential, symptom-based testing is insufficient to eliminate transmission. High quality studies in representative general population samples are needed to better understand the role of asymptomatic individuals in the transmission of SARS-CoV-2.

Diagnostics

Antigen (Ag) tests may provide an easier point-of-care alternative to RT-PCR testing to detect infected individuals by detecting SARS-CoV-2 proteins rather than RNA. The Abbott BinaxNOW™ COVID-19 Ag Card (Binax-CoV2) is a 15-minute test that recently received an emergency use authorization by the US Food and Drug Administration for testing symptomatic individuals for SARS-CoV-2 infection. The US Department of Health and Human Services has ordered 150 million Binax-CoV2 rapid antigen tests, many of which are targeted for high-risk settings.

PREPRINTS (NOT PEER-REVIEWED)

Performance characteristics of a rapid SARS-CoV-2 antigen detection assay at a public plaza testing site in San Francisco. Pilarowski *et al.* MedRxiv (posted November 12, 2020).

Key findings:

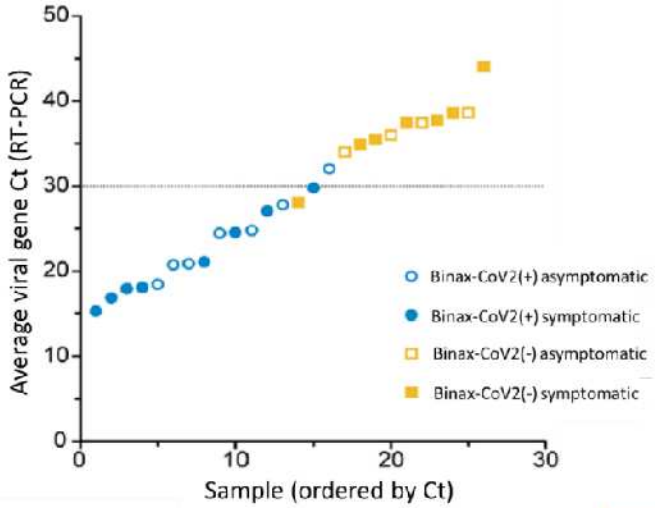
- Criteria for a positive test for the Binax-CoV2 rapid Ag test had to be adjusted when used to screen asymptomatic individuals.
  - When using the manufacturer's recommendation to read any line as "positive," 9 (64%) of 14 Binax-CoV2-positive tests were likely false positives.
- Performance in asymptomatic subjects improved when a positive result was defined as a band extending the full width of the testing strip, regardless of intensity.
  - Sensitivity was 93.8% (95% CI 68.1%-99.8%, n = 16) and specificity was 100%, (95% CI 99.6%-100%, n = 855).
- Samples with false negative Binax-CoV2 tests had low viral loads (high Ct values) (Figure).

Methods: In September 2020, 878 people participated in testing in San Francisco, CA. Binax-CoV2 cards were read by 2 independent observers with a third on hand to be a "tie-breaker." Lab confirmation was done via RT-PCR

testing. *Limitations*: The Binax-CoV2 Ag test currently is validated on symptomatic COVID-19 patients, full validation on asymptomatic individuals has not been done.

Implications: Since the Binax-CoV2 rapid test may be used to screen asymptomatic individuals, the data shown here will be critical in establishing guidance for validating this use case. Manabe *et al.* outline the need for screening tests that can rapidly identify infectious individuals to prevent outbreaks.

Figure:



Note: Adapted from Pilarowski *et al.* Average Ct from all 26 RT-PCR-positive participants for **Binax-CoV2(+)** and **Binax-CoV2(-)** participants with and without symptoms. Licensed under CC-BY-NC-ND 4.0.

In Brief

- Hippich *et al.* **Public health antibody screening indicates a 6-fold higher SARS-CoV-2 exposure rate than reported cases in children**. Med. This serosurvey added SARS-CoV-2 antibody testing to a diabetes screening program of 15,771 persons 1–18 years old and saw six-fold higher seroprevalence than reported cases.

- Qian *et al.* **Indoor transmission of SARS-CoV-2.** Indoor Air. Investigation from China of 318 outbreaks with ≥3 cases from January 4 to February 11, 2020, showed no outbreaks attributed to outdoor settings and only 1.6% with ≥10 cases.

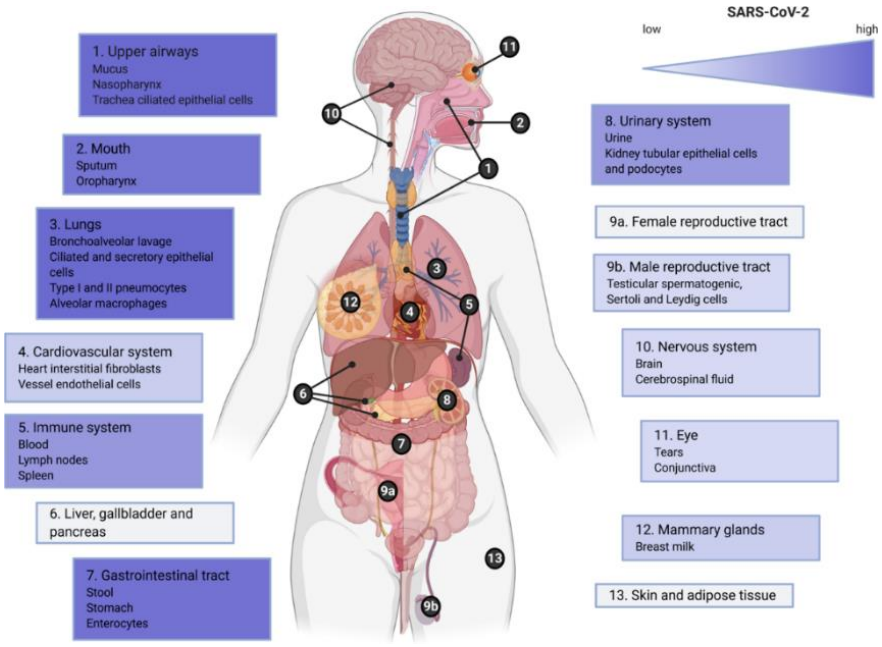
- Prasitlumkum *et al.* **Incidence of myocardial injury in COVID-19-infected patients: A systematic review and meta-analysis.** Diseases. A review of 27 studies found that COVID-19-related myocardial injury ranges from 16.1%–23.8%.

- Anderson *et al.* **Challenges in creating herd immunity to SARS-CoV-2 infection by mass vaccination.** Lancet. The possible outcomes of the 45 candidate COVID-19 vaccines currently in clinical trials are discussed in the context of distribution and long-term immunity.

- Anderson *et al.* **SARS-CoV-2 antibody responses in children with MIS-C and mild and severe COVID-19.** MedRxiv. Pediatric patients with multisystem inflammatory syndrome in children (MIS-C) had higher antibody titers against SARS-CoV-2 spike IgG compared to those with severe COVID-19.

- Trypsteen *et al.* **On the whereabouts of SARS-CoV-2 in the human body: A systematic review.** Plos Pathogens. A review of 186 studies demonstrating the presence of SARS-CoV-2 in organs and tissues throughout the body.

  Figure:



  Note: From Trypsteen *et al*. Overview of body systems where SARS-CoV-2 has been found, with darker shading indicating the strength of the evidence for the virus in that system. Licensed under CC-BY 4.0.

- Jay *et al.* **Neighbourhood income and physical distancing during the COVID-19 pandemic in the United States.** Nature Human Behavior. Data from a large national sample of smartphone users showed that lower-income neighborhoods practiced less physical distancing compared with higher-income neighborhoods, likely because residents of lower-income neighborhoods are more likely to work outside the home.

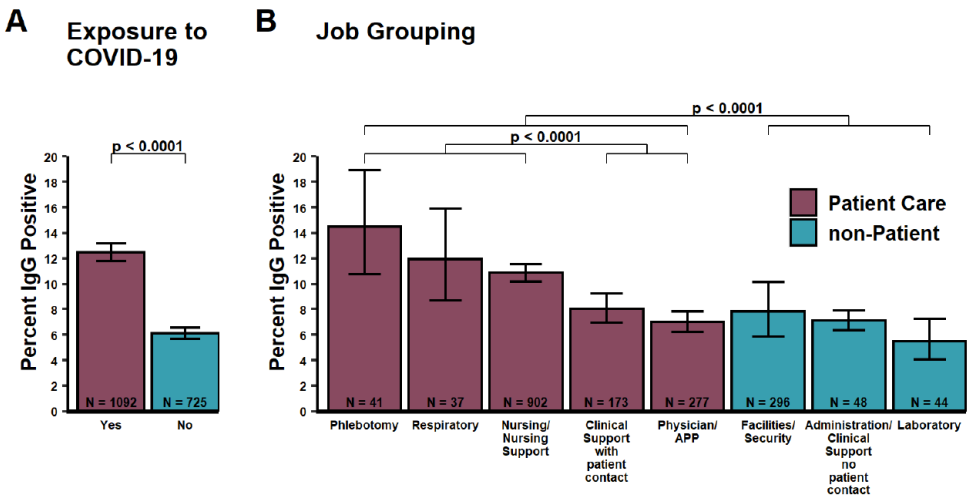
- Hazeldine & Lord. **Immunesenescence: A predisposing risk factor for the development of COVID-19?** Frontiers in Immunology. This article discusses the possibility that the gradual deterioration of the immune system brought on by age, could be a generic contributory factor to the development of severe COVID-19.

- Shi *et al.* **Challenges of drug development during the COVID-19 pandemic: Key considerations for clinical trial designs.** British Journal of Clinical Pharmacology. Translational science principles and strategies for conducting clinical trials in a pandemic and evaluation of trials of drug candidates, particularly repurposed drugs are reviewed.

- Milne *et al.* **Airplane boarding methods that reduce risk from COVID-19.** Safety Science. A number of methods for airplane boarding to minimize both risk and boarding times are evaluated, with videos demonstrating the process.

- Sims *et al.* **COVID-19 seropositivity and asymptomatic rates in healthcare workers are associated with job function and masking**. Clinical Infectious Diseases. Direct contact with COVID-19 patients increased the likelihood of seropositivity among employees of a Michigan healthcare system, but study participants who wore a mask during exposures were less likely to be seropositive.

  Figure:



Note: Adapted from Sims *et al.* **A:** Seropositivity to SARS-CoV-2 in healthcare workers **with COVID-19 patient exposure** or **without COVID-19 patient exposure**. **B:** Seropositivity to SARS-CoV-2 in healthcare workers based on job type with **patient care** or **non-patient care**. Permission request in process.

- Padmanabhan *et al.* **Phase II clinical trial for evaluation of BCG as potential therapy for COVID-19**. MedRxiv. Randomized controlled trial of Bacille Calmette-Guérin (BCG) plus standard of care vs standard of care in 60 COVID-19 patients showed significant improvement in the primary outcome of the ratio of oxygen saturation to fraction of inspired oxygen, an independent indicator of acute respiratory distress syndrome with BCG.

- Rink *et al.* **Competitive sports, the coronavirus disease 2019 pandemic, and Big Ten athletics**. Circulation: Cardiovascular Quality and Outcomes. Perspective from the Big Ten Cardiac Registry Steering Committee reflecting on the reasoning behind the decisions to delay and restart the Big Ten College Football season.

Disclaimer: The purpose of the CDC COVID-19 Science Update is to share public health articles with public health agencies and departments for informational and educational purposes. Materials listed in this Science Update are selected to provide awareness of relevant public health literature. A material's inclusion and the material itself provided here in full or in part, does not necessarily represent the views of the U.S. Department of Health and Human Services or the CDC, nor does it necessarily imply endorsement of methods or findings. While much of the COVID-19 literature is open access or otherwise freely available, it is the responsibility of the third-party user to determine whether any intellectual property rights govern the use of materials in this Science Update prior to use or distribution. Findings are based on research available at the time of this publication and may be subject to change.

CDC Response Website Updates (11/18)

New:

- Toolkit for Clinicians

Updated:

- CDC COVID Data Tracker
- Interim Guidance for Case Investigation and Contact Tracing in K-12 Schools
- Interim Guidance for Case Investigation and Contact Tracing in Institutions of Higher Education (IHEs)
- Considerations for Restaurant and Bar Operators
- COVID-19 and Animals
- Clinical Questions about COVID-19: Questions and Answers

CDC Response Website Updates (11/14)

Updated:

- CDC COVID Data Tracker
- Staffing Resources

CDC Response Website Updates (11/13)

New:

- Information for School Nurses and Other Healthcare Personnel (HCP) Working in Schools and Child Care Settings
- Monitoring and Evaluating Mitigation Strategies in Child Care Programs
- Monitoring and Evaluating Covid-19 Mitigation Strategies in K-12 Schools: Interview Guide
- Monitoring and Evaluating Covid-19 Mitigation Strategies In K-12 Schools: Focus Group Guide
- Monitoring and Evaluating Mitigation Strategies in Child Care, K-12 Schools, and Institutions of Higher Education
- Multisystem Inflammatory Syndrome in Adults (MIS-A)

Updated:

- CDC COVID Data Tracker
- Staffing Resources
- COVID-19 Forecasts: Hospitalizations
- Previous COVID-19 Forecasts: Cases
- COVIDView
- Guidance for Pharmacies

- Phone Advice Line Tools
- Frequently Asked Questions about COVID-19 Vaccination
- Multistate Assessment of SARS-CoV-2 Seroprevalence in Blood Donors
- Community, Work, and School
- Data on COVID-19 during Pregnancy: Severity of Maternal Illness
- Monitoring and Evaluating Mitigation Strategies in K-12 Schools
- Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories (Serology)
- Guidance for SARS-CoV-2 Point-of-Care Testing
- Healthcare Facilities That Have Implemented COVID-19 Electronic Case Reporting
- An Approach for Monitoring and Evaluating Community Mitigation Strategies for COVID-19
- Data on COVID-19 during Pregnancy: Severity of Maternal Illness

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 69
November 23, 2020

The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

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To reduce the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) and its associated impacts on health and society, COVID-19 vaccines are essential. The U.S. government is working to produce and deliver safe and effective COVID-19 vaccines for the entire U.S. population. The Advisory Committee on Immunization Practices (ACIP)* has broadly outlined its approach for developing recommendations for the use of each COVID-19 vaccine authorized or approved by the Food and Drug Administration (FDA) for Emergency Use Authorization or licensure (*1*). ACIP's recommendation process includes an explicit and transparent evidence-based method for assessing a vaccine's safety and efficacy as well as consideration of other factors, including implementation (*2*). Because the initial supply of vaccine will likely be limited, ACIP will also recommend which groups should receive the earliest allocations of vaccine. The ACIP COVID-19 Vaccines Work Group and consultants with expertise in ethics and health equity considered external expert committee reports and published literature and deliberated the ethical issues associated with COVID-19 vaccine allocation decisions. The purpose of this report is to describe the four ethical principles that will assist ACIP in formulating recommendations for the allocation of COVID-19 vaccine while supply is limited, in addition to scientific data and implementation feasibility: 1) maximize benefits and minimize harms; 2) promote justice; 3) mitigate health inequities; and 4) promote transparency. These principles can also aid state, tribal, local, and territorial public health authorities as they develop vaccine implementation strategies within their own communities based on ACIP recommendations.

The ACIP COVID-19 Vaccines Work Group has met several times per month (approximately 25 meetings) since its establishment in April 2020. Work Group discussions included review of the epidemiology of COVID-19 and consultation with experts in ethics and health equity to inform the development of an ethically principled decision-making process. The Work Group reviewed the relevant literature, including frameworks for pandemic influenza planning and COVID-19 vaccine allocation (*3*–*8*); summarized this information; and presented it to ACIP. ACIP supported four fundamental ethical principles to guide COVID-19 vaccine allocation decisions in the setting of a constrained supply. Essential questions that derive from these principles can assist in vaccine allocation planning (Table 1).

Maximize benefits and minimize harms. Allocation of COVID-19 vaccine should maximize the benefits of vaccination to both individual recipients and the population overall. These benefits include the reduction of SARS-CoV-2 infections and COVID-19–associated morbidity and mortality, which in turn reduces the burden on strained health care capacity and facilities; preservation of services essential to the COVID-19 response; and maintenance of overall societal functioning. Identification of groups whose receipt of the vaccine would lead to the greatest benefit should be based on scientific evidence, accounting for those at highest risk for SARS-CoV-2 infection or severe COVID-19–related disease or death, and the essential role of certain workers. The ability of essential workers, including health care workers and non–health care

*The ACIP includes 15 voting members responsible for making vaccine recommendations. Fourteen of the members have expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine; one member is a consumer representative who provides perspectives on the social and community aspects of vaccination. In addition to the 15 voting members, ACIP includes eight ex officio members who represent other federal agencies with responsibility for immunization programs in the United States, and 30 nonvoting representatives of liaison organizations that bring related immunization expertise. https://www.cdc.gov/vaccines/acip/members/index.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

MS-DOH-21-1816-A-002178

TABLE 1. Essential questions for COVID-19 vaccine allocation planning related to ethical principles — United States, 2020

Ethical principle	Essential question
Maximize benefits and minimize harms	What groups are at highest risk for SARS-CoV-2 infection, COVID-19 disease, hospitalization, and death?
	What groups are essential to the COVID-19 response?
	What groups are essential to maintaining critical functions of society?
	What are the important characteristics of these groups (e.g., size or geographic distribution) that might inform the magnitude of benefit based on the amount of vaccine available or its characteristics?
Promote justice	Does the allocation plan result in fair and equitable access of the vaccine for all groups?
	How do characteristics of the vaccine and logistical considerations affect fair access for all persons?
	Does allocation planning include input from groups who are disproportionately affected by COVID-19 or face health inequities resulting from social determinants of health, such as income and health care access?
Mitigate health inequities	Does the plan identify and address barriers to vaccination among any groups who are disproportionately affected by COVID-19 or who face health inequities resulting from social determinants of health, such as income and health care access?
	Does the allocation plan contribute to a reduction in health disparities in COVID-19 disease and death?
	What health inequities might inadvertently result from the allocation plan, and what interventions could remove or reduce them?
	Is there a mechanism for timely assessment of vaccination coverage among groups experiencing disadvantage and the possibility for course correction if inequities are identified?
Promote transparency	How does development of the allocation plan include diverse input, and if possible, public engagement?
	Are the allocation plan and evidence-based methods publicly available?
	Is the allocation plan clear about what is known and unknown and about the quality of available evidence?
	What is the process for revision of allocation plans based on new information?
	Is there a mechanism to report demographic data elements for vaccine recipients (e.g., age, race/ethnicity, and occupation) to support equitable vaccination coverage?

Abbreviation: COVID-19 = coronavirus disease 2019.

workers, to remain healthy has a multiplier effect (i.e., their ability to remain healthy helps to protect the health of others or to minimize societal and economic disruption). Some of these workers are at increased risk for SARS-CoV-2 infection because of their limited ability to maintain physical distance in the workplace or because they do not have consistent access to recommended personal protective equipment.

Promote justice. Inherent in the principle of justice is an obligation to protect and advance equal opportunity for all persons to enjoy the maximal health and well-being possible. Justice rests on the belief in the fundamental value and dignity of all persons. Allocation of COVID-19 vaccine should promote justice by intentionally ensuring that all persons have equal opportunity to be vaccinated, both within the groups recommended for initial vaccination, and as vaccine becomes more widely available. This includes a commitment to removing unfair, unjust, and avoidable barriers to vaccination that disproportionately affect groups that have been economically or socially marginalized, as well as a fair and consistent implementation process. Input from a range of external entities, partners, and community representatives is particularly important in developing and assessing allocation plans.

Mitigate health inequities. Health equity is achieved when every person has the opportunity to attain his or her full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.[†] Disparities in the severity of COVID-19 and COVID-19–related death, as well as inequities in social determinants of health that are linked to COVID-19 risk, such as income or health care access and utilization, are well documented among certain racial and ethnic minority groups (*9*). Vaccine allocation strategies should aim to both reduce existing disparities and to not create new disparities. Efforts should be made to identify and remove obstacles and barriers to receiving COVID-19 vaccine, including limited access to health care or residence in rural, hard-to-reach areas.

Promote transparency. Transparency relates to the decision-making process and is essential to building and maintaining public trust during vaccine program planning and implementation. The underlying principles, decision-making processes, and plans for COVID-19 vaccine allocation must be evidence-based, clear, understandable, and publicly available. To the extent possible, considering the urgency of the COVID-19

[†] https://www.cdc.gov/chronicdisease/healthequity/index.htm.

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response, public participation in the creation and review of the decision-making process should be facilitated. In addition, when feasible, tracking administration of vaccine to the groups recommended for initial vaccine allocation can contribute to transparency and trust in the process. In an ongoing public health response, the situation continually evolves as new information becomes available. Transparency includes being clear about the level of certainty in the available evidence and communicating new information that might change recommendations in a timely fashion.

For the period when the supply of COVID-19 vaccine will be limited, ACIP has considered four groups for initial vaccine allocation. These include health care personnel, other essential workers, adults with high-risk medical conditions, and adults aged ≥65 years (including residents of long-term care facilities) (Table 2). These groups were selected based on available scientific data, vaccine implementation considerations, and ethical principles. The principle of transparency is applied across the entirety of the vaccine allocation decision-making process. ACIP's meetings are open to the public, meeting minutes and archived webcasts are available online, and data (including data from vaccine clinical trials) and analytic methods used in developing ACIP recommendations are publicly available.[§] Members of the public are invited to submit written comments to the Federal Register or provide oral comment during ACIP meetings. ACIP's 30 nonvoting representatives from liaison organizations facilitate engagement with professional medical and public health organizations and other stakeholders and partners.

All four groups proposed for initial allocation of COVID-19 vaccine merit strong consideration from an ethical perspective. Current planning scenarios estimate, however, that the expected number of doses during the first weeks of vaccine distribution might only be sufficient to vaccinate approximately 20 million persons.[¶] Although there is considerable overlap between groups[**] (*10*), the initial supply will not be adequate to vaccinate the entirety of all four groups; for example, there are approximately 100 million health care personnel and essential workers (Table 2). Published frameworks for COVID-19 allocation and ACIP discussions indicate a clear consensus that the first allocation of COVID-19 vaccine supplies should be directed to health care personnel (*1*,*5*–*8*); discussion of allocation to the other three groups is ongoing. As additional vaccine supplies become available, other groups may be vaccinated concurrent with health care personnel.

[§] https://www.cdc.gov/vaccines/acip/index.html.

[¶] https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

[**] There is overlap among these four groups. For example, in one analysis, among the 3.8% of U.S. adults who work directly with patients as health care workers, 38.6% have high-risk medical conditions or are aged >65 years.

Discussion

During a pandemic, ethical guidelines can help steer and support decisions around prioritization of limited resources (*3*,*4*). Consideration of ethical values and principles has featured prominently in discussions about allocation of COVID-19 vaccines. This consideration is particularly relevant because the COVID-19 pandemic has highlighted long-standing, systemic health and social inequities. Although various frameworks for COVID-19 vaccine allocation demonstrate differences in their structure (e.g., based on varying combinations of different goals, objectives, criteria, and other structural elements) and emphasis (e.g., inclusion of global and national considerations), nearly all reference values and principles similar to those which ACIP considers fundamental (*5*–*8*). ACIP viewed the following characteristics as critical for its ethical approach to COVID-19 vaccine allocation when supply is limited: simplicity in structure and definitions; acceptability to stakeholders; and ease of application, both at the national and state, tribal, local, and territorial levels.

Allocation of limited vaccine supplies is complicated by efforts to address the multiple goals of a vaccine program, most notably those related to the reduction of morbidity and mortality and the minimization of disruption to society and the economy. If the goals of a pandemic vaccination program are not clearly articulated and prioritized, drawing distinctions between groups that merit consideration for allocation of vaccine when supply is constrained can become difficult. The unanimity in opinion for early vaccination of health care personnel indicates that maintenance of health care capacity has emerged as a high priority in the context of a severe pandemic. This perspective aligns with ethical considerations for pandemic influenza planning (*3*,*4*). If vaccine supply remains constrained, it might be necessary to identify subsets of other groups for subsequent early allocation of COVID-19 vaccine. At the national, state, tribal, local, and territorial levels, such decisions should be guided, in part, by ethical principles and consideration of essential questions, with particular consideration of mitigation of health inequities in persons experiencing disproportionate COVID-19 morbidity and mortality. In the setting of a constrained supply, the benefits of vaccination will be delayed for some persons; however, as supply increases, there will eventually be enough vaccine for everyone.

In addition to ethical considerations, ACIP's recommendations regarding receipt of the initial allocations of COVID-19 vaccine during the period of constrained supply will be based on science (e.g., available information about the vaccine's characteristics such as safety and efficacy in older adults and epidemiologic risk) and feasibility of implementation (e.g., storage and handling requirements). Thus, ACIP's allocation recommendations will

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TABLE 2. Application of ethical principles to four candidate groups for initial COVID-19 vaccine allocation — United States, 2020

Principles (with transparency across the decision-making process)	Candidate groups* (approximate no.)			
	Health care personnel† (21 million)	**Other essential workers† (87 million)**	**Adults with high-risk medical conditions§ (>100 million)**	**Adults aged ≥65 years (53 million)**
Maximize benefits and minimize harms	Preserves health care services essential to the COVID-19 response and the overall health care system	Preserves services essential to the COVID-19 response and overall functioning of society	Reduces morbidity and mortality in persons with high incidence of COVID-19 disease and death**	Reduces morbidity and mortality in persons with high incidence of COVID-19 disease and death††
	Multiplier effect¶	Multiplier effect¶		
Promote justice	Addresses elevated occupational risk for SARS-CoV-2 exposure for those unable to work from home	Addresses elevated occupational risk for SARS-CoV-2 exposure for those unable to work from home	Will require focused outreach to vaccinate persons in this group who have no or limited access to health care or experience inequities in social determinants of health	Will require focused outreach to vaccinate persons in this group who have no or limited access to health care or experience inequities in social determinants of health
	Promotes access to vaccine across a spectrum of HCP job types and settings	Promotes access to vaccine and reduces barriers to vaccination in occupations with low vaccine uptake§§		
Mitigate health inequities	Racial and ethnic minority groups are disproportionately represented in low-wage HCP¶¶	Racial and ethnic minority groups are disproportionately represented in many essential industries***	Increased prevalence of obesity and diabetes (most prevalent conditions in this group) among some racial and ethnic minority groups; increased prevalence of some medical conditions for persons in rural areas§§§	Although racial and ethnic minority groups are underrepresented among adults aged ≥65 years, certain groups have disproportionate COVID-19–related hospitalization and death rates¶¶¶
		Approximately one quarter of essential workers live in low-income families†††	Could increase health inequities because diagnosis of high-risk medical conditions requires access to health care	Strict age-based criterion could increase disparities due to racial and social inequities, such as occupation, income, access to health care

Abbreviations: COVID-19 = coronavirus disease 2019; HCP = health care personnel.

* Health care personnel: paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials; other essential workers: person who conduct operations vital for continuing critical infrastructure, such as food, agriculture, transportation, education, and law enforcement; adults with high risk medical conditions: adults who have one or more high-risk medical conditions, such as obesity, diabetes, and cardiovascular disease; adults aged ≥65 years: includes adults living at home and approximately 3 million living in long-term care facilities. There is considerable overlap between groups, for example, many adults aged ≥65 years also have high-risk medical conditions.

† Essential workers during the COVID-19 response have been defined by the U.S. Department of Homeland Security Cybersecurity and Infrastructure Security Agency. https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v2_0.pdf.

§ Medical conditions considered high-risk are updated routinely based on the best available scientific data: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

¶ The ability of one or more groups to remain healthy helps protect the health of others and/or minimize disruption to society and the economy.

** As of October 31, 2020, nearly 90% of persons with COVID-19–associated hospitalizations have at least one high-risk condition. Data are routinely updated through COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) (https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html); in-hospital deaths reported to COVID-NET during March–May, 2020 were associated with certain underlying medical conditions (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1012/5872581).

†† As of November 12, 2020, 80% of COVID-19 deaths were among adults aged ≥65 years. Data are routinely updated through CDC case-based surveillance (https://covid.cdc.gov/covid-data-tracker/#demographics); long-term care residents account for a large proportion of deaths among adults aged ≥65 years (https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/).

§§ Influenza vaccination coverage is low among many non–health care essential workers; such coverage is lowest among construction workers (10.7%) (https://www.cdc.gov/niosh/docs/2012-161/pdfs/2012-161.pdf?id = 10.26616/NIOSHPUB2012161).

¶¶ Health Resources and Services Administration estimates from American Community Survey 2011–2015 (https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/diversityushealthoccupationstechnical.pdf).

*** Among 742 food and agriculture workplaces in 30 states, 73% of workers were Hispanic or Latino and 83% of COVID-19 cases occurred in racial or ethnic minority workers (https://wwwnc.cdc.gov/eid/article/27/1/20-3821_article).

††† Center for Economic and Policy Research estimates from American Community Survey, 2014–2018 (https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries).

§§§ National Center for Health Statistics. National Health Interview Survey, 2018. Estimates not available for Hawaiian/other Pacific Islander persons or for chronic kidney disease among American Indian/Alaska Native persons (https://www.cdc.gov/nchs/nhis/ADULTS/www/index.htm; https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm).

¶¶¶ As of October 31, 2020, compared with COVID-19 hospitalization rates for adults aged ≥65 years who are non-Hispanic White, such rates were higher among adults aged ≥65 years who were non-Hispanic Black (rate ratio [RR] = 3.3), Hispanic or Latino (RR = 2.6), and non-Hispanic American Indian or Alaska Native (RR = 2.4). Data are routinely updated through COVID-NET (https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html); adults aged ≥65 years who are Hispanic or non-Hispanic Black experience disproportionate COVID-19–associated death rates (https://www.cdc.gov/nchs/nvss/vsrr/covid19/health_disparities.htm).

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Summary

What is already known about this topic?

During the period when the U.S. supply of COVID-19 vaccines is limited, the Advisory Committee on Immunization Practices (ACIP) will make vaccine allocation recommendations.

What is added by this report?

In addition to scientific data and implementation feasibility, four ethical principles will assist ACIP in formulating recommendations for the initial allocation of COVID-19 vaccine: 1) maximizing benefits and minimizing harms; 2) promoting justice; 3) mitigating health inequities; and 4) promoting transparency.

What are the implications for public health practice?

Ethical principles will aid ACIP in making vaccine allocation recommendations and state, tribal, local, and territorial public health authorities in developing vaccine implementation strategies based on ACIP's recommendations.

be made in conjunction with specific recommendations for the use of each FDA-authorized or licensed COVID-19 vaccine. Although the ethical principles in this report are fundamental for stewardship of limited vaccine supply, they can also be applied when COVID-19 vaccines are widely available, to ensure equitable and just access for all persons.

Acknowledgments

Members of the Advisory Committee on Immunization Practices COVID-19 Vaccines Work Group.

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The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

Nancy McClung, PhD[1]; Mary Chamberland, MD[1,2]; Kathy Kinlaw, MDiv[3]; Dayna Bowen Matthew, JD, PhD[4]; Megan Wallace, DrPH[1,5]; Beth P. Bell, MD[6]; Grace M. Lee, MD[7]; H. Keipp Talbot, MD[8]; José R. Romero, MD[9]; Sara E. Oliver, MD[1]; Kathleen Dooling, MD[1]

To reduce the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) and its associated impacts on health and society, COVID-19 vaccines are essential. The U.S. government is working to produce and deliver safe and effective COVID-19 vaccines for the entire U.S. population. The Advisory Committee on Immunization Practices (ACIP)* has broadly outlined its approach for developing recommendations for the use of each COVID-19 vaccine authorized or approved by the Food and Drug Administration (FDA) for Emergency Use Authorization or licensure (*1*). ACIP's recommendation process includes an explicit and transparent evidence-based method for assessing a vaccine's safety and efficacy as well as consideration of other factors, including implementation (*2*). Because the initial supply of vaccine will likely be limited, ACIP will also recommend which groups should receive the earliest allocations of vaccine. The ACIP COVID-19 Vaccines Work Group and consultants with expertise in ethics and health equity considered external expert committee reports and published literature and deliberated the ethical issues associated with COVID-19 vaccine allocation decisions. The purpose of this report is to describe the four ethical principles that will assist ACIP in formulating recommendations for the allocation of COVID-19 vaccine while supply is limited, in addition to scientific data and implementation feasibility: 1) maximize benefits and minimize harms; 2) promote justice; 3) mitigate health inequities; and 4) promote transparency. These principles can also aid state, tribal, local, and territorial public health authorities as they develop vaccine implementation strategies within their own communities based on ACIP recommendations.

The ACIP COVID-19 Vaccines Work Group has met several times per month (approximately 25 meetings) since its establishment in April 2020. Work Group discussions included review of the epidemiology of COVID-19 and consultation with experts in ethics and health equity to inform the development of an ethically principled decision-making process. The Work Group reviewed the relevant literature, including frameworks for pandemic influenza planning and COVID-19 vaccine allocation (*3*–*8*); summarized this information; and presented it to ACIP. ACIP supported four fundamental ethical principles to guide COVID-19 vaccine allocation decisions in the setting of a constrained supply. Essential questions that derive from these principles can assist in vaccine allocation planning (Table 1).

Maximize benefits and minimize harms. Allocation of COVID-19 vaccine should maximize the benefits of vaccination to both individual recipients and the population overall. These benefits include the reduction of SARS-CoV-2 infections and COVID-19–associated morbidity and mortality, which in turn reduces the burden on strained health care capacity and facilities; preservation of services essential to the COVID-19 response; and maintenance of overall societal functioning. Identification of groups whose receipt of the vaccine would lead to the greatest benefit should be based on scientific evidence, accounting for those at highest risk for SARS-CoV-2 infection or severe COVID-19–related disease or death, and the essential role of certain workers. The ability of essential workers, including health care workers and non–health care

*The ACIP includes 15 voting members responsible for making vaccine recommendations. Fourteen of the members have expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine; one member is a consumer representative who provides perspectives on the social and community aspects of vaccination. In addition to the 15 voting members, ACIP includes eight ex officio members who represent other federal agencies with responsibility for immunization programs in the United States, and 30 nonvoting representatives of liaison organizations that bring related immunization expertise. https://www.cdc.gov/vaccines/acip/members/index.html.

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TABLE 1. Essential questions for COVID-19 vaccine allocation planning related to ethical principles — United States, 2020

Ethical principle	Essential question
Maximize benefits and minimize harms	What groups are at highest risk for SARS-CoV-2 infection, COVID-19 disease, hospitalization, and death?
	What groups are essential to the COVID-19 response?
	What groups are essential to maintaining critical functions of society?
	What are the important characteristics of these groups (e.g., size or geographic distribution) that might inform the magnitude of benefit based on the amount of vaccine available or its characteristics?
Promote justice	Does the allocation plan result in fair and equitable access of the vaccine for all groups?
	How do characteristics of the vaccine and logistical considerations affect fair access for all persons?
	Does allocation planning include input from groups who are disproportionately affected by COVID-19 or face health inequities resulting from social determinants of health, such as income and health care access?
Mitigate health inequities	Does the plan identify and address barriers to vaccination among any groups who are disproportionately affected by COVID-19 or who face health inequities resulting from social determinants of health, such as income and health care access?
	Does the allocation plan contribute to a reduction in health disparities in COVID-19 disease and death?
	What health inequities might inadvertently result from the allocation plan, and what interventions could remove or reduce them?
	Is there a mechanism for timely assessment of vaccination coverage among groups experiencing disadvantage and the possibility for course correction if inequities are identified?
Promote transparency	How does development of the allocation plan include diverse input, and if possible, public engagement?
	Are the allocation plan and evidence-based methods publicly available?
	Is the allocation plan clear about what is known and unknown and about the quality of available evidence?
	What is the process for revision of allocation plans based on new information?
	Is there a mechanism to report demographic data elements for vaccine recipients (e.g., age, race/ethnicity, and occupation) to support equitable vaccination coverage?

Abbreviation: COVID-19 = coronavirus disease 2019.

workers, to remain healthy has a multiplier effect (i.e., their ability to remain healthy helps to protect the health of others or to minimize societal and economic disruption). Some of these workers are at increased risk for SARS-CoV-2 infection because of their limited ability to maintain physical distance in the workplace or because they do not have consistent access to recommended personal protective equipment.

Promote justice. Inherent in the principle of justice is an obligation to protect and advance equal opportunity for all persons to enjoy the maximal health and well-being possible. Justice rests on the belief in the fundamental value and dignity of all persons. Allocation of COVID-19 vaccine should promote justice by intentionally ensuring that all persons have equal opportunity to be vaccinated, both within the groups recommended for initial vaccination, and as vaccine becomes more widely available. This includes a commitment to removing unfair, unjust, and avoidable barriers to vaccination that disproportionately affect groups that have been economically or socially marginalized, as well as a fair and consistent implementation process. Input from a range of external entities, partners, and community representatives is particularly important in developing and assessing allocation plans.

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Promote transparency. Transparency relates to the decision-making process and is essential to building and maintaining public trust during vaccine program planning and implementation. The underlying principles, decision-making processes, and plans for COVID-19 vaccine allocation must be evidence-based, clear, understandable, and publicly available. To the extent possible, considering the urgency of the COVID-19

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response, public participation in the creation and review of the decision-making process should be facilitated. In addition, when feasible, tracking administration of vaccine to the groups recommended for initial vaccine allocation can contribute to transparency and trust in the process. In an ongoing public health response, the situation continually evolves as new information becomes available. Transparency includes being clear about the level of certainty in the available evidence and communicating new information that might change recommendations in a timely fashion.

For the period when the supply of COVID-19 vaccine will be limited, ACIP has considered four groups for initial vaccine allocation. These include health care personnel, other essential workers, adults with high-risk medical conditions, and adults aged ≥65 years (including residents of long-term care facilities) (Table 2). These groups were selected based on available scientific data, vaccine implementation considerations, and ethical principles. The principle of transparency is applied across the entirety of the vaccine allocation decision-making process. ACIP's meetings are open to the public, meeting minutes and archived webcasts are available online, and data (including data from vaccine clinical trials) and analytic methods used in developing ACIP recommendations are publicly available.[§] Members of the public are invited to submit written comments to the Federal Register or provide oral comment during ACIP meetings. ACIP's 30 nonvoting representatives from liaison organizations facilitate engagement with professional medical and public health organizations and other stakeholders and partners.

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[¶] https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

[**] There is overlap among these four groups. For example, in one analysis, among the 3.8% of U.S. adults who work directly with patients as health care workers, 38.6% have high-risk medical conditions or are aged >65 years.

Discussion

During a pandemic, ethical guidelines can help steer and support decisions around prioritization of limited resources (*3*,*4*). Consideration of ethical values and principles has featured prominently in discussions about allocation of COVID-19 vaccines. This consideration is particularly relevant because the COVID-19 pandemic has highlighted long-standing, systemic health and social inequities. Although various frameworks for COVID-19 vaccine allocation demonstrate differences in their structure (e.g., based on varying combinations of different goals, objectives, criteria, and other structural elements) and emphasis (e.g., inclusion of global and national considerations), nearly all reference values and principles similar to those which ACIP considers fundamental (*5*–*8*). ACIP viewed the following characteristics as critical for its ethical approach to COVID-19 vaccine allocation when supply is limited: simplicity in structure and definitions; acceptability to stakeholders; and ease of application, both at the national and state, tribal, local, and territorial levels.

Allocation of limited vaccine supplies is complicated by efforts to address the multiple goals of a vaccine program, most notably those related to the reduction of morbidity and mortality and the minimization of disruption to society and the economy. If the goals of a pandemic vaccination program are not clearly articulated and prioritized, drawing distinctions between groups that merit consideration for allocation of vaccine when supply is constrained can become difficult. The unanimity in opinion for early vaccination of health care personnel indicates that maintenance of health care capacity has emerged as a high priority in the context of a severe pandemic. This perspective aligns with ethical considerations for pandemic influenza planning (*3*,*4*). If vaccine supply remains constrained, it might be necessary to identify subsets of other groups for subsequent early allocation of COVID-19 vaccine. At the national, state, tribal, local, and territorial levels, such decisions should be guided, in part, by ethical principles and consideration of essential questions, with particular consideration of mitigation of health inequities in persons experiencing disproportionate COVID-19 morbidity and mortality. In the setting of a constrained supply, the benefits of vaccination will be delayed for some persons; however, as supply increases, there will eventually be enough vaccine for everyone.

In addition to ethical considerations, ACIP's recommendations regarding receipt of the initial allocations of COVID-19 vaccine during the period of constrained supply will be based on science (e.g., available information about the vaccine's characteristics such as safety and efficacy in older adults and epidemiologic risk) and feasibility of implementation (e.g., storage and handling requirements). Thus, ACIP's allocation recommendations will

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Principles (with transparency across the decision-making process)	Candidate groups* (approximate no.)			
	Health care personnel† (21 million)	**Other essential workers† (87 million)**	**Adults with high-risk medical conditions§ (>100 million)**	**Adults aged ≥65 years (53 million)**
Maximize benefits and minimize harms	Preserves health care services essential to the COVID-19 response and the overall health care system	Preserves services essential to the COVID-19 response and overall functioning of society	Reduces morbidity and mortality in persons with high incidence of COVID-19 disease and death**	Reduces morbidity and mortality in persons with high incidence of COVID-19 disease and death††
	Multiplier effect¶	Multiplier effect¶		
Promote justice	Addresses elevated occupational risk for SARS-CoV-2 exposure for those unable to work from home	Addresses elevated occupational risk for SARS-CoV-2 exposure for those unable to work from home	Will require focused outreach to vaccinate persons in this group who have no or limited access to health care or experience inequities in social determinants of health	Will require focused outreach to vaccinate persons in this group who have no or limited access to health care or experience inequities in social determinants of health
	Promotes access to vaccine across a spectrum of HCP job types and settings	Promotes access to vaccine and reduces barriers to vaccination in occupations with low vaccine uptake§§		
Mitigate health inequities	Racial and ethnic minority groups are disproportionately represented in low-wage HCP¶¶	Racial and ethnic minority groups are disproportionately represented in many essential industries***	Increased prevalence of obesity and diabetes (most prevalent conditions in this group) among some racial and ethnic minority groups; increased prevalence of some medical conditions for persons in rural areas§§§	Although racial and ethnic minority groups are underrepresented among adults aged ≥65 years, certain groups have disproportionate COVID-19–related hospitalization and death rates¶¶¶
		Approximately one quarter of essential workers live in low-income families†††	Could increase health inequities because diagnosis of high-risk medical conditions requires access to health care	Strict age-based criterion could increase disparities due to racial and social inequities, such as occupation, income, access to health care

Abbreviations: COVID-19 = coronavirus disease 2019; HCP = health care personnel.

* Health care personnel: paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials; other essential workers: person who conduct operations vital for continuing critical infrastructure, such as food, agriculture, transportation, education, and law enforcement; adults with high risk medical conditions: adults who have one or more high-risk medical conditions, such as obesity, diabetes, and cardiovascular disease; adults aged ≥65 years: includes adults living at home and approximately 3 million living in long-term care facilities. There is considerable overlap between groups, for example, many adults aged ≥65 years also have high-risk medical conditions.

† Essential workers during the COVID-19 response have been defined by the U.S. Department of Homeland Security Cybersecurity and Infrastructure Security Agency. https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v2_0.pdf.

§ Medical conditions considered high-risk are updated routinely based on the best available scientific data: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

¶ The ability of one or more groups to remain healthy helps protect the health of others and/or minimize disruption to society and the economy.

** As of October 31, 2020, nearly 90% of persons with COVID-19–associated hospitalizations have at least one high-risk condition. Data are routinely updated through COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) (https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html); in-hospital deaths reported to COVID-NET during March–May, 2020 were associated with certain underlying medical conditions (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1012/5872581).

†† As of November 12, 2020, 80% of COVID-19 deaths were among adults aged ≥65 years. Data are routinely updated through CDC case-based surveillance (https://covid.cdc.gov/covid-data-tracker/#demographics); long-term care residents account for a large proportion of deaths among adults aged ≥65 years (https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/).

§§ Influenza vaccination coverage is low among many non–health care essential workers; such coverage is lowest among construction workers (10.7%) (https://www.cdc.gov/niosh/docs/2012-161/pdfs/2012-161.pdf?id = 10.26616/NIOSHPUB2012161).

¶¶ Health Resources and Services Administration estimates from American Community Survey 2011–2015 (https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/diversityushealthoccupationstechnical.pdf).

*** Among 742 food and agriculture workplaces in 30 states, 73% of workers were Hispanic or Latino and 83% of COVID-19 cases occurred in racial or ethnic minority workers (https://wwwnc.cdc.gov/eid/article/27/1/20-3821_article).

††† Center for Economic and Policy Research estimates from American Community Survey, 2014–2018 (https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries).

§§§ National Center for Health Statistics. National Health Interview Survey, 2018. Estimates not available for Hawaiian/other Pacific Islander persons or for chronic kidney disease among American Indian/Alaska Native persons (https://www.cdc.gov/nchs/nhis/ADULTS/www/index.htm; https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm).

¶¶¶ As of October 31, 2020, compared with COVID-19 hospitalization rates for adults aged ≥65 years who are non-Hispanic White, such rates were higher among adults aged ≥65 years who were non-Hispanic Black (rate ratio [RR] = 3.3), Hispanic or Latino (RR = 2.6), and non-Hispanic American Indian or Alaska Native (RR = 2.4). Data are routinely updated through COVID-NET (https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html); adults aged ≥65 years who are Hispanic or non-Hispanic Black experience disproportionate COVID-19–associated death rates (https://www.cdc.gov/nchs/nvss/vsrr/covid19/health_disparities.htm).

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Summary

What is already known about this topic?

During the period when the U.S. supply of COVID-19 vaccines is limited, the Advisory Committee on Immunization Practices (ACIP) will make vaccine allocation recommendations.

What is added by this report?

In addition to scientific data and implementation feasibility, four ethical principles will assist ACIP in formulating recommendations for the initial allocation of COVID-19 vaccine: 1) maximizing benefits and minimizing harms; 2) promoting justice; 3) mitigating health inequities; and 4) promoting transparency.

What are the implications for public health practice?

Ethical principles will aid ACIP in making vaccine allocation recommendations and state, tribal, local, and territorial public health authorities in developing vaccine implementation strategies based on ACIP's recommendations.

be made in conjunction with specific recommendations for the use of each FDA-authorized or licensed COVID-19 vaccine. Although the ethical principles in this report are fundamental for stewardship of limited vaccine supply, they can also be applied when COVID-19 vaccines are widely available, to ensure equitable and just access for all persons.

Acknowledgments

Members of the Advisory Committee on Immunization Practices COVID-19 Vaccines Work Group.

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COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State — Minnesota, August–September 2020

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During August 7–16, 2020, a motorcycle rally was held in western South Dakota that attracted approximately 460,000 persons from across the United States to numerous indoor and outdoor events over a 10-day period. During August–September 2020, the Minnesota Department of Health (MDH) investigated a coronavirus disease 2019 (COVID-19) outbreak associated with the rally in Minnesota residents. Fifty-one primary event-associated cases were identified, and 35 secondary or tertiary cases occurred among household, social, and workplace contacts, for a total of 86 cases; four patients were hospitalized, and one died. Approximately one third (34%) of 87 counties in Minnesota had at least one primary, secondary, or tertiary case associated with this rally. Genomic sequencing supported the associations with the motorcycle rally. These findings support current recommendations for mask use, physical distancing, reducing the number of attendees at gatherings, isolation for patients with COVID-19, and quarantine for close contacts to slow the spread of SARS-CoV-2 (*1*). Furthermore, although these findings did not capture the impact of the motorcycle rally on residents of other states, they demonstrate the rationale for consistent mitigation measures across states.

Investigation and Findings

On August 21, 2020, MDH identified confirmed COVID-19 cases in persons who reported attending the motorcycle rally in the neighboring state of South Dakota. A primary, event-associated case was defined as an illness in a person who reported attending the rally or who traveled to western South Dakota by motorcycle during August 7–16 and who had symptom onset or specimen collection before August 30 (within 14 days after the end of the rally). Reverse transcription–polymerase chain reaction testing for SARS-CoV-2, the virus that causes COVID-19, was used to confirm cases. All confirmed cases among Minnesota residents were reported to MDH. MDH or local public health department staff members interviewed patients with confirmed SARS-CoV-2 infection to identify exposures and persons who might have been in contact with patients during their infectious period (2 days before through 10 days after symptom onset).* To assess exposures, interviews included questions about travel and being in specific settings, such as bars or restaurants, schools, health care facilities, or events or social gatherings in the 14 days before symptom onset. During August–September 2020, MDH and local health department staff members interviewed >80% of patients with a confirmed SARS-CoV-2 infection.

Secondary and tertiary cases were identified from case interview data. Confirmed secondary cases were defined as laboratory-confirmed infections in persons who did not attend the rally but who received SARS-CoV-2–positive test results after having contact with a person who had a primary case during their infectious period. Tertiary cases were laboratory-confirmed cases in persons who had contact with a person who had a secondary case during their infectious period. Likely event-associated secondary cases were confirmed infections in patients who had contact with a person who had symptoms of COVID-19 and had attended the motorcycle rally but who were not tested. Likely event-associated tertiary cases were confirmed infections in patients who had contact with persons who had a likely event-associated secondary case during their infectious period.

* The infectious period was estimated to begin 2 days before symptom onset and end 10 days after symptom onset, according to CDC guidance. https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/investigating-covid-19-case.html.

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To investigate genomic similarity among COVID-19 cases, available SARS-CoV-2 RNA-positive clinical specimens were obtained from clinical laboratories, and whole genome sequencing was conducted at the MDH Public Health Laboratory on 38 specimens using previously described methods (*2*). Phylogenetic relationships, including distinct clustering of viral whole genome sequences, were inferred based on nucleotide differences via IQ-TREE[†] using general time reversible substitution models (*3*) as a part of the Nextstrain[§] workflow (*4*). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[¶]

This investigation identified 86 cases, including 51 (59%) primary event-associated cases,[**] 26 (30%) confirmed secondary and tertiary cases, and nine (10%) likely event-associated secondary or tertiary cases. Four patients were hospitalized, and one died (Table). The median interval between specimen collection and interview was 3 days (range = 1–13 days). Overall, 64 (74%) patients were symptomatic, including 39 (76%) of 51 patients with a primary case and 25 (71%) of 35 patients with secondary and tertiary cases. Among patients with primary cases and symptom onset after the start of the rally, onset dates ranged from August 8 to August 26 (Figure 1). Two patients reported symptom onset before the event and attended the rally during their infectious period. Among primary patients, the median age was 44 years (range = 26–76 years), and 31 (61%) were male. Sixteen (33%) of 48 interviewed patients reported working while infectious, including five who worked at the rally and four who worked in health care after returning from the rally.

Forty-one (80%) interviewed patients with primary event-associated COVID-19 reported having close contact[††] with others during their infectious period, with an average of 2.5 close contacts per patient (range = 1–8). Overall, 36 (75%) of 48 interviewed patients with primary event-associated cases reported having close contact with persons in their household while infectious, and 17 (35%) reported having other (social/workplace) close contacts while infectious. Patients reported a total of 59 household contacts (range = 0–4 per patient) and 43 social/workplace contacts (range = 0–6 per patient).

Among the 35 patients with confirmed or likely event-associated secondary/tertiary COVID-19, 25 (71%) were symptomatic, with symptom onset dates during August 12–29 (Table). The median age was 32 years (range = 1–83 years), and 13 (37%) were male. Fifteen (43%) persons with secondary or tertiary COVID-19 were household contacts of a person with a primary or secondary infection, 12 (34%) were social contacts, and eight (23%) were workplace contacts. Secondary transmission from this rally occurred via two workplace outbreaks, one wedding outbreak, and one funeral outbreak. Approximately one third (34%) of Minnesota's 87 counties had at least one primary, secondary, or tertiary case associated with this rally.

Whole Genome Sequencing

Specimens were obtained from 52 (60%) patients. Among these, 38 (73%) specimens (23 [61%] from primary and 15 [39%] from secondary and tertiary cases) were successfully sequenced, covering at least 98% of the SARS-CoV-2 genome. Six genetically similar clusters with known epidemiologic links were identified (i.e., cases in patients who were close contacts or who had common exposures at the rally), five of which demonstrated secondary or secondary and tertiary transmission. Cluster A (Figure 2) included genetically similar specimens for seven primary cases and one secondary case (specimen MN-MDH-1710). Among primary cases, specimens were collected from two patients who reported working at the rally, including one who worked at a restaurant. Two other patients in this cluster reported visiting that restaurant. Another patient who attended the rally also reported visiting the same restaurant; this patient was a household contact of the patient with specimen MN-MDH-1710. Cluster B represented a chain of transmission in a workplace setting that included five cases. The secondary case in this cluster (with specimen MN-MDH-STU0004) occurred in a workplace contact of a motorcycle rally attendee (specimen MN-MDH-STU0001) and a social contact of one of the persons with a tertiary case (specimen MN-MDH-STU0008). Another secondary case[§§] in this cluster was in a workplace contact of the rally attendee and was a household contact of two of the three patients with tertiary cases in this cluster (specimens MN-MDH-1708 and MN-MDH-1709). Cluster C represented secondary transmission from a rally attendee (specimen MN-MDH-1651) to a household contact (specimen MN-MD-1705). Cluster D represented likely event-associated cases of secondary transmission (specimens MN-MDH-STU0002, MN-MDH-1706, and MD-MDH-1712) and tertiary transmission (specimens MN-MDH-STU-0005 and MN-MDH-1711) related to a wedding. The index patient at this wedding reportedly had COVID-19–like symptoms at the wedding after attending the rally but did not receive testing. Cluster E comprised two

[†] http://www.iqtree.org/.
[§] https://nextstrain.org/.
[¶] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.
[**] One patient reported attending the rally but refused interview. Two additional patients who refused to be interviewed were identified as having attended the rally through secondary case interviews in which other patients reported them as primary event-associated contacts.
[††] Close contact was defined as being within 6 feet of a patient with laboratory-confirmed COVID-19 infection for ≥15 minutes. https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/contact-tracing.html.
[§§] Although the specimen from this patient was obtained, sequencing was incomplete.

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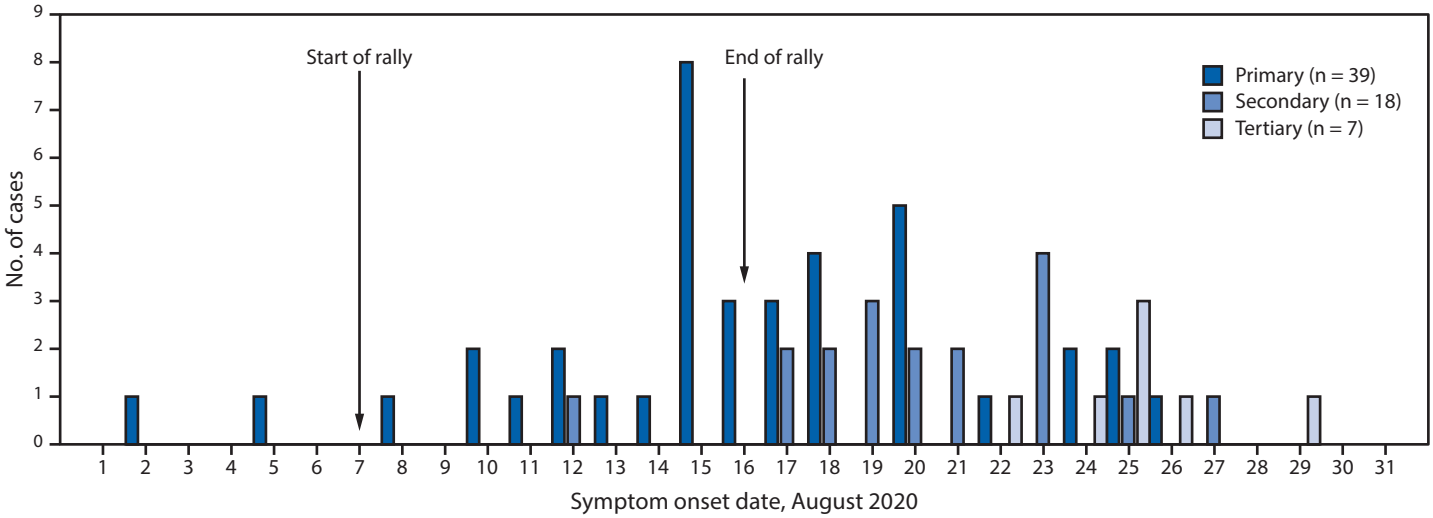
FIGURE 1. Date of symptom onset among symptomatic patients with primary,* secondary,† and tertiary§ COVID-19 (N = 64) associated with a motorcycle rally in a neighboring state — Minnesota, August 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

* Laboratory-confirmed SARS-CoV-2 infection in a person who attended the motorcycle rally or traveled to western South Dakota by motorcycle during August 7–16 and had symptom onset or specimen collection within 14 days of the end of the rally.

† Laboratory-confirmed infection in a person who had contact with a laboratory-confirmed primary case during the infectious period or with a symptomatic rally attendee who was not tested.

§ Laboratory-confirmed infection in a person who had contact with a secondary case or likely event-associated secondary case.

cases (specimens MN-MDH-1567 and MN-MH-1714) in persons who were household contacts, both of whom attended the rally. Cluster F represents workplace and household contacts (specimens MN-MDH-1715, MN-MDH-1716, MN-MDH-1713, and MN-MDH-STU0007) of the primary patient with specimen MN-MDH-1569. Specimen MN-MDH-1569 was from a musician who performed at the rally and later at another concert with a different band whose members did not attend the rally. Primary event-associated cases with specimens MN-MDH-1571 and MN-MDH-1572 had no known connection to each other or identified common exposure at the rally; however, the reported symptom onset dates and travel dates for these cases were identical. Similarly, primary event-associated cases with specimens MN-MDH-1568 and MN-MDH-1707 had no known epidemiologic link but had identical symptom onset dates. This might indicate a common exposure that was not identified through epidemiologic evidence.

Public Health Response

On August 5, MDH recommended through media events that motorcycle rally attendees quarantine for 14 days upon return and be tested 5–7 days later even if they were asymptomatic. Attendees and their close contacts with confirmed COVID-19 were instructed to self-isolate. Contacts of patients with confirmed COVID-19 were instructed to quarantine.

Discussion

Eighty-six Minnesota COVID-19 cases were associated with the South Dakota motorcycle rally; approximately one third of counties in Minnesota reported at least one case epidemiologically linked to this event. These findings highlight the far-reaching effects that gatherings in one area might have on another area. The motorcycle rally was held in a neighboring state that did not have policies regarding event size and mask use, underscoring the implications of policies within and across jurisdictions. The findings suggest that this rally not only had a direct impact on the health of attendees, but also led to subsequent SARS-CoV-2 transmission among household, social, and workplace contacts of rally attendees upon their return to Minnesota. Whole genome sequencing results supported the finding of secondary and tertiary transmission associated with this rally.

The findings in this report are subject to at least three limitations. First, despite in-depth epidemiologic investigation, the findings represent an underestimate of the motorcycle rally's impact in Minnesota and did not capture the impact within South Dakota or other states. Case interviews were voluntary, and patients could choose not to respond to certain questions. Ten patients reported having close contacts but refused to disclose additional details regarding these contacts. Therefore, it was not possible to identify all contacts of patients who attended the rally. Second, attendees and their contacts might not have been tested for SARS-CoV-2. Two rally attendees

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TABLE. Demographic and clinical characteristics of confirmed* and likely event-associated COVID-19 cases (N = 86) associated with a 10-day motorcycle rally in a neighboring state — Minnesota, August–September 2020

Characteristic	No. of cases (%)		
	Primary event–associated† (n = 51)	Confirmed secondary§/tertiary¶ (n = 26)	Likely event-associated secondary**/tertiary†† (n = 9)
Demographic			
Sex			
Female	20 (39.2)	16 (61.5)	6 (66.7)
Male	31 (60.8)	10 (38.5)	3 (33.3)
Age, yrs, median (range)	44 (26–76)	43 (12–83)	22 (1–51)
Age group, yrs			
<18	0 (—)	3 (11.5)	3 (33.3)
18–24	0 (—)	2 (7.7)	2 (22.2)
25–44	26 (51.0)	8 (30.8)	3 (33.3)
45–64	21 (41.2)	10 (38.5)	1 (11.1)
≥65	4 (7.8)	3 (11.5)	0 (—)
Race/Ethnicity			
White, NH	43 (84.3)	22 (84.6)	8 (88.9)
More than one race/Other, NH	1 (2.0)	0 (—)	1 (11.1)
Unknown	7 (13.7)	4 (15.4)	0 (—)
Clinical			
Symptomatic§§	39 (76.5)	19 (73.1)	6 (66.7)
Hospitalized	3 (5.9)	1 (3.8)	0 (—)
ICU admission	1 (2.0)	0 (—)	0 (—)
Died	1 (2.0)	0 (—)	0 (—)
Close contacts			
Household	NA	12	3
Social	NA	6	6
Workplace	NA	8	0

Abbreviations: COVID-19 = coronavirus disease 2019; ICU = intensive care unit; NA = not applicable; NH = non-Hispanic.
* Receipt of a positive SARS-CoV-2 reverse transcription–polymerase chain reaction test result.
† Laboratory-confirmed SARS-CoV-2 infection in a person who attended the motorcycle rally or traveled to western South Dakota by motorcycle during August 7–16 and had symptom onset or specimen collection within 14 days of the end of the rally.
§ Laboratory-confirmed infection in a person who had contact with a primary case during that person's infectious period.
¶ Laboratory-confirmed infection in a person who had contact with a secondary case during that person's infectious period.
** Laboratory-confirmed infection in a person who had contact with a symptomatic person who attended the rally but was not tested.
†† Laboratory-confirmed infection in a person who had contact with a likely secondary case.
§§ Symptom status was unknown for three patients with a primary case, three with a secondary/tertiary case, and one with a likely event-associated secondary/tertiary case.

indicated that their contacts had COVID-19–like symptoms but did not plan to be tested. As such, the findings underrepresent the number of cases, close contacts, and secondary and tertiary cases. Finally, only 52 specimens were received at the MDH Public Health Laboratory because many testing laboratories do not retain or store specimens long-term. Among these specimens, only 38 were successfully sequenced. The lack of whole genome sequencing data from all cases hindered establishment of complete genetic relatedness for epidemiologic investigation.

A large event in a neighboring state triggered chains of SARS-CoV-2 transmission within Minnesota. Other studies have shown that chains of transmission associated with gatherings are not uncommon within the United States (*5*,*6*). Despite underascertainment of the rally's full impact in Minnesota and other states, these findings highlight the importance of reducing the number of attendees at gatherings and emphasizing mask use, physical distancing, isolation for patients with COVID-19, and quarantine for close contacts as strategies for reducing the spread of COVID-19. Furthermore, these findings demonstrate the rationale for consistent mitigation measures across states.

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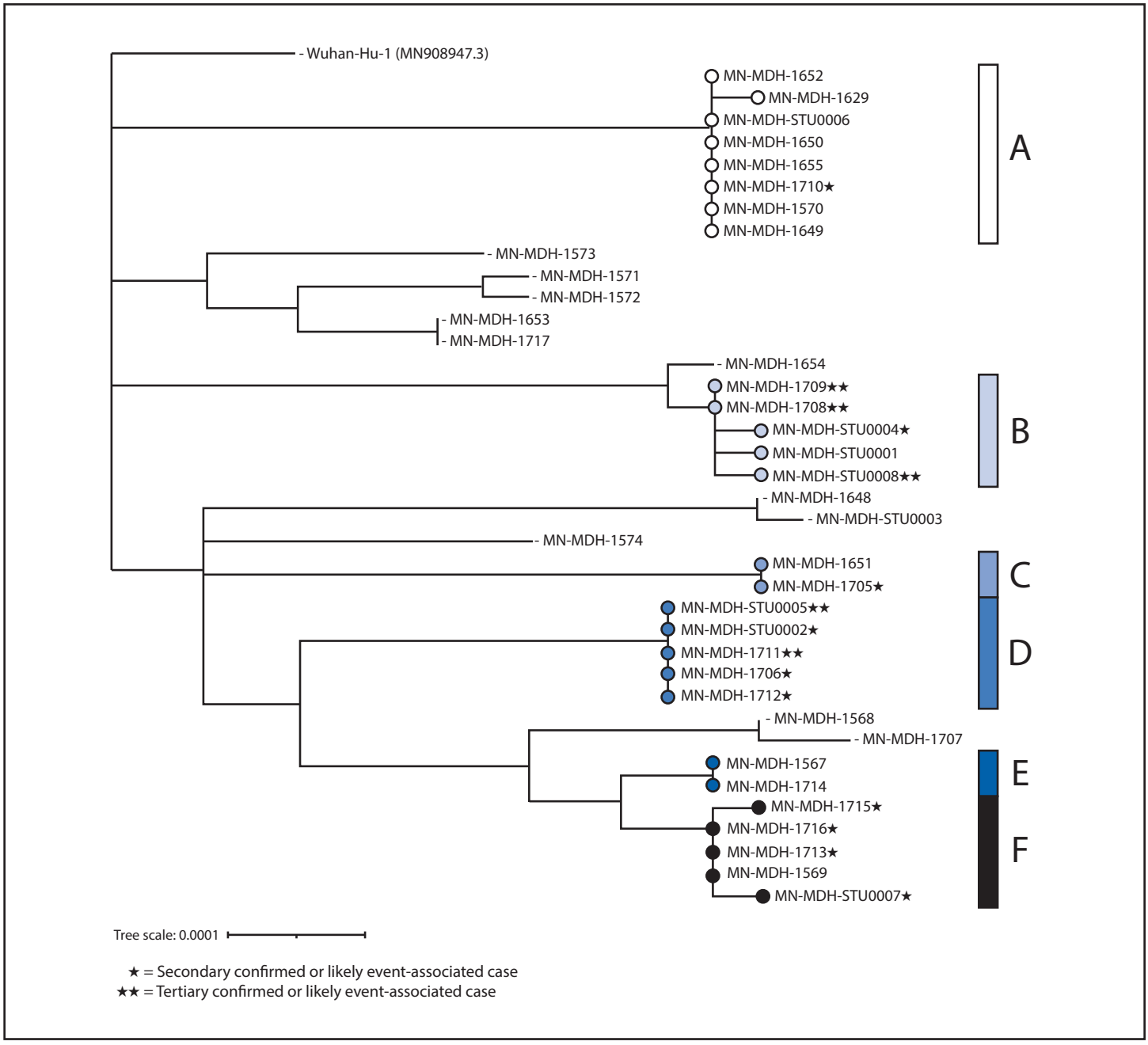
FIGURE 2. Phylogenetic tree* showing genetic distance between available† SARS-CoV-2 virus specimens collected from South Dakota motorcycle rally attendees and their contacts (N = 38) — Minnesota, August 2020



* This figure was created using Interactive Tree of Life (version 5.7; European Molecular Biology Laboratory). https://itol.embl.de/.

† Genetic divergence based on nucleotide difference is indicated by length of branches in substitutions per site. Available specimens include specimens from clinical labs where specimens could be retrieved and RNA could be extracted.

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Summary

What is already known about this topic?

Gatherings present an opportunity for rapid spread of COVID-19.

What is added by this report?

Following a 10-day motorcycle rally in South Dakota attended by approximately 460,000 persons, 51 confirmed primary event-associated cases, 21 secondary cases, and five tertiary cases were identified in Minnesota residents. An additional nine likely rally-associated secondary or tertiary cases occurred. Four patients were hospitalized, and one died. Genomic sequencing supported the associations with the motorcycle rally.

What are the implications for public health practice?

The impact of gatherings as a source of virus transmission underscores the importance of reducing the number of attendees at gatherings, using face masks, and encouraging physical distancing to prevent ongoing transmission of SARS-CoV-2. Furthermore, these findings demonstrate the rationale for consistent mitigation measures across states.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Matthew J. Binnicker reports personal fees from DiaSorin Molecular for an educational webinar on COVID-19 diagnostics and as a member of the advisory board. No other potential conflicts of interest were disclosed.

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COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State — Minnesota, August–September 2020

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During August 7–16, 2020, a motorcycle rally was held in western South Dakota that attracted approximately 460,000 persons from across the United States to numerous indoor and outdoor events over a 10-day period. During August–September 2020, the Minnesota Department of Health (MDH) investigated a coronavirus disease 2019 (COVID-19) outbreak associated with the rally in Minnesota residents. Fifty-one primary event-associated cases were identified, and 35 secondary or tertiary cases occurred among household, social, and workplace contacts, for a total of 86 cases; four patients were hospitalized, and one died. Approximately one third (34%) of 87 counties in Minnesota had at least one primary, secondary, or tertiary case associated with this rally. Genomic sequencing supported the associations with the motorcycle rally. These findings support current recommendations for mask use, physical distancing, reducing the number of attendees at gatherings, isolation for patients with COVID-19, and quarantine for close contacts to slow the spread of SARS-CoV-2 (*1*). Furthermore, although these findings did not capture the impact of the motorcycle rally on residents of other states, they demonstrate the rationale for consistent mitigation measures across states.

Investigation and Findings

On August 21, 2020, MDH identified confirmed COVID-19 cases in persons who reported attending the motorcycle rally in the neighboring state of South Dakota. A primary, event-associated case was defined as an illness in a person who reported attending the rally or who traveled to western South Dakota by motorcycle during August 7–16 and who had symptom onset or specimen collection before August 30 (within 14 days after the end of the rally). Reverse transcription–polymerase chain reaction testing for SARS-CoV-2, the virus that causes COVID-19, was used to confirm cases. All confirmed cases among Minnesota residents were reported to MDH. MDH or local public health department staff members interviewed patients with confirmed SARS-CoV-2 infection to identify exposures and persons who might have been in contact with patients during their infectious period (2 days before through 10 days after symptom onset).* To assess exposures, interviews included questions about travel and being in specific settings, such as bars or restaurants, schools, health care facilities, or events or social gatherings in the 14 days before symptom onset. During August–September 2020, MDH and local health department staff members interviewed >80% of patients with a confirmed SARS-CoV-2 infection.

Secondary and tertiary cases were identified from case interview data. Confirmed secondary cases were defined as laboratory-confirmed infections in persons who did not attend the rally but who received SARS-CoV-2–positive test results after having contact with a person who had a primary case during their infectious period. Tertiary cases were laboratory-confirmed cases in persons who had contact with a person who had a secondary case during their infectious period. Likely event-associated secondary cases were confirmed infections in patients who had contact with a person who had symptoms of COVID-19 and had attended the motorcycle rally but who were not tested. Likely event-associated tertiary cases were confirmed infections in patients who had contact with persons who had a likely event-associated secondary case during their infectious period.

* The infectious period was estimated to begin 2 days before symptom onset and end 10 days after symptom onset, according to CDC guidance. https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/investigating-covid-19-case.html.

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To investigate genomic similarity among COVID-19 cases, available SARS-CoV-2 RNA-positive clinical specimens were obtained from clinical laboratories, and whole genome sequencing was conducted at the MDH Public Health Laboratory on 38 specimens using previously described methods (*2*). Phylogenetic relationships, including distinct clustering of viral whole genome sequences, were inferred based on nucleotide differences via IQ-TREE[†] using general time reversible substitution models (*3*) as a part of the Nextstrain[§] workflow (*4*). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[¶]

This investigation identified 86 cases, including 51 (59%) primary event-associated cases,[**] 26 (30%) confirmed secondary and tertiary cases, and nine (10%) likely event-associated secondary or tertiary cases. Four patients were hospitalized, and one died (Table). The median interval between specimen collection and interview was 3 days (range = 1–13 days). Overall, 64 (74%) patients were symptomatic, including 39 (76%) of 51 patients with a primary case and 25 (71%) of 35 patients with secondary and tertiary cases. Among patients with primary cases and symptom onset after the start of the rally, onset dates ranged from August 8 to August 26 (Figure 1). Two patients reported symptom onset before the event and attended the rally during their infectious period. Among primary patients, the median age was 44 years (range = 26–76 years), and 31 (61%) were male. Sixteen (33%) of 48 interviewed patients reported working while infectious, including five who worked at the rally and four who worked in health care after returning from the rally.

Forty-one (80%) interviewed patients with primary event-associated COVID-19 reported having close contact[††] with others during their infectious period, with an average of 2.5 close contacts per patient (range = 1–8). Overall, 36 (75%) of 48 interviewed patients with primary event-associated cases reported having close contact with persons in their household while infectious, and 17 (35%) reported having other (social/workplace) close contacts while infectious. Patients reported a total of 59 household contacts (range = 0–4 per patient) and 43 social/workplace contacts (range = 0–6 per patient).

Among the 35 patients with confirmed or likely event-associated secondary/tertiary COVID-19, 25 (71%) were symptomatic, with symptom onset dates during August 12–29 (Table). The median age was 32 years (range = 1–83 years), and 13 (37%) were male. Fifteen (43%) persons with secondary or tertiary COVID-19 were household contacts of a person with a primary or secondary infection, 12 (34%) were social contacts, and eight (23%) were workplace contacts. Secondary transmission from this rally occurred via two workplace outbreaks, one wedding outbreak, and one funeral outbreak. Approximately one third (34%) of Minnesota's 87 counties had at least one primary, secondary, or tertiary case associated with this rally.

Whole Genome Sequencing

Specimens were obtained from 52 (60%) patients. Among these, 38 (73%) specimens (23 [61%] from primary and 15 [39%] from secondary and tertiary cases) were successfully sequenced, covering at least 98% of the SARS-CoV-2 genome. Six genetically similar clusters with known epidemiologic links were identified (i.e., cases in patients who were close contacts or who had common exposures at the rally), five of which demonstrated secondary or secondary and tertiary transmission. Cluster A (Figure 2) included genetically similar specimens for seven primary cases and one secondary case (specimen MN-MDH-1710). Among primary cases, specimens were collected from two patients who reported working at the rally, including one who worked at a restaurant. Two other patients in this cluster reported visiting that restaurant. Another patient who attended the rally also reported visiting the same restaurant; this patient was a household contact of the patient with specimen MN-MDH-1710. Cluster B represented a chain of transmission in a workplace setting that included five cases. The secondary case in this cluster (with specimen MN-MDH-STU0004) occurred in a workplace contact of a motorcycle rally attendee (specimen MN-MDH-STU0001) and a social contact of one of the persons with a tertiary case (specimen MN-MDH-STU0008). Another secondary case[§§] in this cluster was in a workplace contact of the rally attendee and was a household contact of two of the three patients with tertiary cases in this cluster (specimens MN-MDH-1708 and MN-MDH-1709). Cluster C represented secondary transmission from a rally attendee (specimen MN-MDH-1651) to a household contact (specimen MN-MD-1705). Cluster D represented likely event-associated cases of secondary transmission (specimens MN-MDH-STU0002, MN-MDH-1706, and MD-MDH-1712) and tertiary transmission (specimens MN-MDH-STU-0005 and MN-MDH-1711) related to a wedding. The index patient at this wedding reportedly had COVID-19–like symptoms at the wedding after attending the rally but did not receive testing. Cluster E comprised two

[†] http://www.iqtree.org/.
[§] https://nextstrain.org/.
[¶] 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.
[**] One patient reported attending the rally but refused interview. Two additional patients who refused to be interviewed were identified as having attended the rally through secondary case interviews in which other patients reported them as primary event-associated contacts.
[††] Close contact was defined as being within 6 feet of a patient with laboratory-confirmed COVID-19 infection for ≥15 minutes. https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/contact-tracing.html.
[§§] Although the specimen from this patient was obtained, sequencing was incomplete.

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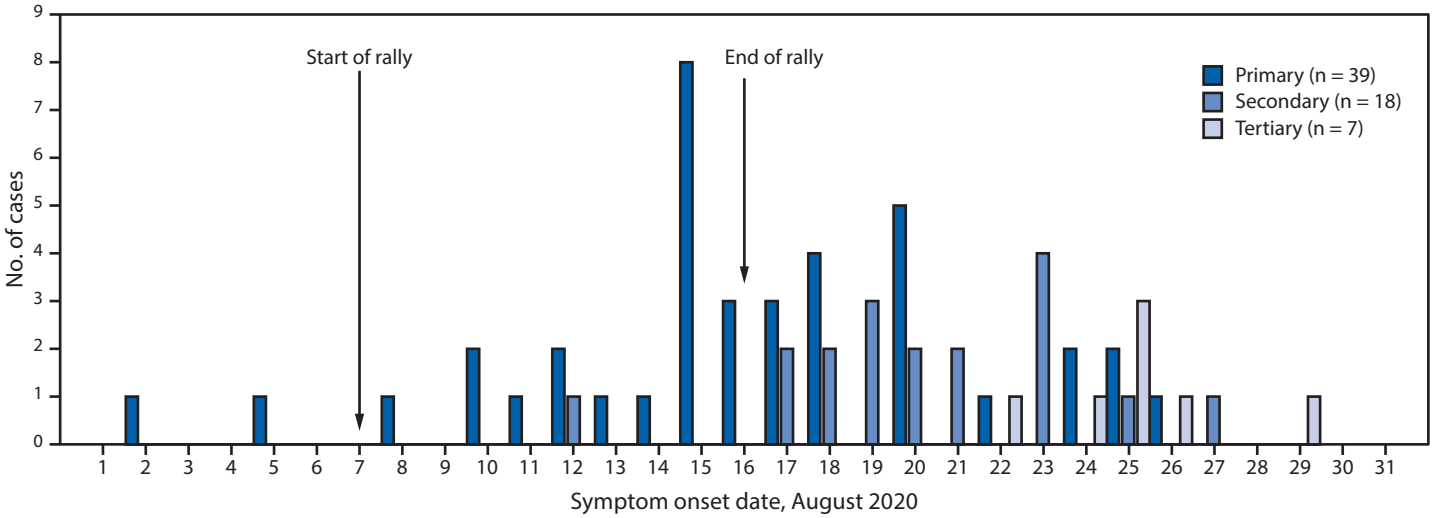
FIGURE 1. Date of symptom onset among symptomatic patients with primary,* secondary,† and tertiary§ COVID-19 (N = 64) associated with a motorcycle rally in a neighboring state — Minnesota, August 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

* Laboratory-confirmed SARS-CoV-2 infection in a person who attended the motorcycle rally or traveled to western South Dakota by motorcycle during August 7–16 and had symptom onset or specimen collection within 14 days of the end of the rally.

† Laboratory-confirmed infection in a person who had contact with a laboratory-confirmed primary case during the infectious period or with a symptomatic rally attendee who was not tested.

§ Laboratory-confirmed infection in a person who had contact with a secondary case or likely event-associated secondary case.

cases (specimens MN-MDH-1567 and MN-MH-1714) in persons who were household contacts, both of whom attended the rally. Cluster F represents workplace and household contacts (specimens MN-MDH-1715, MN-MDH-1716, MN-MDH-1713, and MN-MDH-STU0007) of the primary patient with specimen MN-MDH-1569. Specimen MN-MDH-1569 was from a musician who performed at the rally and later at another concert with a different band whose members did not attend the rally. Primary event-associated cases with specimens MN-MDH-1571 and MN-MDH-1572 had no known connection to each other or identified common exposure at the rally; however, the reported symptom onset dates and travel dates for these cases were identical. Similarly, primary event-associated cases with specimens MN-MDH-1568 and MN-MDH-1707 had no known epidemiologic link but had identical symptom onset dates. This might indicate a common exposure that was not identified through epidemiologic evidence.

Public Health Response

On August 5, MDH recommended through media events that motorcycle rally attendees quarantine for 14 days upon return and be tested 5–7 days later even if they were asymptomatic. Attendees and their close contacts with confirmed COVID-19 were instructed to self-isolate. Contacts of patients with confirmed COVID-19 were instructed to quarantine.

Discussion

Eighty-six Minnesota COVID-19 cases were associated with the South Dakota motorcycle rally; approximately one third of counties in Minnesota reported at least one case epidemiologically linked to this event. These findings highlight the far-reaching effects that gatherings in one area might have on another area. The motorcycle rally was held in a neighboring state that did not have policies regarding event size and mask use, underscoring the implications of policies within and across jurisdictions. The findings suggest that this rally not only had a direct impact on the health of attendees, but also led to subsequent SARS-CoV-2 transmission among household, social, and workplace contacts of rally attendees upon their return to Minnesota. Whole genome sequencing results supported the finding of secondary and tertiary transmission associated with this rally.

The findings in this report are subject to at least three limitations. First, despite in-depth epidemiologic investigation, the findings represent an underestimate of the motorcycle rally's impact in Minnesota and did not capture the impact within South Dakota or other states. Case interviews were voluntary, and patients could choose not to respond to certain questions. Ten patients reported having close contacts but refused to disclose additional details regarding these contacts. Therefore, it was not possible to identify all contacts of patients who attended the rally. Second, attendees and their contacts might not have been tested for SARS-CoV-2. Two rally attendees

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TABLE. Demographic and clinical characteristics of confirmed* and likely event-associated COVID-19 cases (N = 86) associated with a 10-day motorcycle rally in a neighboring state — Minnesota, August–September 2020

Characteristic	No. of cases (%)		
	Primary event–associated† (n = 51)	Confirmed secondary§/tertiary¶ (n = 26)	Likely event-associated secondary**/tertiary†† (n = 9)
Demographic			
Sex			
Female	20 (39.2)	16 (61.5)	6 (66.7)
Male	31 (60.8)	10 (38.5)	3 (33.3)
Age, yrs, median (range)	44 (26–76)	43 (12–83)	22 (1–51)
Age group, yrs			
<18	0 (—)	3 (11.5)	3 (33.3)
18–24	0 (—)	2 (7.7)	2 (22.2)
25–44	26 (51.0)	8 (30.8)	3 (33.3)
45–64	21 (41.2)	10 (38.5)	1 (11.1)
≥65	4 (7.8)	3 (11.5)	0 (—)
Race/Ethnicity			
White, NH	43 (84.3)	22 (84.6)	8 (88.9)
More than one race/Other, NH	1 (2.0)	0 (—)	1 (11.1)
Unknown	7 (13.7)	4 (15.4)	0 (—)
Clinical			
Symptomatic§§	39 (76.5)	19 (73.1)	6 (66.7)
Hospitalized	3 (5.9)	1 (3.8)	0 (—)
ICU admission	1 (2.0)	0 (—)	0 (—)
Died	1 (2.0)	0 (—)	0 (—)
Close contacts			
Household	NA	12	3
Social	NA	6	6
Workplace	NA	8	0

Abbreviations: COVID-19 = coronavirus disease 2019; ICU = intensive care unit; NA = not applicable; NH = non-Hispanic.
* Receipt of a positive SARS-CoV-2 reverse transcription–polymerase chain reaction test result.
† Laboratory-confirmed SARS-CoV-2 infection in a person who attended the motorcycle rally or traveled to western South Dakota by motorcycle during August 7–16 and had symptom onset or specimen collection within 14 days of the end of the rally.
§ Laboratory-confirmed infection in a person who had contact with a primary case during that person's infectious period.
¶ Laboratory-confirmed infection in a person who had contact with a secondary case during that person's infectious period.
** Laboratory-confirmed infection in a person who had contact with a symptomatic person who attended the rally but was not tested.
†† Laboratory-confirmed infection in a person who had contact with a likely secondary case.
§§ Symptom status was unknown for three patients with a primary case, three with a secondary/tertiary case, and one with a likely event-associated secondary/tertiary case.

indicated that their contacts had COVID-19–like symptoms but did not plan to be tested. As such, the findings underrepresent the number of cases, close contacts, and secondary and tertiary cases. Finally, only 52 specimens were received at the MDH Public Health Laboratory because many testing laboratories do not retain or store specimens long-term. Among these specimens, only 38 were successfully sequenced. The lack of whole genome sequencing data from all cases hindered establishment of complete genetic relatedness for epidemiologic investigation.

A large event in a neighboring state triggered chains of SARS-CoV-2 transmission within Minnesota. Other studies have shown that chains of transmission associated with gatherings are not uncommon within the United States (*5*,*6*). Despite underascertainment of the rally's full impact in Minnesota and other states, these findings highlight the importance of reducing the number of attendees at gatherings and emphasizing mask use, physical distancing, isolation for patients with COVID-19, and quarantine for close contacts as strategies for reducing the spread of COVID-19. Furthermore, these findings demonstrate the rationale for consistent mitigation measures across states.

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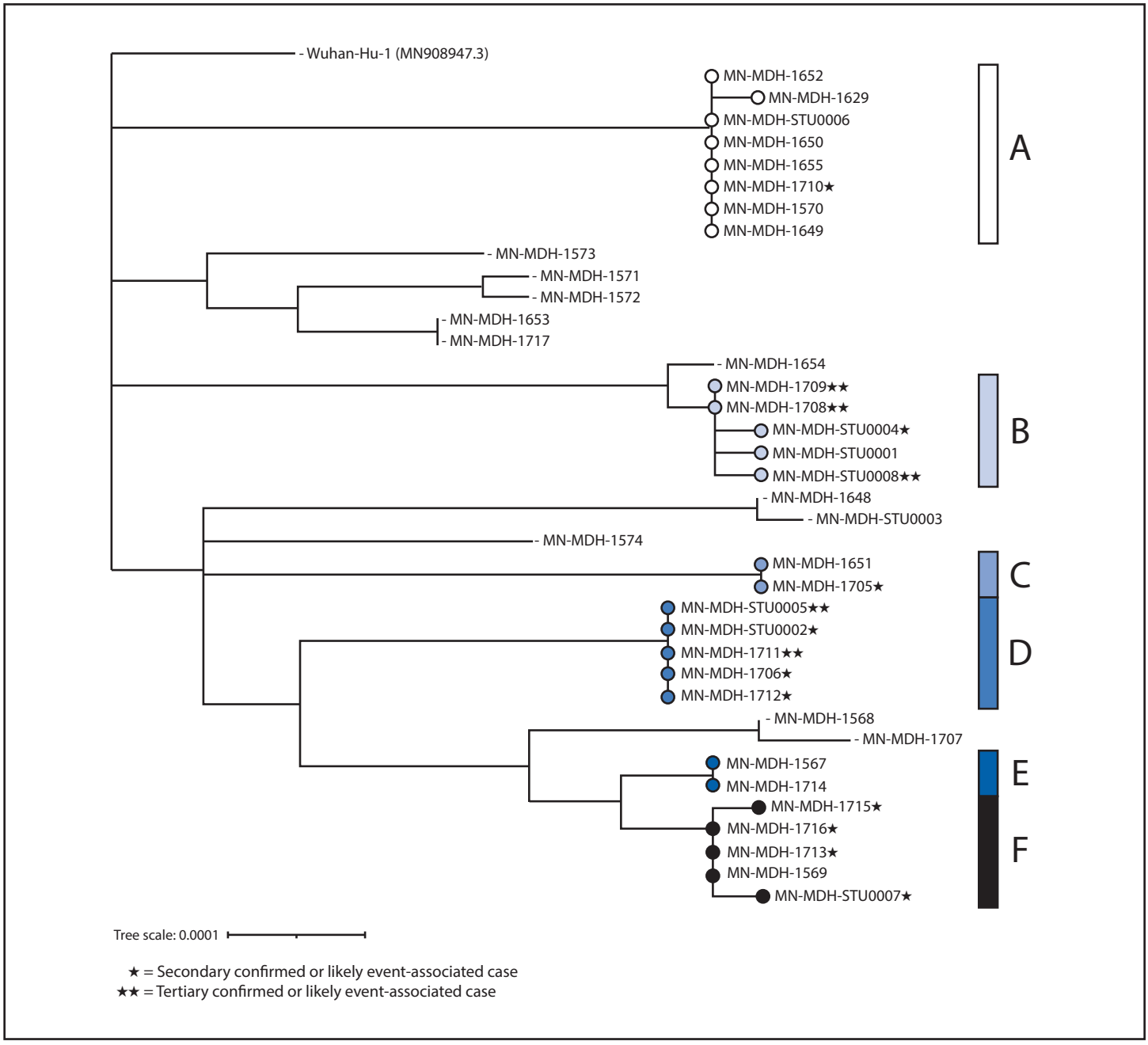
FIGURE 2. Phylogenetic tree* showing genetic distance between available† SARS-CoV-2 virus specimens collected from South Dakota motorcycle rally attendees and their contacts (N = 38) — Minnesota, August 2020



* This figure was created using Interactive Tree of Life (version 5.7; European Molecular Biology Laboratory). https://itol.embl.de/.
† Genetic divergence based on nucleotide difference is indicated by length of branches in substitutions per site. Available specimens include specimens from clinical labs where specimens could be retrieved and RNA could be extracted.

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Summary

What is already known about this topic?

Gatherings present an opportunity for rapid spread of COVID-19.

What is added by this report?

Following a 10-day motorcycle rally in South Dakota attended by approximately 460,000 persons, 51 confirmed primary event-associated cases, 21 secondary cases, and five tertiary cases were identified in Minnesota residents. An additional nine likely rally-associated secondary or tertiary cases occurred. Four patients were hospitalized, and one died. Genomic sequencing supported the associations with the motorcycle rally.

What are the implications for public health practice?

The impact of gatherings as a source of virus transmission underscores the importance of reducing the number of attendees at gatherings, using face masks, and encouraging physical distancing to prevent ongoing transmission of SARS-CoV-2. Furthermore, these findings demonstrate the rationale for consistent mitigation measures across states.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Matthew J. Binnicker reports personal fees from DiaSorin Molecular for an educational webinar on COVID-19 diagnostics and as a member of the advisory board. No other potential conflicts of interest were disclosed.

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Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020

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Wearing masks is a CDC-recommended* approach to reduce the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), by reducing the spread of respiratory droplets into the air when a person coughs, sneezes, or talks and by reducing the inhalation of these droplets by the wearer. On July 2, 2020, the governor of Kansas issued an executive order† (state mandate), effective July 3, requiring masks or other face coverings in public spaces. CDC and the Kansas Department of Health and Environment analyzed trends in county-level COVID-19 incidence before (June 1–July 2) and after (July 3–August 23) the governor's executive order among counties that ultimately had a mask mandate in place and those that did not. As of August 11, 24 of Kansas's 105 counties did not opt out of the state mandate§ or adopted their own mask mandate shortly before or after the state mandate was issued; 81 counties opted out of the state mandate, as permitted by state law, and did not adopt their own mask mandate. After the governor's executive order, COVID-19 incidence (calculated as the 7-day rolling average number of new daily cases per 100,000 population) decreased (mean decrease of 0.08 cases per 100,000 per day; net decrease of 6%) among counties with a mask mandate (mandated counties) but continued to increase (mean increase of 0.11 cases per 100,000 per day; net increase of 100%) among counties without a mask mandate (nonmandated counties). The decrease in cases among mandated counties and the continued increase in cases in nonmandated counties adds to the evidence supporting the importance of wearing masks and implementing policies requiring their use to mitigate the spread of SARS-CoV-2 (*1*–*6*). Community-level mitigation strategies emphasizing wearing masks, maintaining physical distance, staying at home when ill, and enhancing hygiene practices can help reduce transmission of SARS-CoV-2.

The Kansas mandate requiring the wearing of face coverings in public spaces became effective July 3, 2020. Data on county mask mandates were obtained from the Kansas Health Institute.¶ A Kansas state law** enacted on June 9, 2020, authorizes counties to issue public health orders that are less stringent than the provisions of statewide executive orders issued by the governor, which allowed counties to opt out of the state mask mandate. For this study, counties in Kansas that, as of August 11, 2020, did not opt out of the state mandate or adopted their own mask mandate were considered to have a mask mandate in place; those that opted out of the state mandate and did not adopt their own mask mandate were considered to not have a mask mandate in place.

* https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html?fbclid=IwAR28PppCa6x2uxwO8Z2baHM0KHS4JXx0inzzMQs3zRHV1qql_0a8mxZfpCw. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html.

† https://governor.kansas.gov/wp-content/uploads/2020/07/20200702093130003.pdf.

§ Allen, Atchison, Bourbon, Crawford, Dickinson, Douglas, Franklin, Geary, Gove, Harvey, Jewell, Johnson, Mitchell, Montgomery, Morris, Pratt, Reno, Republic, Saline, Scott, Sedgwick, Shawnee, Stanton, and Wyandotte counties. Data on county orders were collected through point-in-time surveys of local health department and other county officials and were supplemented with online searches for published orders and announcements on social media and local news sites. Text in the county orders was analyzed to determine whether mask mandates were in place as of August 11, 2020. Counties that took no official action to opt out of the state mask mandate or adopted their own mask mandate shortly before or after the state mandate were considered to have a mask mandate in place. Counties were considered to not have a mask mandate in place if they took official action to opt out of the state mask mandate and did not adopt their own mask mandate or if their official action used only the language of guidance (e.g., "should" or "recommend").

¶ https://www.khi.org/policy/article/20-25. https://www.khi.org/assets/uploads/news/15015/august_11_update1105.pdf.

** https://ag.ks.gov/docs/default-source/documents/addendum-3-to-march-24-law-enforcement-duties-and-authorities-memo.pdf?sfvrsn = d088af1a_3.

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Daily county-level COVID-19 incidence (cases per 100,000 population) was calculated using case and population counts accessed from USAFacts[††] for Kansas counties during June 1–August 23.[§§] Rates were calculated as 7-day rolling averages. Segmented regression[¶¶] was used to examine changes in COVID-19 incidence before and after July 3, 2020, among mandated and nonmandated counties. Mandated and nonmandated counties were compared to themselves over time, allowing for the control of constant county-related characteristics (e.g., urbanicity or rurality) that might otherwise confound a comparison between mandated and nonmandated counties. Sensitivity analyses were also conducted by 1) examining incidence trends after July 3 separately among mandated counties with and without other public health mitigation strategies and 2) recategorizing nonmandated counties that included cities mandating masks (n=6) as mandated counties. Analyses were conducted using SAS software (version 9.4; SAS Institute).

As of August 11, 24 (23%) Kansas counties had a mask mandate in place, and 81 did not. Mandated counties accounted for two thirds of the Kansas population (1,960,703 persons; 67.3%)[***] and were spread throughout the state, although they tended to cluster together. Six (25%) mandated and 13 (16%) nonmandated counties were metropolitan areas.[†††] Thirteen (54%) mandated counties and seven (9%) nonmandated counties had implemented at least one other public health mitigation strategy not related to the use of masks (e.g., limits on size of gatherings and occupancy for restaurants). During June 1–7, 2020, the 7-day rolling average of daily COVID-19 incidence among counties that ultimately had a mask mandate was three cases per 100,000, and among counties that did not, was four per 100,000 (Table). By the week of the governor's executive order requiring masks (July 3–9), COVID-19 incidence had increased 467% to 17 per 100,000 in mandated counties and 50% to six per 100,000 among nonmandated counties. By August 17–23, 2020, the 7-day rolling average COVID-19 incidence had decreased by 6% to 16 cases per 100,000 among mandated counties and increased by 100% to 12 per 100,000 among nonmandated counties.

Trend analyses using segmented regression (Figure) indicated that during June 1–July 2, 2020, the COVID-19 7-day rolling average incidence increased each day in both counties that ultimately had mask mandates in place (mean increase = 0.25 cases per 100,000 per day; 95% confidence interval [CI] = 0.17–0.33) and counties that did not (mean increase = 0.08 cases per 100,000 per day; 95% CI = 0.01–0.14). After the governor's executive order, COVID-19 incidence decreased each day in mandated counties (mean decrease = 0.08 cases per 100,000 per day; 95% CI = –0.14 to –0.03); in nonmandated counties, incidence continued to increase each day (mean increase = 0.11 cases per 100,000 per day; 95% CI = 0.01–0.21).

Discussion

After implementation of mask mandates in 24 Kansas counties, the increasing trend in COVID-19 incidence reversed. Although rates were considerably higher in mandated counties than in nonmandated counties by the executive order, rates in mandated counties declined markedly after July 3, compared with those in nonmandated counties. Kansas counties that had mask mandates in place appear to have mitigated the transmission of COVID-19, whereas counties that did not have mask mandates continued to experience increases in cases.

The findings in this report are consistent with declines in COVID-19 cases observed in 15 states and the District of Columbia, which mandated masks, compared with states that did not have mask mandates (*7*). Mask requirements were also implemented as part of a multicomponent approach in Arizona, where COVID-19 incidence stabilized and then decreased after implementation of a combination of voluntary and enforceable community-level mitigation strategies, including mask requirements, limitations on public events, enhanced sanitation practices, and closures of certain services and businesses (*8*). The combining of community-level mitigation strategies including physical distancing and enhanced hygiene practices, in addition to consistent and correct use of masks, is a CDC-recommended approach.[§§§] The decreased COVID-19 incidence among mask-mandated counties in Kansas occurred during a time when the only other state mandates issued were focused on mitigation strategies for schools as they reopened in mid-August. In at least 13 (54%) of the 24 mandated counties, the mask mandates occurred alongside other county-level recommended or mandated mitigation strategies (e.g., limits on

[††] https://usafacts.org/visualizations/coronavirus-covid-19-spread-map.

[§§] August 23, 2020, was selected as the study end date because most Kansas counties had already started or were about to begin school the week of August 24, 2020. The implementation of in-person schooling would have signified an important change in events influencing COVID-19 incidence rates after the executive order.

[¶¶] Generalized estimating equation regression modeling with an autoregressive correlation variance structure was used to estimate trends over time within counties. Trends in 7-day rolling average of daily COVID-19 incidence among mask mandated counties and among non–mask-mandated counties were analyzed separately before (June 1–July 2, 2020) and after (July 3–August 23, 2020) the governor's executive order requiring masks, effective July 3.

[***] Total population in mask-mandated counties = 1,960,703; total population in non–mask-mandated counties = 952,611; based on 2019 U.S. Census data.

[†††] As designated by the 2013 National Center for Health Statistics Urban-Rural Classification Scheme for Counties. https://www.cdc.gov/nchs/data_access/urban_rural.htm#Data_Files_and_Documentation.

[§§§] https://www.cdc.gov/coronavirus/2019-ncov/community/community-mitigation.html.

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TABLE. Confirmed COVID-19 infection 7-day rolling average case counts, rates, and percentage changes, by mask mandate status[*,†] and period — Kansas, June 1–August 23, 2020

Characteristic	Before executive order June 1–June 7	Executive order effective[§] July 3–9	After executive order August 17–23	% Change in incidence[¶] June 1–7 versus July 3–9	% Change in incidence[¶] July 3–9 versus August 17–23
Mandated counties (N = 24)[*,]**					
No. of daily cases[††]	60	333	310	N/A	N/A
Incidence[§§]	3	17	16	467	–6
Nonmandated counties (N = 81)[†,]**					
No. of daily cases[††]	40	59	118	N/A	N/A
Incidence[§§]	4	6	12	50	100

Abbreviations: COVID-19 = coronavirus disease 2019; mandated = counties with a mask mandate; N/A = not applicable; nonmandated = counties without a mask mandate.

* Counties that as of August 11 did not opt out of the state mandate or adopted their own mask mandate shortly before or after the state mandate include Allen, Atchison, Bourbon, Crawford, Dickinson, Douglas, Franklin, Geary, Gove, Harvey, Jewell, Johnson, Mitchell, Montgomery, Morris, Pratt, Reno, Republic, Saline, Scott, Sedgwick, Shawnee, Stanton and Wyandotte. Total population in mask-mandated counties = 1,960,703 based on 2019 U.S. Census Bureau data.

† Counties that took no official action to opt out of the state mask mandate or adopted their own mask mandate shortly before or after the state mandate were considered to have a mask mandate in place. Counties were considered to not have a mask mandate in place if they took official action to opt out of the state mask mandate and did not adopt their own mask mandate or if their official action used only the language of guidance (e.g., "should" or "recommend"). Total population in non–mask-mandated counties = 952,611 based on 2019 U.S. Census Bureau data.

§ Week of governor's executive order (effective July 3, 2020).

¶ Change in incidence = [(incidence in period – incidence in previous period)/incidence in previous period] X 100.

** Data on county orders were collected through point-in-time surveys of local health department and other county officials and were supplemented with online searches for published orders and announcements on social media and local news sites. Text in the county orders was analyzed to determine whether mask mandates were in place as of August 11, 2020.

†† Seven-day rolling average number of new daily cases.

§§ Seven-day rolling average number of new daily cases per 100,000 population.

size of gatherings and occupancy for restaurants), facilitating a potential synergistic effect resulting from combining community mitigation strategies. However, in sensitivity analyses, similar decreases in COVID-19 incidence after July 3 were observed among mandated counties with and without other mitigation strategies. Therefore, although implementing multiple mitigation strategies is the recommended approach, strategies related to mask use mandates appear to be important. Additional information on the utility and acceptability of mask mandates in public settings could help further inform health education campaigns aimed at increasing proper use of masks and strengthening mandate adherence.

The findings in this report are subject to at least four limitations. First, the ecologic design of this study and limited information on community mask-wearing behaviors and county implementation and enforcement provisions of mask mandates limit the ability to determine the extent to which the countywide mask mandates accounted for the observed declines in COVID-19 incidence in mandated counties. Second, this analysis did not account for mask ordinances in six cities in non–mask-mandated counties. However, in sensitivity analyses recategorizing nonmandated counties that included cities mandating masks as mandated counties, results were consistent with those in primary analyses, although they were attenuated. In those analyses, after the governor's executive order, COVID-19 incidence among mandated counties stabilized rather than decreased, and incidence continued to increase among nonmandated counties. Third, although the design of this study limits potential confounding from constant county-related characteristics, the findings in this report are conditional on the absence of any time-varying factors (e.g., mobility patterns, changes in other community-level mitigation strategies, and access to testing) within counties before and after July 3. Nonetheless, in additional analyses examining testing data among Kansas counties during the study period,

Summary

What is already known about this this topic?

Wearing face masks in public spaces reduces the spread of SARS-CoV-2.

What is added by this report?

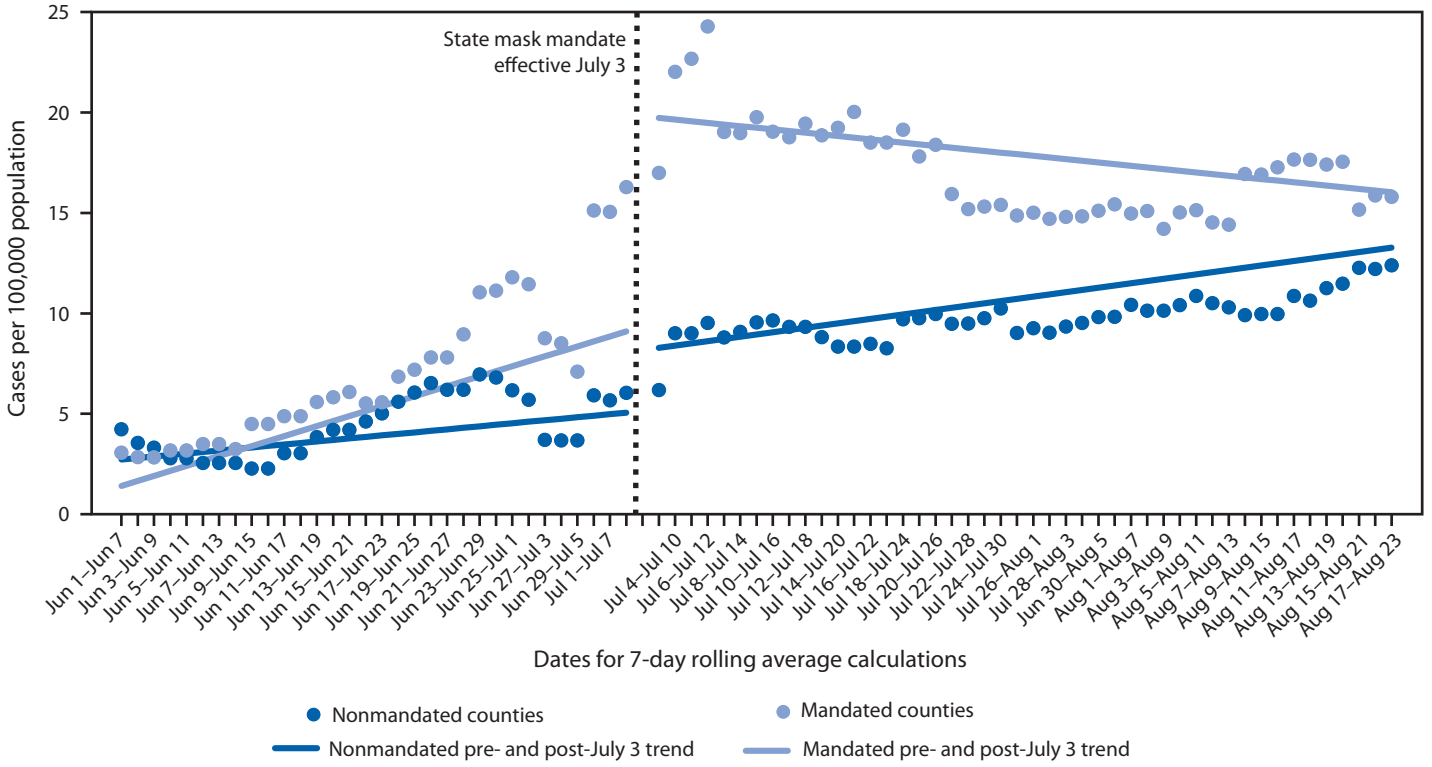
The governor of Kansas issued an executive order requiring wearing masks in public spaces, effective July 3, 2020, which was subject to county authority to opt out. After July 3, COVID-19 incidence decreased in 24 counties with mask mandates but continued to increase in 81 counties without mask mandates.

What are the implications for public health practice?

Countywide mask mandates appear to have contributed to the mitigation of COVID-19 transmission in mandated counties. Community-level mitigation strategies emphasizing use of masks, physical distancing, staying at home when ill, and enhanced hygiene practices can help reduce the transmission of SARS-CoV-2.

MS-DOH-21-1816-A-002202

FIGURE. Trends* in 7-day rolling average of new daily COVID-19 cases per 100,000 population among mask-mandated† and non–mask-mandated counties before (June 1–July 2)§ and after (July 3–August 23)¶ the governor's executive order requiring masks — Kansas, June 1–August 23, 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

* Generalized estimating equation regression modeling with an autoregressive correlation variance structure was used to estimate trends over time within counties. Trends in 7-day rolling average of daily COVID-19 incidence among mask-mandated counties and non–mask-mandated counties were analyzed separately before (June 1–July 2, 2020) and after (July 3–August 23, 2020) the governor's executive order requiring masks, effective July 3.

† Kansas counties (n = 24) that as of August 11 did not opt out of the state mandate effective July 3, 2020, or adopted their own mask mandate shortly before or after the state mandate include Allen, Atchison, Bourbon, Crawford, Dickinson, Douglas, Franklin, Geary, Gove, Harvey, Jewell, Johnson, Mitchell, Montgomery, Morris, Pratt, Reno, Republic, Saline, Scott, Sedgwick, Shawnee, Stanton and Wyandotte. Data on county orders were collected through point-in-time surveys of local health department and other county officials and were supplemented with online searches for published orders and announcements on social media and local news sites. Text in the county orders was analyzed to determine whether mask mandates were in place as of August 11, 2020. Counties that took no official action to opt out of the state mask mandate or adopted their own mask mandate shortly before or after the state mandate were considered to have a mask mandate in place. Counties were considered to not have a mask mandate in place if they took official action to opt out of the state mask mandate and did not adopt their own mask mandate or if their official action used only the language of guidance (e.g., "should" or "recommend").

§ Before the mask mandate (June 1–July 2), 7-day rolling average COVID-19 incidence increased each day (mean increase = 0.25 cases per 100,000 persons per day; 95% confidence interval [CI] = 0.17–0.33) in mask-mandated counties and increased each day (mean increase = 0.08 cases per 100,000 per day; 95% CI = 0.01–0.14) in nonmandated counties.

¶ After the mask mandate (July 3–August 23), 7-day rolling average COVID-19 incidence decreased each day (mean decrease = 0.08 cases per 100,000 persons per day; 95% CI = –0.14 to –0.03) in mask-mandated counties and increased each day (mean increase = 0.11 cases per 100,000 per day; 95% CI = 0.01–0.21) in nonmandated counties.

testing rates were observed to increase overall over time. Therefore, despite increases in testing during this period, decreases in COVID-19 incidence were observed in mandated counties after July 3. Finally, counties in Kansas with a mask mandate might not be representative of other U.S. counties. However, the findings are consistent with observations from other states that mask mandates are associated with declines in COVID-19 cases (*7*).

Masks are an important intervention for mitigating the transmission of SARS-CoV-2 (*1*–*6*), and countywide mask mandates appear to have contributed to the mitigation of COVID-19 spread in Kansas counties that had them in place. Community-level mitigation strategies emphasizing use of masks, physical distancing, staying at home when ill, and enhanced hygiene practices can help reduce the transmission of SARS-CoV-2.

Acknowledgments

Melanie Firestone, Epidemic Intelligence Service, CDC; Laura Gieraltowski, Jamie Perniciaro, CDC COVID-19 Response Team.

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Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020

Miriam E. Van Dyke, PhD[1]; Tia M. Rogers, PhD[1]; Eric Pevzner, PhD[2]; Catherine L. Satterwhite, PhD[3]; Hina B. Shah, MPH[4]; Wyatt J. Beckman, MPH[4]; Farah Ahmed, PhD[5]; D. Charles Hunt, MPH[4]; John Rule[6]

Wearing masks is a CDC-recommended* approach to reduce the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), by reducing the spread of respiratory droplets into the air when a person coughs, sneezes, or talks and by reducing the inhalation of these droplets by the wearer. On July 2, 2020, the governor of Kansas issued an executive order† (state mandate), effective July 3, requiring masks or other face coverings in public spaces. CDC and the Kansas Department of Health and Environment analyzed trends in county-level COVID-19 incidence before (June 1–July 2) and after (July 3–August 23) the governor's executive order among counties that ultimately had a mask mandate in place and those that did not. As of August 11, 24 of Kansas's 105 counties did not opt out of the state mandate§ or adopted their own mask mandate shortly before or after the state mandate was issued; 81 counties opted out of the state mandate, as permitted by state law, and did not adopt their own mask mandate. After the governor's executive order, COVID-19 incidence (calculated as the 7-day rolling average number of new daily cases per 100,000 population) decreased (mean decrease of 0.08 cases per 100,000 per day; net decrease of 6%) among counties with a mask mandate (mandated counties) but continued to increase (mean increase of 0.11 cases per 100,000 per day; net increase of 100%) among counties without a mask mandate (nonmandated counties). The decrease in cases among mandated counties and the continued increase in cases in nonmandated counties adds to the evidence supporting the importance of wearing masks and implementing policies requiring their use to mitigate the spread of SARS-CoV-2 (*1*–*6*). Community-level mitigation strategies emphasizing wearing masks, maintaining physical distance, staying at home when ill, and enhancing hygiene practices can help reduce transmission of SARS-CoV-2.

The Kansas mandate requiring the wearing of face coverings in public spaces became effective July 3, 2020. Data on county mask mandates were obtained from the Kansas Health Institute.¶ A Kansas state law** enacted on June 9, 2020, authorizes counties to issue public health orders that are less stringent than the provisions of statewide executive orders issued by the governor, which allowed counties to opt out of the state mask mandate. For this study, counties in Kansas that, as of August 11, 2020, did not opt out of the state mandate or adopted their own mask mandate were considered to have a mask mandate in place; those that opted out of the state mandate and did not adopt their own mask mandate were considered to not have a mask mandate in place.

* https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html?fbclid=IwAR28PppCa6x2uxwO8Z2baHM0KHS4JXx0inzzMQs3zRHV1qql_0a8mxZfpCw. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html.

† https://governor.kansas.gov/wp-content/uploads/2020/07/20200702093130003.pdf.

§ Allen, Atchison, Bourbon, Crawford, Dickinson, Douglas, Franklin, Geary, Gove, Harvey, Jewell, Johnson, Mitchell, Montgomery, Morris, Pratt, Reno, Republic, Saline, Scott, Sedgwick, Shawnee, Stanton, and Wyandotte counties. Data on county orders were collected through point-in-time surveys of local health department and other county officials and were supplemented with online searches for published orders and announcements on social media and local news sites. Text in the county orders was analyzed to determine whether mask mandates were in place as of August 11, 2020. Counties that took no official action to opt out of the state mask mandate or adopted their own mask mandate shortly before or after the state mandate were considered to have a mask mandate in place. Counties were considered to not have a mask mandate in place if they took official action to opt out of the state mask mandate and did not adopt their own mask mandate or if their official action used only the language of guidance (e.g., "should" or "recommend").

¶ https://www.khi.org/policy/article/20-25. https://www.khi.org/assets/uploads/news/15015/august_11_update1105.pdf.

** https://ag.ks.gov/docs/default-source/documents/addendum-3-to-march-24-law-enforcement-duties-and-authorities-memo.pdf?sfvrsn = d088af1a_3.

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Centers for Disease Control and Prevention

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Daily county-level COVID-19 incidence (cases per 100,000 population) was calculated using case and population counts accessed from USAFacts[††] for Kansas counties during June 1–August 23.[§§] Rates were calculated as 7-day rolling averages. Segmented regression[¶¶] was used to examine changes in COVID-19 incidence before and after July 3, 2020, among mandated and nonmandated counties. Mandated and nonmandated counties were compared to themselves over time, allowing for the control of constant county-related characteristics (e.g., urbanicity or rurality) that might otherwise confound a comparison between mandated and nonmandated counties. Sensitivity analyses were also conducted by 1) examining incidence trends after July 3 separately among mandated counties with and without other public health mitigation strategies and 2) recategorizing nonmandated counties that included cities mandating masks (n=6) as mandated counties. Analyses were conducted using SAS software (version 9.4; SAS Institute).

As of August 11, 24 (23%) Kansas counties had a mask mandate in place, and 81 did not. Mandated counties accounted for two thirds of the Kansas population (1,960,703 persons; 67.3%)[***] and were spread throughout the state, although they tended to cluster together. Six (25%) mandated and 13 (16%) nonmandated counties were metropolitan areas.[†††] Thirteen (54%) mandated counties and seven (9%) nonmandated counties had implemented at least one other public health mitigation strategy not related to the use of masks (e.g., limits on size of gatherings and occupancy for restaurants). During June 1–7, 2020, the 7-day rolling average of daily COVID-19 incidence among counties that ultimately had a mask mandate was three cases per 100,000, and among counties that did not, was four per 100,000 (Table). By the week of the governor's executive order requiring masks (July 3–9), COVID-19 incidence had increased 467% to 17 per 100,000 in mandated counties and 50% to six per 100,000 among nonmandated counties. By August 17–23, 2020, the 7-day rolling average COVID-19 incidence had decreased by 6% to 16 cases per 100,000 among mandated counties and increased by 100% to 12 per 100,000 among nonmandated counties.

Trend analyses using segmented regression (Figure) indicated that during June 1–July 2, 2020, the COVID-19 7-day rolling average incidence increased each day in both counties that ultimately had mask mandates in place (mean increase = 0.25 cases per 100,000 per day; 95% confidence interval [CI] = 0.17–0.33) and counties that did not (mean increase = 0.08 cases per 100,000 per day; 95% CI = 0.01–0.14). After the governor's executive order, COVID-19 incidence decreased each day in mandated counties (mean decrease = 0.08 cases per 100,000 per day; 95% CI = –0.14 to –0.03); in nonmandated counties, incidence continued to increase each day (mean increase = 0.11 cases per 100,000 per day; 95% CI = 0.01–0.21).

Discussion

After implementation of mask mandates in 24 Kansas counties, the increasing trend in COVID-19 incidence reversed. Although rates were considerably higher in mandated counties than in nonmandated counties by the executive order, rates in mandated counties declined markedly after July 3, compared with those in nonmandated counties. Kansas counties that had mask mandates in place appear to have mitigated the transmission of COVID-19, whereas counties that did not have mask mandates continued to experience increases in cases.

The findings in this report are consistent with declines in COVID-19 cases observed in 15 states and the District of Columbia, which mandated masks, compared with states that did not have mask mandates (*7*). Mask requirements were also implemented as part of a multicomponent approach in Arizona, where COVID-19 incidence stabilized and then decreased after implementation of a combination of voluntary and enforceable community-level mitigation strategies, including mask requirements, limitations on public events, enhanced sanitation practices, and closures of certain services and businesses (*8*). The combining of community-level mitigation strategies including physical distancing and enhanced hygiene practices, in addition to consistent and correct use of masks, is a CDC-recommended approach.[§§§] The decreased COVID-19 incidence among mask-mandated counties in Kansas occurred during a time when the only other state mandates issued were focused on mitigation strategies for schools as they reopened in mid-August. In at least 13 (54%) of the 24 mandated counties, the mask mandates occurred alongside other county-level recommended or mandated mitigation strategies (e.g., limits on

[††] https://usafacts.org/visualizations/coronavirus-covid-19-spread-map.

[§§] August 23, 2020, was selected as the study end date because most Kansas counties had already started or were about to begin school the week of August 24, 2020. The implementation of in-person schooling would have signified an important change in events influencing COVID-19 incidence rates after the executive order.

[¶¶] Generalized estimating equation regression modeling with an autoregressive correlation variance structure was used to estimate trends over time within counties. Trends in 7-day rolling average of daily COVID-19 incidence among mask mandated counties and among non–mask-mandated counties were analyzed separately before (June 1–July 2, 2020) and after (July 3–August 23, 2020) the governor's executive order requiring masks, effective July 3.

[***] Total population in mask-mandated counties = 1,960,703; total population in non–mask-mandated counties = 952,611; based on 2019 U.S. Census data.

[†††] As designated by the 2013 National Center for Health Statistics Urban-Rural Classification Scheme for Counties. https://www.cdc.gov/nchs/data_access/urban_rural.htm#Data_Files_and_Documentation.

[§§§] https://www.cdc.gov/coronavirus/2019-ncov/community/community-mitigation.html.

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TABLE. Confirmed COVID-19 infection 7-day rolling average case counts, rates, and percentage changes, by mask mandate status[*,†] and period — Kansas, June 1–August 23, 2020

Characteristic	Before executive order June 1–June 7	Executive order effective[§] July 3–9	After executive order August 17–23	% Change in incidence[¶] June 1–7 versus July 3–9	% Change in incidence[¶] July 3–9 versus August 17–23
Mandated counties (N = 24)[*,]**					
No. of daily cases[††]	60	333	310	N/A	N/A
Incidence[§§]	3	17	16	467	–6
Nonmandated counties (N = 81)[†,]**					
No. of daily cases[††]	40	59	118	N/A	N/A
Incidence[§§]	4	6	12	50	100

Abbreviations: COVID-19 = coronavirus disease 2019; mandated = counties with a mask mandate; N/A = not applicable; nonmandated = counties without a mask mandate.

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§ Week of governor's executive order (effective July 3, 2020).

¶ Change in incidence = [(incidence in period – incidence in previous period)/incidence in previous period] X 100.

** Data on county orders were collected through point-in-time surveys of local health department and other county officials and were supplemented with online searches for published orders and announcements on social media and local news sites. Text in the county orders was analyzed to determine whether mask mandates were in place as of August 11, 2020.

†† Seven-day rolling average number of new daily cases.

§§ Seven-day rolling average number of new daily cases per 100,000 population.

size of gatherings and occupancy for restaurants), facilitating a potential synergistic effect resulting from combining community mitigation strategies. However, in sensitivity analyses, similar decreases in COVID-19 incidence after July 3 were observed among mandated counties with and without other mitigation strategies. Therefore, although implementing multiple mitigation strategies is the recommended approach, strategies related to mask use mandates appear to be important. Additional information on the utility and acceptability of mask mandates in public settings could help further inform health education campaigns aimed at increasing proper use of masks and strengthening mandate adherence.

The findings in this report are subject to at least four limitations. First, the ecologic design of this study and limited information on community mask-wearing behaviors and county implementation and enforcement provisions of mask mandates limit the ability to determine the extent to which the countywide mask mandates accounted for the observed declines in COVID-19 incidence in mandated counties. Second, this analysis did not account for mask ordinances in six cities in non–mask-mandated counties. However, in sensitivity analyses recategorizing nonmandated counties that included cities mandating masks as mandated counties, results were consistent with those in primary analyses, although they were attenuated. In those analyses, after the governor's executive order, COVID-19 incidence among mandated counties stabilized rather than decreased, and incidence continued to increase among nonmandated counties. Third, although the design of this study limits potential confounding from constant county-related characteristics, the findings in this report are conditional on the absence of any time-varying factors (e.g., mobility patterns, changes in other community-level mitigation strategies, and access to testing) within counties before and after July 3. Nonetheless, in additional analyses examining testing data among Kansas counties during the study period,

Summary

What is already known about this this topic?

Wearing face masks in public spaces reduces the spread of SARS-CoV-2.

What is added by this report?

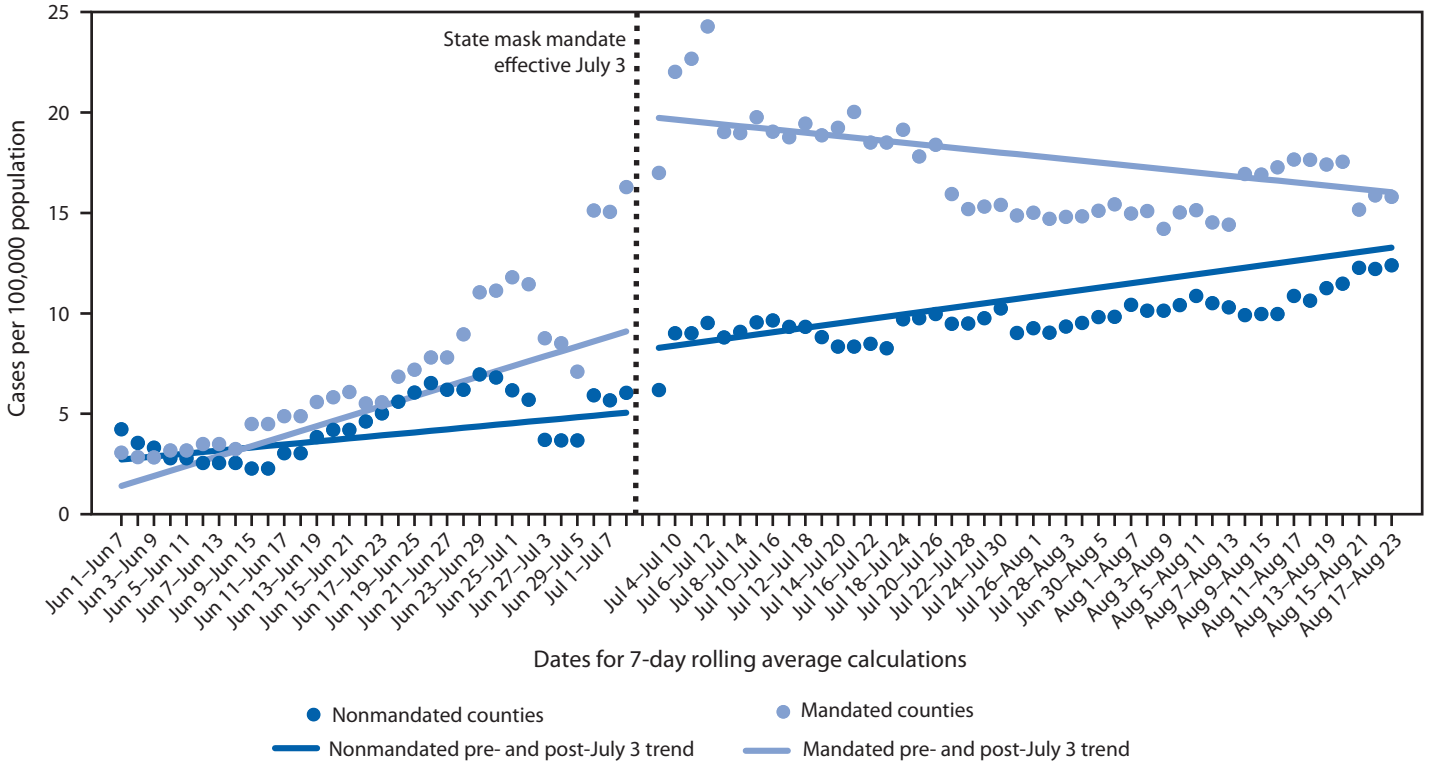
The governor of Kansas issued an executive order requiring wearing masks in public spaces, effective July 3, 2020, which was subject to county authority to opt out. After July 3, COVID-19 incidence decreased in 24 counties with mask mandates but continued to increase in 81 counties without mask mandates.

What are the implications for public health practice?

Countywide mask mandates appear to have contributed to the mitigation of COVID-19 transmission in mandated counties. Community-level mitigation strategies emphasizing use of masks, physical distancing, staying at home when ill, and enhanced hygiene practices can help reduce the transmission of SARS-CoV-2.

MS-DOH-21-1816-A-002207

FIGURE. Trends* in 7-day rolling average of new daily COVID-19 cases per 100,000 population among mask-mandated† and non–mask-mandated counties before (June 1–July 2)§ and after (July 3–August 23)¶ the governor's executive order requiring masks — Kansas, June 1–August 23, 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

* Generalized estimating equation regression modeling with an autoregressive correlation variance structure was used to estimate trends over time within counties. Trends in 7-day rolling average of daily COVID-19 incidence among mask-mandated counties and non–mask-mandated counties were analyzed separately before (June 1–July 2, 2020) and after (July 3–August 23, 2020) the governor's executive order requiring masks, effective July 3.

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¶ After the mask mandate (July 3–August 23), 7-day rolling average COVID-19 incidence decreased each day (mean decrease = 0.08 cases per 100,000 persons per day; 95% CI = –0.14 to –0.03) in mask-mandated counties and increased each day (mean increase = 0.11 cases per 100,000 per day; 95% CI = 0.01–0.21) in nonmandated counties.

testing rates were observed to increase overall over time. Therefore, despite increases in testing during this period, decreases in COVID-19 incidence were observed in mandated counties after July 3. Finally, counties in Kansas with a mask mandate might not be representative of other U.S. counties. However, the findings are consistent with observations from other states that mask mandates are associated with declines in COVID-19 cases (*7*).

Masks are an important intervention for mitigating the transmission of SARS-CoV-2 (*1*–*6*), and countywide mask mandates appear to have contributed to the mitigation of COVID-19 spread in Kansas counties that had them in place. Community-level mitigation strategies emphasizing use of masks, physical distancing, staying at home when ill, and enhanced hygiene practices can help reduce the transmission of SARS-CoV-2.

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MS-DOH-21-1816-A-002209

Subject: CDC's New Travel Planner is LIVE to travelers

Dear Health Department Partner,

CDC's new **COVID-19 Travel Planner is now LIVE to travelers**! Travel Planner is a centralized communication platform that travelers can search to find COVID-19 information for the state, local, territorial, and tribal communities they're passing through and for their destinations. We need your help to keep the web portal updated when your jurisdiction's restrictions and policies change.

As a health department, you can use Travel Planner to reach travelers and share your COVID-19 policies relevant to travelers entering and departing your jurisdiction.

I have not added my jurisdiction's information yet, can I still add it?

Yes, you can still add your information to Travel Planner. Identify a few people who can be responsible for inputting your health department's COVID-19 information, such as a communication specialist, administrative assistant, intern, or other staff member. If these staff members don't already have a CDC Secure Access Management Services (SAMS) account, they should email travelplanner@cdc.gov to request enrollment in SAMS and access to the COVID-19 Travel Planner webform. If they already have a SAMS account, they will need to email travelplanner@cdc.gov to request access to the COVID-19 Travel Planner webform.

Note: Due to delays in SAMS processing, at this time it would be best to identify someone who already has a SAMS account with Level 2 approvals.

How can I promote the Travel Planner?

We have provided materials you can use to help promote the Travel Planner to your residents, visitors, and those passing through your community:

- Graphic
- Social media posts
- A badge you can add to your website

We hope you will find the Travel Planner a helpful tool that reduces some of the inquiries you receive about travel restrictions and guidance in your jurisdiction. We welcome any questions or feedback at travelplanner@cdc.gov.

Thank you,

Global Migration Task Force
COVID-19 Response
Centers for Disease Control and Prevention

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Nov. 6 (incl. CDC Lab Alert and Advisory, MMWR Early Release, CDC Web Updates, CDC Science Update)
Date:	Friday, November 6, 2020 3:14:20 PM
Attachments:	image001.png image002.png MMWR ER - Declines in SARS-CoV-2 Transmission, Hospitalizations, and Mortality After Implementation of Mitigation Measures - November 6, 2020.pdf CDC Response Website Updates (Oct 31–Nov 6).docx 2020_11_03_Science-Update_FINAL-Public.pdf

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[PureMessage: Suspect .eml attachment quarantined.]

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of recent Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

- CDC Lab Alert: FDA Issues Safety Letter about Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 [Attachment, Link]
    - Please see the following message from CDC's Laboratory Outreach Communication System (LOCS):
      "On November 3, 2020, the U.S. Food and Drug Administration (FDA) issued a Letter to Clinical Laboratory Staff and Health Care Providers to alert clinical laboratory staff and health care providers that false positive results can occur with antigen tests, including when users do not follow the instructions for use of antigen tests for the rapid detection of SARS-CoV-2. This letter includes important information about potential false positive results with antigen tests for rapid detection of SARS-CoV-2:
        - *Details on false positive results with antigen tests*
        - *Recommendations for health care providers and clinical laboratory staff*
        - *Actions FDA is taking*
        - *Instructions for reporting problems with a device*

      For questions about this letter, email COVID19DX@fda.hhs.gov."
- CDC Lab Advisory: CDC Updates Specimen Collection Guidelines for COVID-19 [Attachment, Link]
    - Please see the following message from CDC's Laboratory Outreach Communication

System (LOCS):
"On November 3, 2020, CDC updated the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19 web page. The updated guidelines provide more detailed recommendations for several methods of collecting specimens for SARS-CoV-2 testing:

- *Nasopharyngeal swabs*
- *Nasal mid-turbinate swabs*
- *Anterior nares specimen collection*
- *Saliva*

- MMWR Early Release: "Declines in SARS-CoV-2 Transmission, Hospitalizations, and Mortality After Implementation of Mitigation Measures— Delaware, March–June 2020" [Attachment, Link]
  - From the summary: *"State-mandated stay-at-home orders and public mask mandates coupled with case investigations with contact tracing contributed to an 82% reduction in COVID-19 incidence, 88% reduction in hospitalizations, and 100% reduction in mortality in Delaware during late April–June."*
- CDC Response Website Updates [Attachment]
  - for October 31–November 6
- CDC COVID-19 Science Update (November 3) [Attachment, Link]
  - The *COVID-19 Science Update* is a publication series from CDC that provides brief summaries of new COVID-19-related studies, intended for use by public health professionals responding to this pandemic. Summaries are released every Tuesday and Friday. All previous COVID-19 Science Updates are available on CDC's website here.
- Reminder: Request for CSTE COVID-19 Call Topics [Link]
  - To ensure timely and relevant information is provided to our members, CSTE has developed a topic submission form, available here. Please submit suggestions for topics (or speakers) to be discussed on future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations.

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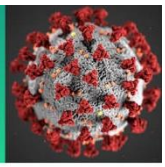
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
Business Hours Line: 770.458.3811
After-Hours Line: 678.256.3945
preparedness.cste.org

COVID-19 Science Update



From the Office of the Chief Medical Officer, CDC COVID-19 Response, and the CDC Library, Atlanta, GA.
Intended for use by public health professionals responding to the COVID-19 pandemic.

***** Available on-line at https://www.cdc.gov/library/covid19 *****

Neuropilin-1

The SARS-CoV-2 major spike protein (S) is cleaved by a host protease to create S1 and S2 functional polypeptides. The S1 polypeptide has a carboxy-terminal sequence that binds to host cell surface neuropilin-1 (NRP1) and neuropilin-2 (NRP2) receptors. NRP receptors facilitate viral entry for several viruses due to their abundance on cells that are exposed to the external environment – cells that paradoxically express low levels of angiotensin-converting enzyme-2 (ACE2), the known SARS-CoV-2 receptor. Here we present two articles that evaluated the potential for NRP1 to act as a co-receptor for SARS-CoV-2.

PEER-REVIEWED

Neuropilin-1 is a host factor for SARS-CoV-2 infection. Daly *et al.* Science (October 20, 2020).

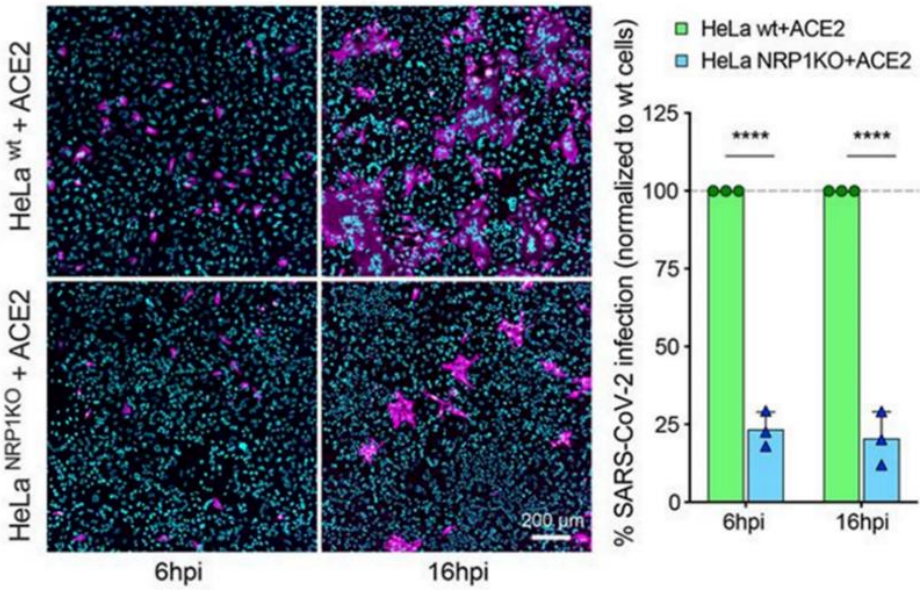
Key findings:

- The S1 fragment of the cleaved SARS-CoV-2 spike protein binds to the cell surface receptor neuropilin-1 (NRP1).
- SARS-CoV-2 utilizes NRP1 for cell entry as evidenced by decreased infectivity of cells in the presence of:
  - NRP1 deletion ($p < 0.0001$) (Figure).
  - Three different anti-NRP1 monoclonal antibodies ($p < 0.001$).
  - Selective NRP1 antagonist, EG00229 ($p < 0.01$).

Methods: Binding of the S1 fragment to NRP1 was assessed and ability of SARS-CoV-2 to use NRP1 to infect cells was measured in angiotensin-converting enzyme-2 (ACE-2)-expressing cell lines by knocking out NRP1 expression, blocking NRP1 with 3 different anti-NRP1 monoclonal antibodies, or using NRP1 small molecule antagonists.
Limitations: Upstream research and implications for treatment or prevention of infection unclear.

MS-DOH-21-1816-A-002213

Figure:



Note: Adapted from Daly *et al*. Fluorescent image of HeLa cells transfected to express ACE2 (SARS-CoV-2 receptor) with stains for SARS-CoV-2 nucleocapsid protein and nucleic acid, 6 and 16 hours post-infection (hpi). ACE-2 HeLa cells are wild-type (wt, top) or with a NRP1 deletion (NRP1KO, bottom). Bar graph shows % SARS-CoV-2-infected wild-type cells or NRP1-knockout cells. Licensed under CC-BY 4.0.

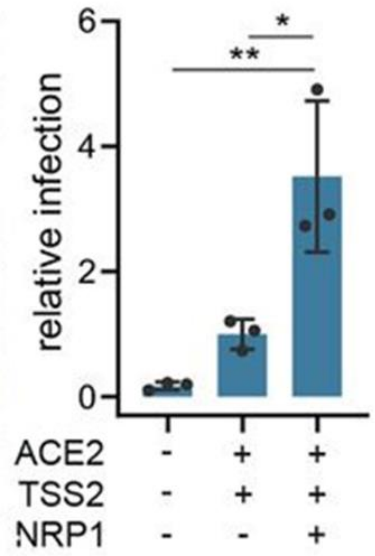
Neuropilin-1 facilitates SARS-CoV-2 cell entry and infectivity. Cantuti-Castelvetri *et al.* Science (October 20, 2020).

Key findings:

- Infectivity of cells expressing angiotensin converting enzyme-2 (ACE2, receptor for SARS-CoV-2), transmembrane protease serine-2 (TSS2, primes the Spike [S] protein), and neuropilin-1 (NRP1) with pseudovirus expressing the SARS-CoV-2 S1 protein was approximately 3-fold higher than in cells expressing either ACE2 or TSS2 alone ($p < 0.05$) (Figure 1).
- Analysis of autopsy tissue from COVID-19 patients showed co-localization of the SARS-CoV-2 spike (S) protein and NRP1 in olfactory and respiratory epithelium (Figure 2).

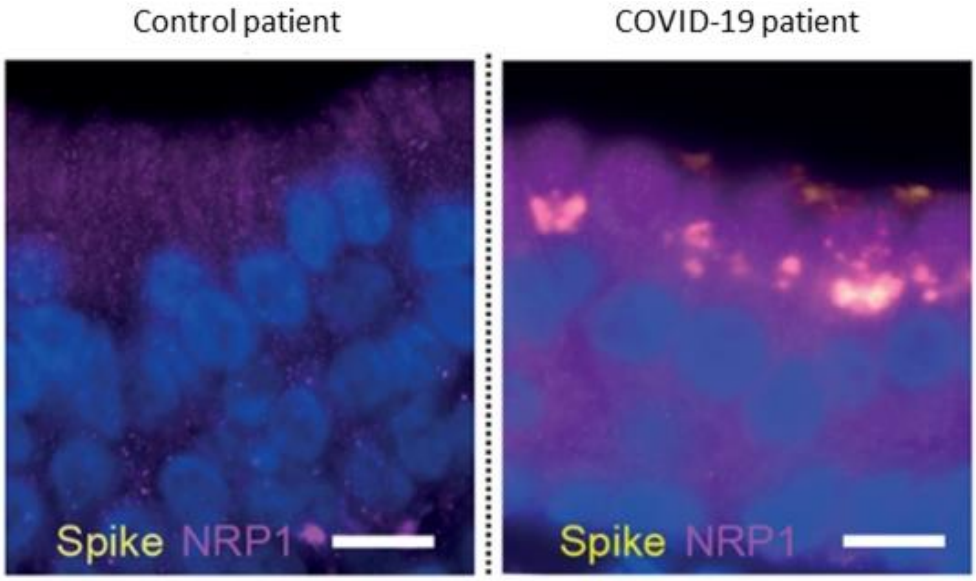
Methods: Cell lines were modified to express ACE2 and TSS2, the two known SARS-CoV-2 host factors, and NRP1 to assess the contribution of NRP1 to infection. Autopsy specimens from multiple airway sites were stained with antibodies against SARS-CoV-2 proteins, ACE2, and NRP1, to visualize co-localization of proteins. *Limitations:* Upstream research and implications for treatment or prevention of infection unclear.

Figure 1



Note: Adapted from Cantuti-Castelvetri *et al*. Infectivity of SARS-CoV-2 in cultured cells that express no known host factors (first bar), the host factors ACE2 and TSS2 (middle bar) and ACE2, TSS2, and NRP1 (third bar). *p <0.05, **p <0.01. Licensed under CC-BY 4.0.

Figure 2



Note: Adapted from Cantuti-Castelvetri *et al*. Co-localization of NRP1 and Spike protein in olfactory epithelial cells in a control patient (left) and a COVID-19 patient (right). Licensed under CC-BY 4.0.

Implications for 2 studies (Daly *et al.* & Cantuti-Castelvetri *et al.*) These two articles provide evidence that NRP1 facilitates SARS-CoV-2 entry into cells that express ACE2. These studies elucidate a route by which SARS-CoV-2 infects cells that do not express high levels of the ACE2 receptor and also suggests potential therapeutic options to decrease infection by blocking SARS-CoV-2-NRP1 interactions.

Laboratory Science

PEER-REVIEWED

Neutralizing antibody responses in COVID-19 convalescent sera. Lee *et al*. Journal of Infectious Diseases (October 26, 2020).

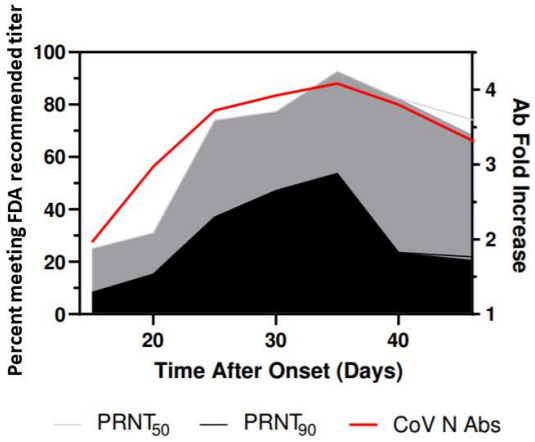
Key findings:

- Neutralizing antibody (nAb) activity increased for several weeks post-symptom onset (Figure).
  - 93% of sera had titers ≥1:160 (the initial FDA recommended level for nAb for convalescent plasma donation) at the 50% viral neutralization level, 31–35 days post-symptom onset.
  - 54% of sera had titers ≥1:160 at the 90% viral neutralization level, 31–35 days post-symptom onset.
  - 24% of sera had titers of ≥1:160 at the 90% viral neutralization level beyond day 35.
- Sera with antibody titers >1:960 generally had higher neutralizing activity, but not all contained nAbs at the initial FDA recommended levels.

Methods: Serum specimens from 3,426 COVID-19 convalescent patients were tested for SARS-CoV-2 antibodies to the receptor binding protein, spike protein, or nucleocapsid. Reactive sera were tested for ability to neutralize SARS-CoV-2 infection using plaque reduction assays. *Limitations:* Short follow-up period.

Implications: There may be a narrow window to collect convalescent plasma with maximal neutralizing activity for use as potential COVID-19 therapy. Findings also highlight the importance of characterizing serum neutralizing activity.

Figure:



Note: Adapted from Lee *et al*. Percentage of specimens that can **neutralize 50%** or **neutralize 90%** or of viral plaque formation with an antibody titer of ≥1:160 (left Y-axis) and the fold increase of **mean antibody levels** to the SARS-CoV-2 nucleocapsid (right Y-axis). Lee et al. Neutralizing antibody responses in COVID-19 convalescent sera. Journal of Infectious Diseases. DOI: https://doi.org/10.1093/infdis/jiaa673 ; Used by permission of the Infectious Diseases Society of America.

Frequency and duration of SARS-CoV-2 shedding in oral fluid samples assessed by a modified commercial rapid molecular assay. Bordi *et al.* Viruses (October 20, 2020).

Key findings:

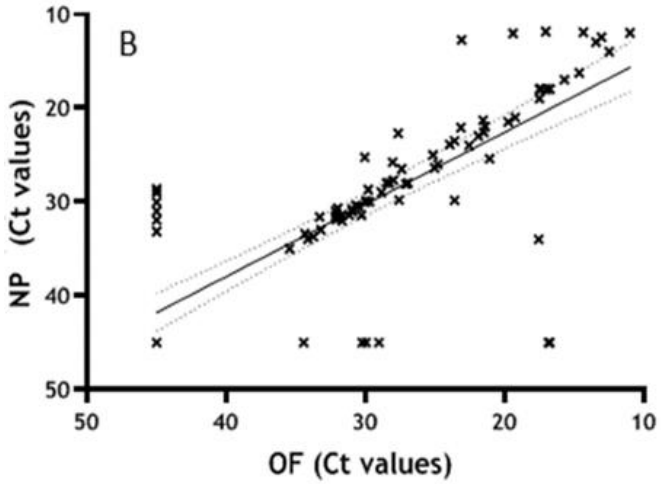
- Parallel testing for SARS-CoV-2 RNA in 337 oral fluid (OF) and nasopharyngeal (NP) specimens found 309 concordant and 28 discordant results (kappa statistic = 0.831, 95% CI 0.771-0.891).

  - Ct values for OF and NP specimens were highly correlated (correlation coefficient r = 0.921; p <0.0001) (Figure).
- SARS-CoV-2 RNA was observed in:
  - 67% of OF and 72% of NP specimens collected within 30 days of symptom onset (DSO).
  - 65% of OF and 76% of NP specimens collected between 30 and 60 DSO.
  - 32% of OF and 29% of NP specimens collected between 60 and 100 DSO.

Methods: The Simplexa™ COVID-19 Direct assay was used to test concordance in 337 paired OF and NP specimens from 164 patients hospitalized with suspected COVID-19. A sub-sample of 162 specimens was analyzed for viral RNA in OF and NP specimens, by DSO range. ***Limitations***: Did not evaluate effectiveness of OF or NP samples for specific clinical, surveillance, and epidemiologic uses.

Implications: Several assays find that OF samples are highly correlated with NP samples and may be an alternative to NP samples for diagnosis of SARS-CoV-2 infection. As noted in a recent paper in Clinical Infectious Diseases (Azzi, L. Saliva is the Key Element for SARS-CoV-2 Mass Screening), saliva can be easily and noninvasively self-collected, minimizing transmission risk to clinicians and facilitating more frequent testing of contacts, which may be critical to containing spread of SARS-CoV-2.

Figure:



Note: Adapted from Bordi *et al*. Results from samples tested for SARS-CoV-2 RNA both in NP and OF displayed in linear regression adjusted for repeated measures, sex and age (r = 0.921; p <0.0001). Licensed under CC-BY 4.0.

PREPRINT (NOT PEER-REVIEWED)

Prevalence of antibodies to SARS-CoV-2 in healthy blood donors in New York. Kamath *et al.* MedRxiv (October 21, 2020).

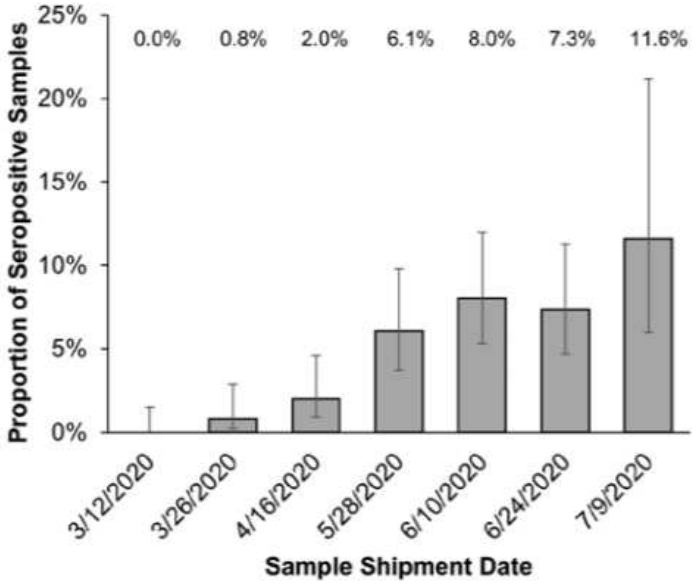
Key findings:

- 68 of 1,559 blood donor samples had IgG antibodies against SARS-CoV-2.
  - Seropositivity rate increased from 0% (95% CI 0-1.5%) in March 2020 to 11.6% (95% CI 6.0-21.2%) in July 2020.

Methods: Screen for antibodies to SARS-CoV-2 in samples from 1,559 healthy blood donors from the greater New York metropolitan area between March and July 2020. ***Limitations***: Unclear what proportion of donors were asymptomatic cases.

Implications: Although the pandemic significantly affected the greater New York metropolitan area, seropositivity for SARS-CoV-2 antibodies was low indicating that the population is far from reaching a threshold for herd immunity.

Figure:



Note: Adapted from Kamath *et al*. SARS-CoV-2 seropositivity over time in blood donors. Shipment date is when sample was sent to the laboratory for testing (within 2 weeks of sample collection). I bar represents the 95% CI. Used by permission of author.

Epidemiology

PEER-REVIEWED

COVID-19 transmission in US child care programs. Gilliam *et al.* Pediatrics (October 1, 2020).

Key findings:

- 0.7% (n = 427) of child care providers reported testing positive or being hospitalized for COVID-19.
  - No association was found between exposure to child care programs and COVID-19 (OR 0.94; 95% CI 0.73-1.21).
  - Being a home-based rather than center-based provider was associated with diagnosis of COVID-19 (OR 1.59, 95%CI 1.14-2.23) but this was independent of reported exposure.

Methods: Survey of 57,335 child care providers between May 22 and June 8, 2020, identified through two national child care organizations and 28 state child care workforce registries. Participants were surveyed on exposure to child care programs in the previous 8 weeks and whether they had tested positive for SARS-CoV-2 or had been hospitalized for COVID-19. Logistic regression was conducted to control for confounders (county COVID-19 mortality rate, hand washing and social distancing, child care facility type). *Limitations*: Child care program not defined; state policy-level variables may not have been adequately controlled.

Implications: Early in the pandemic, exposure to child care programs did not appear to place child care providers at increased risk of COVID-19. This may be partially attributable to infection mitigation efforts in child care programs and background incidence rates. Infections among child care providers will need to be re-evaluated once facilities more broadly re-open.

Social determinants of COVID-19 mortality at the county level. Fielding-Miller *et al.* PLoS One (October 14, 2020).

Key findings:

- The number of COVID-19 deaths per 100,000 was substantially higher in urban than non-urban counties, 39.1 per 100,000 (IQR: 15.0–107.3) and 5.6 (IQR: 0–19.7), respectively.
- Factors independently associated with higher numbers of deaths for the US overall included:
  - % of farmworkers (5.79 additional deaths per percentage point increase of farmworkers, p = 0.001).
  - % of residents living in poverty (4.41 additional deaths per percentage point increase, p <0.001).
  - % of residents aged >65 years (4.58 additional deaths per percentage point increase, p = 0.002).
  - Population density (0.25 additional deaths per resident per square mile, p <0.001).
- Factors independently associated with deaths per 100,000 persons varied substantially by census region.

Methods: Spatial models to determine county-level associations between COVID-19 mortality and percentage of hired farmworkers, percentage of households without a fluent, adult English-speaker, percentage of uninsured individuals under the age of 65, and percentage of individuals living at or below the federal poverty line, across all 3,024 counties as of July 12, 2020. *Limitations*: Negative associations in some regions might represent unmeasured confounding or gaps in testing or data collection for poor and uninsured individuals.

Implications: Findings indicate that the epidemic is heterogenous and is affecting geographic regions differently. The differences in geographic regions might, in part, reflect regional demographic variation or varied state and local social distancing and other public health policies.

PREPRINT (NOT PEER-REVIEWED)

What predicts adherence to COVID-19 government guidelines? Longitudinal analyses of 51,000 UK adults. Wright *et al.* MedRxiv. (October 21, 2020).

Key findings:

- Increased confidence in government to handle the pandemic was related to higher compliance with government COVID-19 guidelines.
- Mental health and wellbeing, worries about future adversities, and social isolation and loneliness were unrelated to compliance.

Methods: Data from a longitudinal study of over 51,000 adults in the UK were used to determine factors associated with compliance with government guidelines during the initial implementation of social distancing measures (April 1 to June 22, 2020). Factors studied included mental health and wellbeing, social experiences, confidence in institutions, knowledge of COVID-19, and time spent on various activities. *Limitations:* All data were self-reported.

Implications: Findings highlight the role of policy makers in shaping the impact of compliance with mitigation efforts.

Clinical Treatment & Management

PEER-REVIEWED

Registry of arterial and venous thromboembolic complications in patients with COVID-19. Piazza *et al.* Journal of the American College of Cardiology (November 3, 2020)

Key findings:

- 4.6%, 5.9%, and 8.3% of COVID-19 patients experienced a symptomatic thromboembolic event (VTE), a major arterial or venous VTE, or major adverse cardiovascular event, respectively, within 30 days of diagnosis.
    - Events occurred despite high rates of thromboprophylaxis in ICU (90%) and general medical ward (GMW) (85%) patients.
    - No events occurred in outpatients.

Methods: Retrospective study of patients diagnosed with RT-PCR-confirmed COVID-19 at one health network between March 13 and April 3, 2020. Primary outcome was the proportion of ICU patients (n = 170), GMW patients (n = 229) and outpatients (n = 715) who experienced a symptomatic VTE (e.g., deep vein thrombosis), major arterial or VTE (e.g., stroke) or major adverse cardiovascular event (e.g., heart failure) within 30 days of diagnosis. *Limitations*: Microvascular thrombosis was not assessed; unable to assess adherence to antiplatelet or antithrombotic therapy prior to COVID-19.

Implications The high frequency of arterial or venous thromboembolism in hospitalized patients with COVID-19, despite routine thromboprophylaxis, suggests the need for improved risk stratification and enhanced preventive efforts.

PREPRINTS (NOT PEER-REVIEWED)

Viral infections have been associated with several autoimmune diseases. These infections can trigger production of autoantibodies that are directed toward the host's own body potentially causing tissue damage and transient or chronic symptoms and disease.

Clinically identifiable autoreactivity is common in severe SARS-CoV-2 infection. Woodruff *et al.* MedRxiv (October 28, 2020).

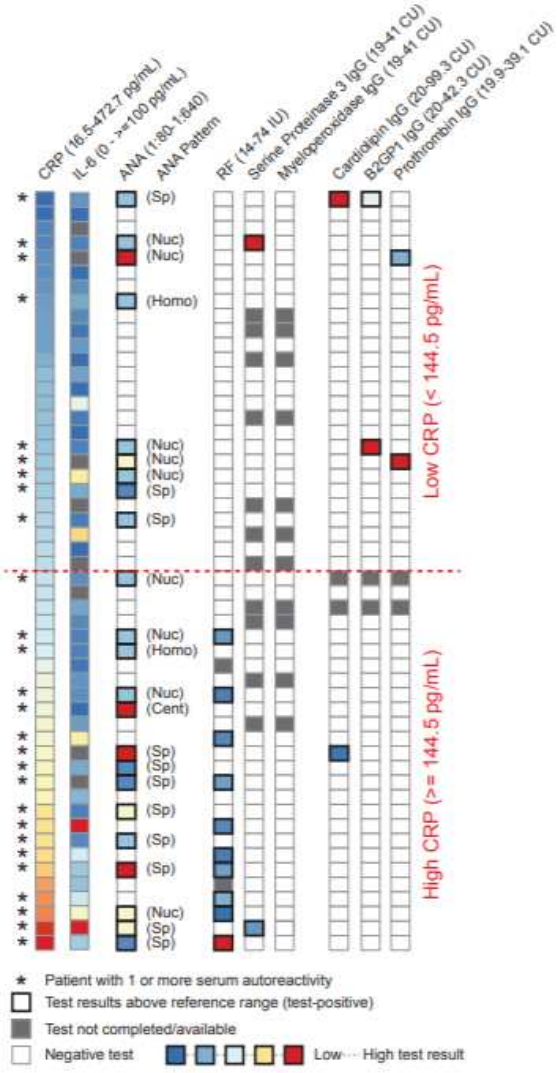
Key findings:

- 44% of patients had antinuclear antibody (ANA) ≥1:80 (the diagnostic threshold for the autoimmune disease systemic lupus erythematosus) and 81% of these positive tests had titers ≥1:160.
    - 59% of ANA-positive patients had ≥1 other positive autoreactive antibody test such as rheumatoid factor (10/52), phospholipids (3/52), prothrombin (2/52), or antineutrophil cytoplasmic antibodies (2/52) (Figure).
    - All patients with >1 positive autoreactive antibody test were positive for either ANA or rheumatoid factor.
- Autoreactivity was correlated with increasing serum levels of c-reactive protein (CRP), a protein found in the bloodstream in response to inflammation.

Methods: Study of 52 severe or critically ill patients with COVID-19 and no known history of autoimmune disease treated at two ICUs in Atlanta, Georgia, between June 1st and July 2nd, 2020. Patients were tested for a variety of autoimmune antibodies. *Limitations*: Limited follow-up.

Implications: Severe COVID-19 may cause *de novo* autoreactive antibody production against a variety of self-antigens which could argue for clinical interventions aimed at modifying the immune response.

Figure:



Note: Adapted from Woodruff *et al*. Heatmap display of clinical results organized by ascending CRP values. Values for individual tests are indicated following the test name (top of figure). **Horizontal red dotted line** indicates low or high levels of serum CRP. Used by permission of author.

Cognitive deficits in people who have recovered from COVID-19 relative to controls: An N = 84,285 online study. Hampshire *et al.* MedRxiv. (October 21, 2020).

Key findings:

- Decreased global cognitive performance was seen among the following (Figure 1):
  - In persons hospitalized and on ventilators cognitive performance was -0.57 standard deviations (SDs) below healthy controls (approximates an 8.5-point difference in IQ).
  - Persons hospitalized but not on a ventilator, -0.45 SDs.
  - Persons assisted at home for respiratory difficulty, -0.12 SDs.
  - Persons with respiratory difficulty but received no medical assistance, -0.10 SDs.

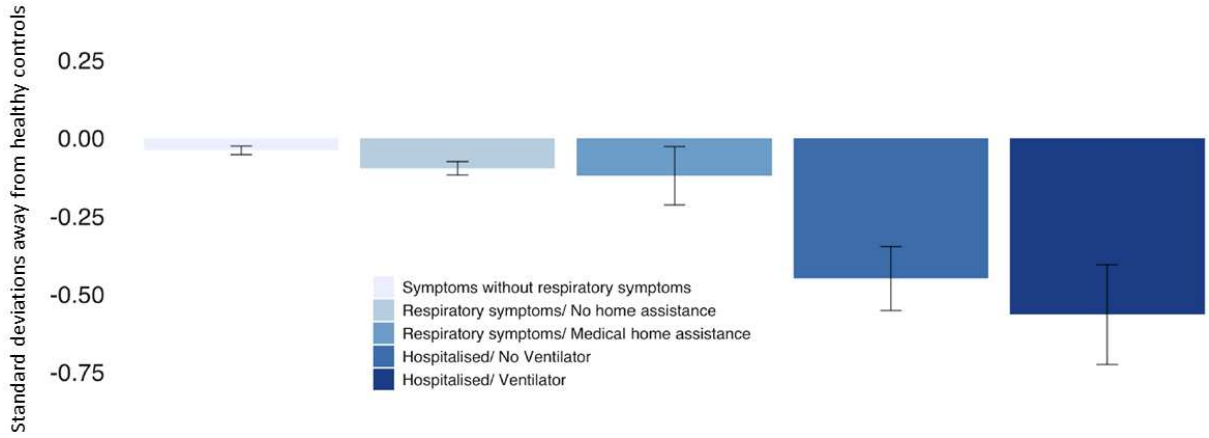
- Persons ill without respiratory difficulty, -0.04 SDs.

- The most apparent deficits were in semantic problem solving and visual selective attention which were associated with disease severity (Figure 2).

Methods: An online survey of cognition, wellbeing, and behavior of 84,285 participants who completed a questionnaire regarding impacts of the pandemic among persons with suspected (n = 12,689) and confirmed (n = 361) SARS-CoV-2 infection were analyzed to determine associations between COVID-19 and cognitive deficits. Testing addressed semantic problem solving, spatial working memory, selective attention and emotional processing. *Limitations*: Most cases unconfirmed; symptom severity was self-reported; cross-sectional design.

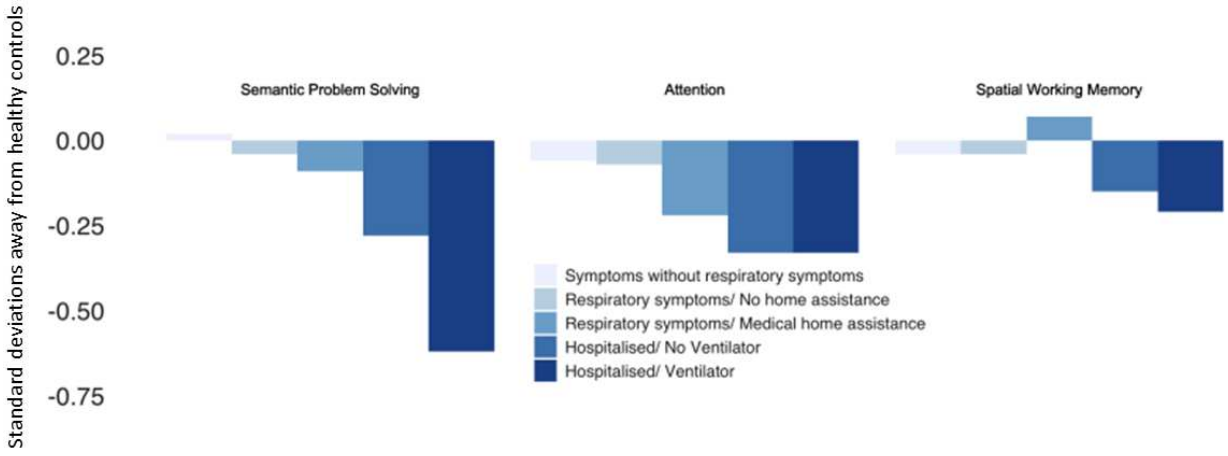
Implications: Cognitive deficits were found in persons with history of COVID-19 and there may be a need for cognitive assessment of persons recovered from COVID-19.

Figure 1



Note: Adapted from Hampshire *et a*l. Global cognitive performance by COVID-19 symptom severity. Licensed under CC-BY 4.0.

Figure 2



Note: Adapted from Hampshire *et al*. Cognitive domain performance by symptom severity. Licensed under CC-BY 4.0.

In Brief

Testing

- Rafiei & Mello. **The missing piece — SARS-CoV-2 testing and school reopening.** NEJM. Authors argue that SARS-CoV-2 testing is necessary to safely re-open schools and discuss challenges in implementing school testing programs and ways in which state and federal governments can assist.
- Rubin, R. **The challenges of expanding rapid tests to curb COVID-19.** JAMA. Authors discuss the merits of ramping up rapid SARS-CoV-2 testing and challenges including variable test accuracy, manufacturing logistics and public perceptions that testing can be used in lieu of other preventive measures such as mask wearing.

Mental health and well being

- Fong & Iarocci. **Child and family outcomes following pandemics: A systematic review and recommendations on COVID-19 policies.** Journal of Pediatric Psychology. A systematic review of mental health outcomes and needs of children and families during past pandemics.
- Ickert *et al*. **Maintaining resident social connections during COVID-19: Considerations for long-term care.** Gerentology and Geriatric Medicine. Considerations for facilitating social connections of long-term care residents and their families while restrictions on visitation are in place.

Miscellaneous

- Vignesh *et al*. **Is herd immunity against SARS-CoV-2 a silver lining?** Frontiers in Immunology. Authors discuss a variety of elements that factor into whether populations reach herd immunity thresholds and argue that the most practical way to achieve this is through vaccination.
- Blecker *et al*. **Hospitalizations for chronic disease and acute conditions in the time of COVID-19**. JAMA Internal Medicine. Study found a substantial decrease in the number of non-COVID-19 related hospitalizations between March 22 to April 11, 2020.
- Lan *et al*. **Effects of universal masking on Massachusetts healthcare workers' COVID-19 incidence.** Occupational Medicine. Study found universal masking, implemented in healthcare systems statewide, was associated with decreasing incidence trend of COVID-19 among healthcare workers while incidence rose in the surrounding community.
- Figueiredo-Campos *et al*. **Seroprevalence of anti-SARS-CoV-2 antibodies in COVID-19 patients and healthy volunteers up to six months post disease onset.** European Journal of Immunology. Study of 2,998 COVID-19 patients demonstrated that IgG antibodies to SARS-CoV-2 receptor-binding domain protein lasted up to 6 months post-symptom onset and that titers were proportional to neutralizing activity.
- Ong *et a*l. **Environmental contamination in a COVID-19 intensive care unit (ICU) – what is the risk?** Infection Control and Hospital Epidemiology. Study found that environmental contamination with SARS-CoV-2 in a hospital intensive care unit was lower than that of a general medical floor and that use of mechanical ventilation or high-flow nasal oxygen was not associated with greater surface contamination.

Disclaimer: The purpose of the CDC COVID-19 Science Update is to share public health articles with public health agencies and departments for informational and educational purposes. Materials listed in this Science Update are selected to provide awareness of relevant public health literature. A material's inclusion and the material itself provided here in full or in part, does not necessarily represent the views of the U.S. Department of Health and Human Services or the CDC, nor does it necessarily imply endorsement of methods or findings. While much of the COVID-19 literature is open access or otherwise freely available, it is the responsibility of the third-party user to determine whether any intellectual property rights govern the use of materials in this Science Update prior to use or distribution. Findings are based on research available at the time of this publication and may be subject to change.

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CDC Response Website Updates (11/5)

New:

- Maternal, Neonatal, and Child Health Surveillance During COVID-19
- Maternal, Neonatal, and Child Health Services during COVID-19
- Developing a Framework for Assessing and Managing Individual-Level Risk of Coronavirus Disease 2019 (COVID-19) Exposure in Mobile Populations
- Providing Spiritual and Psychosocial Support to People with COVID-19 at Home (Non-US Settings)

Updated:

- CDC COVID Data Tracker
- Staffing resources
- COVID-19 Forecasts: Cases
- Previous COVID-19 Forecasts: Cases
- COVID-19 Forecasts: Deaths
- COVID-19 Forecasts: Hospitalizations
- Previous COVID-19 Forecasts: Hospitalizations
- Operational Considerations for Adapting a Contact Tracing Program to Respond to the COVID-19 Pandemic
- Toolkit for People 15 to 21
- Social Media Toolkit
- Toolkit for People with Disabilities
- Frequently Asked Questions: Hand Sanitizer on Pets
- COVID-19 Webinar and Partner Calls Videos
- Community Organizations and Gatherings
- Daily Activities and Going Out
- CDC COVID-19 Global Response
- What Do You Do if You Are Sick
- Data on COVID-19 during Pregnancy: Severity of Maternal Illness

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CDC Response Website Updates (11/2)

New:

- I wear a mask because…

Updated:

- CDC COVID Data Tracker
- Staffing Resources

- Investigating the Impact of COVID-19 During Pregnancy
- COVID-19 By the Numbers
- People with Certain Medical Conditions
- Evidence used to update the list of underlying medical conditions that increase a person's risk of severe illness from COVID-19
- COVID-19 Contact Tracing Training
- Data on COVID-19 during Pregnancy
- How to Report COVID-19 Laboratory Data
- Treatments Your Healthcare Provider Might Recommend for Severe Illness
- Information for Clinicians on Investigational Therapeutics for Patients with COVID-19
- COVID-19 Electronic Laboratory Reporting Implementation by State

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

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Declines in SARS-CoV-2 Transmission, Hospitalizations, and Mortality After Implementation of Mitigation Measures— Delaware, March–June 2020

Florence A. Kanu[1,2]; Erica E. Smith[3]; Tabatha Offutt-Powell[3]; Rick Hong[3], Delaware Case Investigation and Contact Tracing Teams[3]; Thu-Ha Dinh[2]; Eric Pevzner[2]

Mitigation measures, including stay-at-home orders and public mask wearing, together with routine public health interventions such as case investigation with contact tracing and immediate self-quarantine after exposure, are recommended to prevent and control the transmission of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) (*1*–*3*). On March 11, the first COVID-19 case in Delaware was reported to the Delaware Division of Public Health (DPH). The state responded to ongoing community transmission with investigation of all identified cases (commencing March 11), issuance of statewide stay-at-home orders (March 24–June 1), a statewide public mask mandate (from April 28), and contact tracing (starting May 12). The relationship among implementation of mitigation strategies, case investigations, and contact tracing and COVID-19 incidence and associated hospitalization and mortality was examined during March–June 2020. Incidence declined by 82%, hospitalization by 88%, and mortality by 100% from late April to June 2020, as the mask mandate and contact tracing were added to case investigations and the stay-at-home order. Among 9,762 laboratory-confirmed COVID-19 cases reported during March 11–June 25, 2020, two thirds (6,527; 67%) of patients were interviewed, and 5,823 (60%) reported completing isolation. Among 2,834 contacts reported, 882 (31%) were interviewed and among these contacts, 721 (82%) reported completing quarantine. Implementation of mitigation measures, including mandated mask use coupled with public health interventions, was followed by reductions in COVID-19 incidence and associated hospitalizations and mortality. The combination of state-mandated community mitigation efforts and routine public health interventions can reduce the occurrence of new COVID-19 cases, hospitalizations, and deaths.

Using laboratory and case investigation data, changes in COVID-19 incidence and associated hospitalization and mortality in Delaware during March 11–June 25 were assessed. Laboratory data from the Delaware Electronic Reporting and Surveillance System (DERSS) and case investigation data from Delaware DPH were obtained. DERSS data included case classification (e.g., laboratory-confirmed or probable*); case investigation data included hospitalization status and outcome, including death. Incidence was defined as the number of newly confirmed COVID-19 patients per 10,000 Delaware residents per week (*4*). Hospitalization and mortality rates were calculated similarly, as the number of patients with confirmed COVID-19 who were hospitalized or died per 10,000 persons per week. Percent change was calculated to describe the magnitude of rate change. Delaware mitigation and public health interventions included 1) case investigations (starting March 11), which involved interviewing patients with SARS-CoV-2 infection, asking each to immediately self-isolate while collecting information on demographic characteristics, potential exposure source, symptoms,† and close contacts§;

* A probable case was defined as an illness meeting clinical criteria and having an epidemiologic link with no confirmatory laboratory testing performed for COVID-19, or an illness with presumptive laboratory evidence (detection of antigen or antibody) and either meeting clinical criteria or having an epidemiologic link, or an illness in a person meeting vital records criteria with no confirmatory laboratory testing for COVID-19 performed. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/faq-surveillance.html.

† The following signs and symptoms were monitored: cough, fever, fatigue, body aches, loss of taste/smell, shortness of breath, chills, and sore throat.

§ Case investigation included inquiries about close contacts in May 2020. At time of data collection, CDC guidance on contact definition was "persons less than 6 feet from a confirmed case for at least 10 minutes." CDC guidance now defines contacts as any person within 6 feet of an infected person for a cumulative total of 15 minutes or more over a 24-hour period starting from 2 days before illness onset (or, for asymptomatic patients, 2 days prior to test specimen collection). https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#contact.

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2) statewide mandated stay-at-home order[¶] (March 24–June 1); 3) statewide mandated mask use in public[**] (instituted April 28); and 4) contact tracing (starting May 12), wherein close contacts were interviewed and asked to self-quarantine and report symptoms for 14 days following an exposure. Changes in COVID-19 incidence and associated hospitalizations and mortality from March through June were assessed.

After the initial case report and stay-at-home order, COVID-19 incidence, hospitalization, and mortality rates increased, peaking during the week of April 13 at 15.0, 2.0, and 0.8 per 10,000 persons, respectively (Figure). After the peak, incidence declined by 18%, hospitalizations by 20%, and deaths by 13%, before increasing slightly during the week of April 20. Rates declined again the same week the mask mandate went into effect (April 28) and continued to decline by 82% (incidence), 88% (hospitalization) and 100% (mortality) from late April through June, as contact tracing was added to case investigations, the stay-at-home order, and the mask mandate.

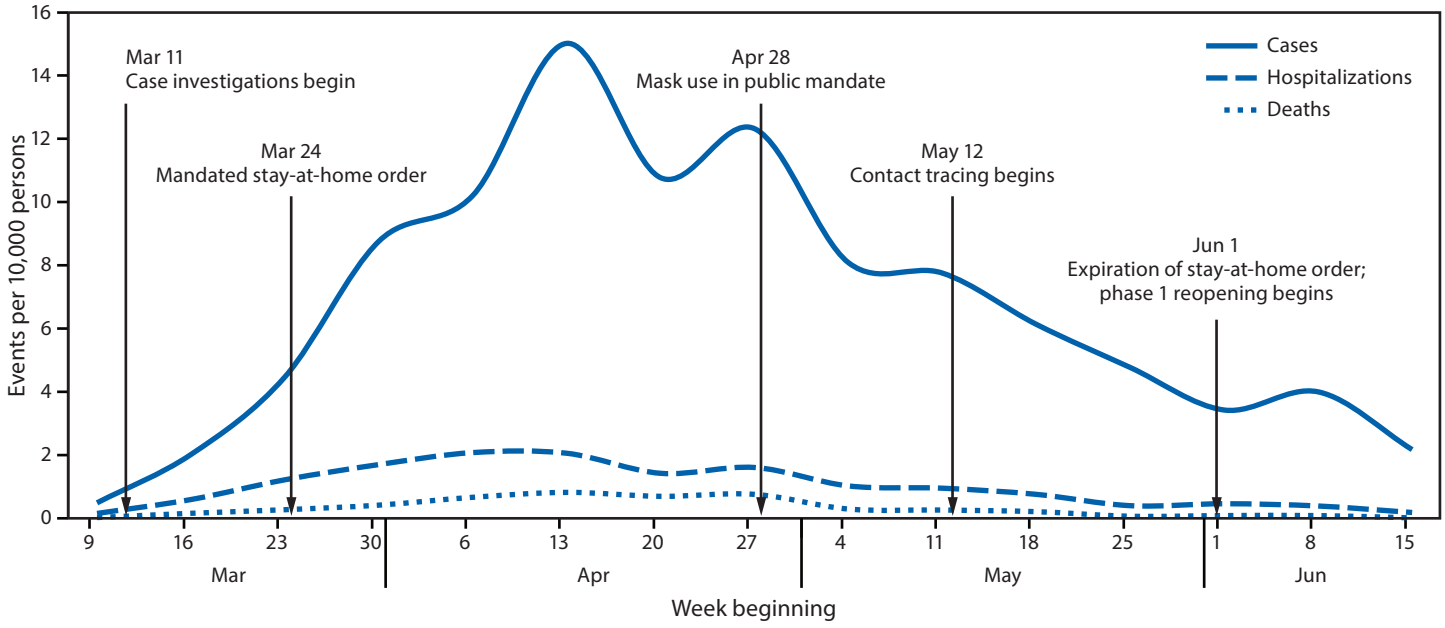
During March 11–June 25, a total of 9,762 newly confirmed COVID-19 cases were identified in DERSS; among these cases, 6,527 (67%) patients were interviewed and asked to self-isolate, among whom 5,823 (89%) had been released from isolation[††] at the time of data collection. Median patient age was 41 years (interquartile range [IQR] = 28–54 years), and 55% were female (Table). The median interval from receiving a positive test result to interview was 8 days (IQR = 6–12 days) and from DPH's receipt of case report to interview was 5 days (IQR = 2–8 days). Patients who were not interviewed were those who did not respond to call attempts (1,134, 12%), were in a hospital/long-term care facility at time of contact (788, 8%), did not have an available phone number (673, 7%), had died (433, 4%), or were not interviewed for other reasons[¶¶] (207, 2%). Among interviewed patients, 5,742 (88%) reported having any COVID-19–related symptoms before the interview date, and 55% reported close contact with someone with diagnosed COVID-19.

Among 6,527 interviewed patients with laboratory-confirmed COVID-19, 5,390 (83%) either refused to name contacts or could not recall contacts. The mean number of contacts reported per patient who reported one or more contacts was 2.5 (IQR = 1–3). Among the 2,834 contacts reported, complete contact information was obtained for 1,869 (66%), and 882 (47%) of those were interviewed and asked to self-quarantine. The median interval from patient interview to contact interview was 2 days (IQR = 1–4 days). The median age of interviewed contacts was 25 years (IQR = 14–47 years), 433 (49%) were female, 721 (82%) did not develop symptoms during quarantine, and 771 (87%) lived in the same household as someone with confirmed

[¶] https://governor.delaware.gov/health-soe/fifth-state-of-emergency/.
[**] https://governor.delaware.gov/health-soe/thirteenth-state-of-emergency/.
[††] Release from isolation was dependent on CDC guidance during this study period: initially, patients were asked to isolate for 14 days from symptom onset or test date and be symptom-free for 7 days. Later, patients were asked to isolate for 10 days from symptom onset or test date and be symptom-free for 3 days. Patients with asymptomatic cases were asked to isolate for 10 days after test date.

[¶¶] Other status was reserved for unique circumstances that could not be addressed by case investigators or contact tracers without additional information.

FIGURE. Confirmed COVID-19 cases, associated hospitalizations, and deaths reported to Delaware Division of Public Health, by week, and COVID-19 mitigation efforts — Delaware Department of Health and Social Services, March 9–June 15, 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

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COVID-19. Overall, 161 (18%) of the 882 contacts who were reached experienced symptoms during quarantine and were urged to be tested for SARS-CoV-2. A manual search of DERSS data determined that among 161 symptomatic contacts, 20 (12%) were tested, four of whom (3%) received a COVID-19 diagnosis. Reasons for not interviewing contacts included that the contact did not respond to call attempts (265, 14%), had no available phone number (208, 11%), refused (88, 5%), was a non-Delaware resident (20, 1%), or other reasons (406, 22%).

TABLE. Characteristics of persons with confirmed COVID-19 (patients) and contacts interviewed during case and contact investigations — Delaware, March–June 2020

Characteristic	No. (%)	
	Interviewed patients (n = 6,527)	Interviewed contacts (n = 882)
Age, yrs, median (IQR)	41 (28–54)	25 (14–74)
Time from positive COVID-19 test to interview, days, median (IQR)	8 (6–12)	N/A
Time from report to interview, days, median (IQR)	5 (2–8)	2 (1–4)
Sex		
Male	2,911 (44.6)	449 (50.9)
Female	3,614 (55.4)	433 (49.1)
Missing	2 (0.03)	0 (—)
Race/Ethnicity		
White, non-Hispanic	1,769 (27.1)	202 (22.9)
Black or African American, non-Hispanic	1,949 (29.9)	155 (17.6)
Hispanic/Latino	2,237 (34.3)	350 (39.7)
Asian, non-Hispanic	128 (2.0)	6 (0.7)
Other/Multiple races, non-Hispanic	327 (5.0)	20 (2.3)
Unknown/Missing	117 (1.8)	149 (16.9)
Any symptoms*		
No	753 (11.5)	721 (81.8)
Yes	5,742 (88.0)	161 (18.3)
Unknown/Missing	32 (0.5)	0 (—)
Close contact with confirmed COVID-19 case		
No	2,222 (34.0)	N/A
Yes	3,574 (54.8)	882 (100)
Unknown/Missing	731 (11.2)	0 (—)
Household exposure† to known COVID-19 case		
No	1,235 (19.0)	100 (11.3)
Yes	2,039 (31.3)	771 (87.4)
Unknown/Missing	3,253 (49.8)	11 (1.3)
Hospitalized		
No	5,606 (85.9)	N/A
Yes	742 (11.4)	N/A
Unknown/Missing	179 (2.7)	N/A
Died from COVID-19		
No	6,477 (99.2)	N/A
Yes	14 (0.2)	N/A
Unknown/Missing	36 (0.6)	N/A

Sources: Delaware Case Investigation and Contract Tracing Systems, Delaware Department of Health and Social Services, Division of Public Health.
Abbreviations: COVID-19 = coronavirus disease 2019; IQR = interquartile range; N/A = not applicable.
* Patients were asked if they had symptoms from 14 days before test date to date of interview; contacts were asked during monitoring period if they had symptoms.
† Household exposure defined as possible exposure to COVID-19 from a household member with confirmed COVID-19.

Discussion

A stay-at-home order and case investigations instituted weeks before the peak in COVID-19 cases (week of April 13) in Delaware likely contributed to the subsequent decline observed in COVID-19 incidence and associated hospitalization and deaths. As expected, the impact on incidence was not immediate but occurred weeks after measures were implemented, as new cases represented exposure that occurred during previous weeks. Additional steep declines in reports of new cases occurred after a public mask use mandate was issued in late April. Masks are critical for reducing SARS-CoV-2 transmission from persons with symptomatic or asymptomatic infection (*5*). Wearing masks can prevent respiratory droplets containing SARS-CoV-2 from traveling into the air and being transmitted to other persons and thus can reduce exposures and infections (*6*,*7*).

Early detection, self-isolation, and investigation of COVID-19 cases and self-quarantine of close contacts can be effective in preventing community transmission, if contacts are identified and reached soon after exposure (*8*). Because of limited resources and the growing number of cases, contact tracing in Delaware officially began in May when the Delaware National Guard was activated to assist Delaware DPH. In Delaware, contacts were monitored until symptom onset or quarantine completion. Testing was recommended for contacts reporting symptoms; however, no active follow-up was performed because of constrained resources. Case investigation was completed among contacts who received positive test results; therefore, having active follow-up and referral systems for testing contacts could expand disease prevention and containment opportunities.

Several barriers to case investigation and contact tracing were identified. First, low numbers of contacts were identified: 83% of interviewed patients either refused to disclose contacts or could not recall contacts. Second, cases were contacted a median of 8 days after receiving their positive test result and 5 days after report of this result to DPH. Earlier initiation of case investigation might increase recall and early identification of close contacts and thus prevent further disease transmission. Lastly, 22% of contacts could not be reached for reasons designated as "other," an interaction outcome in case investigations and contact tracing reserved for circumstances interviewers could not address without additional information. Daily and weekly data monitoring to provide additional information for those with "other" as an interaction outcome could increase the number of persons reached. These barriers to contact tracing might have limited effectiveness and were missed opportunities to recommend other mitigation strategies (e.g., testing, quarantine, or isolation).

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Summary

What is already known about this topic?

COVID-19 mitigation measures (e.g., stay-at-home orders and public mask mandate) and fundamental public health interventions (e.g., case investigations and contact tracing with prompt isolation or quarantine) are primary approaches to preventing and controlling SARS-CoV-2 community transmission.

What is added by this report?

State-mandated stay-at-home orders and public mask mandates coupled with case investigations with contact tracing contributed to an 82% reduction in COVID-19 incidence, 88% reduction in hospitalizations, and 100% reduction in mortality in Delaware during late April–June.

What are the implications for public health practice?

The combination of state-mandated community mitigation efforts and routine public health interventions can reduce the occurrence of new COVID-19 cases, hospitalizations, and deaths.

The findings in this report are subject to at least three limitations. First, data on adherence to the state-mandated stay-at-home order and use of masks in public were not available. Second, adherence to self-quarantine was self-reported. Finally, because of the observational design of the study, the decline in COVID-19 incidence, hospitalization, and mortality could not be attributed to the relative contribution of each mitigation measure.

A combination of mitigation measures including stay-at-home orders, mandated mask use in public, and case investigations with contact tracing, can reduce COVID-19 incidence and associated deaths (*9*). No single mitigation strategy is likely to be effective alone. These strategies are effective in limiting potential exposure to SARS-CoV-2 and reducing community transmission when implemented as part of a multicomponent strategy (*10*). In Delaware, state-mandated community mitigation efforts, such as stay-at-home orders, coupled with mask use, likely contributed to the decline in new COVID-19 cases. SARS-CoV-2 community transmission, hospitalization, and mortality can be reduced with statewide mitigation strategies implemented in tandem with the routine public health interventions of case investigation with contact tracing, and immediate self-isolation of cases and self-quarantine of contacts.

Acknowledgments

COVID-19 Case Investigation and Contact Tracing teams, Delaware Division of Public Health; Delaware National Guard; CDC COVID-19 Health Department Task Force

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[1]Epidemic Intelligence Service, CDC; [2]CDC COVID-19 Response Team; [3]COVID-19 Outbreak Response Team, Division of Public Health, Delaware Department of Health and Social Services.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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Mitigation measures, including stay-at-home orders and public mask wearing, together with routine public health interventions such as case investigation with contact tracing and immediate self-quarantine after exposure, are recommended to prevent and control the transmission of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) (*1*–*3*). On March 11, the first COVID-19 case in Delaware was reported to the Delaware Division of Public Health (DPH). The state responded to ongoing community transmission with investigation of all identified cases (commencing March 11), issuance of statewide stay-at-home orders (March 24–June 1), a statewide public mask mandate (from April 28), and contact tracing (starting May 12). The relationship among implementation of mitigation strategies, case investigations, and contact tracing and COVID-19 incidence and associated hospitalization and mortality was examined during March–June 2020. Incidence declined by 82%, hospitalization by 88%, and mortality by 100% from late April to June 2020, as the mask mandate and contact tracing were added to case investigations and the stay-at-home order. Among 9,762 laboratory-confirmed COVID-19 cases reported during March 11–June 25, 2020, two thirds (6,527; 67%) of patients were interviewed, and 5,823 (60%) reported completing isolation. Among 2,834 contacts reported, 882 (31%) were interviewed and among these contacts, 721 (82%) reported completing quarantine. Implementation of mitigation measures, including mandated mask use coupled with public health interventions, was followed by reductions in COVID-19 incidence and associated hospitalizations and mortality. The combination of state-mandated community mitigation efforts and routine public health interventions can reduce the occurrence of new COVID-19 cases, hospitalizations, and deaths.

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2) statewide mandated stay-at-home order[¶] (March 24–June 1); 3) statewide mandated mask use in public[**] (instituted April 28); and 4) contact tracing (starting May 12), wherein close contacts were interviewed and asked to self-quarantine and report symptoms for 14 days following an exposure. Changes in COVID-19 incidence and associated hospitalizations and mortality from March through June were assessed.

After the initial case report and stay-at-home order, COVID-19 incidence, hospitalization, and mortality rates increased, peaking during the week of April 13 at 15.0, 2.0, and 0.8 per 10,000 persons, respectively (Figure). After the peak, incidence declined by 18%, hospitalizations by 20%, and deaths by 13%, before increasing slightly during the week of April 20. Rates declined again the same week the mask mandate went into effect (April 28) and continued to decline by 82% (incidence), 88% (hospitalization) and 100% (mortality) from late April through June, as contact tracing was added to case investigations, the stay-at-home order, and the mask mandate.

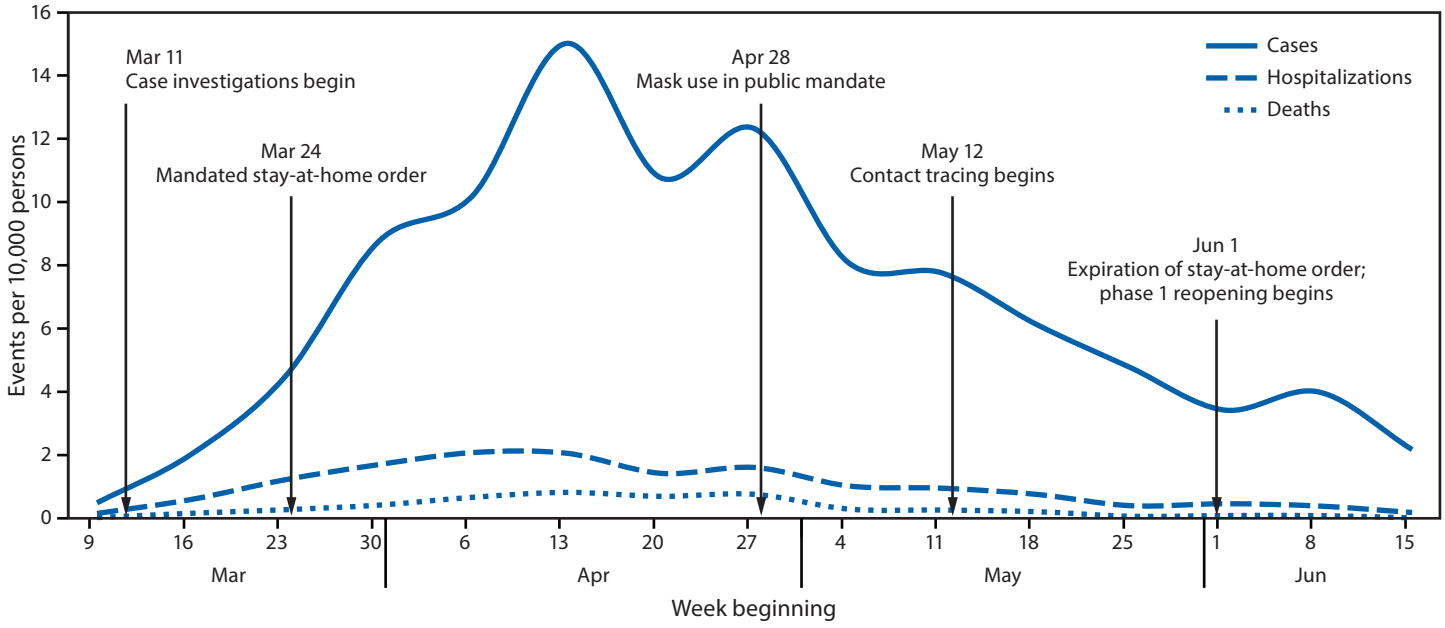
During March 11–June 25, a total of 9,762 newly confirmed COVID-19 cases were identified in DERSS; among these cases, 6,527 (67%) patients were interviewed and asked to self-isolate, among whom 5,823 (89%) had been released from isolation[††] at the time of data collection. Median patient age was 41 years (interquartile range [IQR] = 28–54 years), and 55% were female (Table). The median interval from receiving a positive test result to interview was 8 days (IQR = 6–12 days) and from DPH's receipt of case report to interview was 5 days (IQR = 2–8 days). Patients who were not interviewed were those who did not respond to call attempts (1,134, 12%), were in a hospital/long-term care facility at time of contact (788, 8%), did not have an available phone number (673, 7%), had died (433, 4%), or were not interviewed for other reasons[¶¶] (207, 2%). Among interviewed patients, 5,742 (88%) reported having any COVID-19–related symptoms before the interview date, and 55% reported close contact with someone with diagnosed COVID-19.

Among 6,527 interviewed patients with laboratory-confirmed COVID-19, 5,390 (83%) either refused to name contacts or could not recall contacts. The mean number of contacts reported per patient who reported one or more contacts was 2.5 (IQR = 1–3). Among the 2,834 contacts reported, complete contact information was obtained for 1,869 (66%), and 882 (47%) of those were interviewed and asked to self-quarantine. The median interval from patient interview to contact interview was 2 days (IQR = 1–4 days). The median age of interviewed contacts was 25 years (IQR = 14–47 years), 433 (49%) were female, 721 (82%) did not develop symptoms during quarantine, and 771 (87%) lived in the same household as someone with confirmed

[¶] https://governor.delaware.gov/health-soe/fifth-state-of-emergency/.
[**] https://governor.delaware.gov/health-soe/thirteenth-state-of-emergency/.
[††] Release from isolation was dependent on CDC guidance during this study period: initially, patients were asked to isolate for 14 days from symptom onset or test date and be symptom-free for 7 days. Later, patients were asked to isolate for 10 days from symptom onset or test date and be symptom-free for 3 days. Patients with asymptomatic cases were asked to isolate for 10 days after test date.

[¶¶] Other status was reserved for unique circumstances that could not be addressed by case investigators or contact tracers without additional information.

FIGURE. Confirmed COVID-19 cases, associated hospitalizations, and deaths reported to Delaware Division of Public Health, by week, and COVID-19 mitigation efforts — Delaware Department of Health and Social Services, March 9–June 15, 2020



Abbreviation: COVID-19 = coronavirus disease 2019.

MS-DOH-21-1816-A-002233

COVID-19. Overall, 161 (18%) of the 882 contacts who were reached experienced symptoms during quarantine and were urged to be tested for SARS-CoV-2. A manual search of DERSS data determined that among 161 symptomatic contacts, 20 (12%) were tested, four of whom (3%) received a COVID-19 diagnosis. Reasons for not interviewing contacts included that the contact did not respond to call attempts (265, 14%), had no available phone number (208, 11%), refused (88, 5%), was a non-Delaware resident (20, 1%), or other reasons (406, 22%).

TABLE. Characteristics of persons with confirmed COVID-19 (patients) and contacts interviewed during case and contact investigations — Delaware, March–June 2020

Characteristic	No. (%)	
	Interviewed patients (n = 6,527)	Interviewed contacts (n = 882)
Age, yrs, median (IQR)	41 (28–54)	25 (14–74)
Time from positive COVID-19 test to interview, days, median (IQR)	8 (6–12)	N/A
Time from report to interview, days, median (IQR)	5 (2–8)	2 (1–4)
Sex		
Male	2,911 (44.6)	449 (50.9)
Female	3,614 (55.4)	433 (49.1)
Missing	2 (0.03)	0 (—)
Race/Ethnicity		
White, non-Hispanic	1,769 (27.1)	202 (22.9)
Black or African American, non-Hispanic	1,949 (29.9)	155 (17.6)
Hispanic/Latino	2,237 (34.3)	350 (39.7)
Asian, non-Hispanic	128 (2.0)	6 (0.7)
Other/Multiple races, non-Hispanic	327 (5.0)	20 (2.3)
Unknown/Missing	117 (1.8)	149 (16.9)
Any symptoms*		
No	753 (11.5)	721 (81.8)
Yes	5,742 (88.0)	161 (18.3)
Unknown/Missing	32 (0.5)	0 (—)
Close contact with confirmed COVID-19 case		
No	2,222 (34.0)	N/A
Yes	3,574 (54.8)	882 (100)
Unknown/Missing	731 (11.2)	0 (—)
Household exposure† to known COVID-19 case		
No	1,235 (19.0)	100 (11.3)
Yes	2,039 (31.3)	771 (87.4)
Unknown/Missing	3,253 (49.8)	11 (1.3)
Hospitalized		
No	5,606 (85.9)	N/A
Yes	742 (11.4)	N/A
Unknown/Missing	179 (2.7)	N/A
Died from COVID-19		
No	6,477 (99.2)	N/A
Yes	14 (0.2)	N/A
Unknown/Missing	36 (0.6)	N/A

Sources: Delaware Case Investigation and Contract Tracing Systems, Delaware Department of Health and Social Services, Division of Public Health.
Abbreviations: COVID-19 = coronavirus disease 2019; IQR = interquartile range; N/A = not applicable.
* Patients were asked if they had symptoms from 14 days before test date to date of interview; contacts were asked during monitoring period if they had symptoms.
† Household exposure defined as possible exposure to COVID-19 from a household member with confirmed COVID-19.

Discussion

A stay-at-home order and case investigations instituted weeks before the peak in COVID-19 cases (week of April 13) in Delaware likely contributed to the subsequent decline observed in COVID-19 incidence and associated hospitalization and deaths. As expected, the impact on incidence was not immediate but occurred weeks after measures were implemented, as new cases represented exposure that occurred during previous weeks. Additional steep declines in reports of new cases occurred after a public mask use mandate was issued in late April. Masks are critical for reducing SARS-CoV-2 transmission from persons with symptomatic or asymptomatic infection (*5*). Wearing masks can prevent respiratory droplets containing SARS-CoV-2 from traveling into the air and being transmitted to other persons and thus can reduce exposures and infections (*6*,*7*).

Early detection, self-isolation, and investigation of COVID-19 cases and self-quarantine of close contacts can be effective in preventing community transmission, if contacts are identified and reached soon after exposure (*8*). Because of limited resources and the growing number of cases, contact tracing in Delaware officially began in May when the Delaware National Guard was activated to assist Delaware DPH. In Delaware, contacts were monitored until symptom onset or quarantine completion. Testing was recommended for contacts reporting symptoms; however, no active follow-up was performed because of constrained resources. Case investigation was completed among contacts who received positive test results; therefore, having active follow-up and referral systems for testing contacts could expand disease prevention and containment opportunities.

Several barriers to case investigation and contact tracing were identified. First, low numbers of contacts were identified: 83% of interviewed patients either refused to disclose contacts or could not recall contacts. Second, cases were contacted a median of 8 days after receiving their positive test result and 5 days after report of this result to DPH. Earlier initiation of case investigation might increase recall and early identification of close contacts and thus prevent further disease transmission. Lastly, 22% of contacts could not be reached for reasons designated as "other," an interaction outcome in case investigations and contact tracing reserved for circumstances interviewers could not address without additional information. Daily and weekly data monitoring to provide additional information for those with "other" as an interaction outcome could increase the number of persons reached. These barriers to contact tracing might have limited effectiveness and were missed opportunities to recommend other mitigation strategies (e.g., testing, quarantine, or isolation).

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Summary

What is already known about this topic?

COVID-19 mitigation measures (e.g., stay-at-home orders and public mask mandate) and fundamental public health interventions (e.g., case investigations and contact tracing with prompt isolation or quarantine) are primary approaches to preventing and controlling SARS-CoV-2 community transmission.

What is added by this report?

State-mandated stay-at-home orders and public mask mandates coupled with case investigations with contact tracing contributed to an 82% reduction in COVID-19 incidence, 88% reduction in hospitalizations, and 100% reduction in mortality in Delaware during late April–June.

What are the implications for public health practice?

The combination of state-mandated community mitigation efforts and routine public health interventions can reduce the occurrence of new COVID-19 cases, hospitalizations, and deaths.

The findings in this report are subject to at least three limitations. First, data on adherence to the state-mandated stay-at-home order and use of masks in public were not available. Second, adherence to self-quarantine was self-reported. Finally, because of the observational design of the study, the decline in COVID-19 incidence, hospitalization, and mortality could not be attributed to the relative contribution of each mitigation measure.

A combination of mitigation measures including stay-at-home orders, mandated mask use in public, and case investigations with contact tracing, can reduce COVID-19 incidence and associated deaths (*9*). No single mitigation strategy is likely to be effective alone. These strategies are effective in limiting potential exposure to SARS-CoV-2 and reducing community transmission when implemented as part of a multicomponent strategy (*10*). In Delaware, state-mandated community mitigation efforts, such as stay-at-home orders, coupled with mask use, likely contributed to the decline in new COVID-19 cases. SARS-CoV-2 community transmission, hospitalization, and mortality can be reduced with statewide mitigation strategies implemented in tandem with the routine public health interventions of case investigation with contact tracing, and immediate self-isolation of cases and self-quarantine of contacts.

Acknowledgments

COVID-19 Case Investigation and Contact Tracing teams, Delaware Division of Public Health; Delaware National Guard; CDC COVID-19 Health Department Task Force

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[1]Epidemic Intelligence Service, CDC; [2]CDC COVID-19 Response Team; [3]COVID-19 Outbreak Response Team, Division of Public Health, Delaware Department of Health and Social Services.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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MS-DOH-21-1816-A-002235

From:	CSTE Emergency Response
To:	CSTE Emergency Response
Cc:	CSTE Novel Coronavirus 2019
Subject:	CSTE COVID-19 Response | Digest for Oct. 5 (incl. CDC Lab Alert, MMWR Early Release, FDA Home Test Authorization, and more)
Date:	Tuesday, October 5, 2021 3:22:46 PM
Attachments:	image003.png image004.png MMWR ER - October 5, 2021.pdf Lab Alert Ellume Issues Voluntary Recall of Specific Lots of Ellume COVID-19 Home Tests.msg MasK-12-508.pdf COVID-19 Partner Updates October 4 2021.msg HHS COVID-19 Update - 104.msg FDA Authorizes COVID-19 Over-the-Counter Home Antigen Test.msg

Sent to State Epidemiologists, Deputy State Epidemiologists, CLUE, Infectious Disease Points of Contact, and the CSTE Executive Board

Good afternoon,

Please see below for a collection of Coronavirus Disease 2019 (COVID-19) information, gathered for your awareness:

New Information

- CDC Lab Alert: Ellume Issues Voluntary Recall of Specific Lots of Ellume COVID-19 Home Tests [Attachment, Links]
    - Please see the following message from CDC's Laboratory Outreach Communication System (LOCS):
      *"On **October 1**, the digital diagnostics company Ellume announced a voluntary recall on specific lots of the Ellume COVID-19 Home Test, the company's rapid, self-administered COVID-19 antigen test, because there is an increased chance that tests from the affected lot numbers may give a false positive result. Ellume advises consumers to visit their website to check whether their product is part of the affected lots and, if affected, to receive further instructions."*
- MMWR Early Release: "National and State Trends in Anxiety and Depression Severity Scores Among Adults During the COVID-19 Pandemic — United States, 2020–2021" [Attachment, Link]
    - From the summary: *"Nationwide, average anxiety severity scores increased 13% from August to December 2020 and then decreased 26.8% from December 2020 to June 2021. Similar increases and decreases occurred in depression severity scores."*
- FDA Authorizes Additional OTC Home Test to Increase Access to Rapid Testing for Consumers [Attachment, Link]

On **October 4**, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the ACON Laboratories Flowflex COVID-19 Home Test, an over-the-counter (OTC) COVID-19 antigen test, which adds to the growing list of tests that can be used at home without a prescription. This action (linked here and attached) should significantly increase the availability of rapid, at-home tests and is expected to double rapid at-home testing capacity in the U.S. over the next several weeks. By years end, the manufacturer plans to produce more than 100 million tests per month, and this number will rise to 200 million per month by February 2022.

- CDC MasK-12 Project [Attachment]
    - CDC is partnering with schools and districts in states throughout the U.S. this fall to evaluate mask adherence in K-12 schools. CDC will train school-identified observers to collect data on mask adherence across participating schools. Observers may include high school students who are interested in science or public health, and the project offers a great opportunity for real-world public health experience. Schools can also use staff or volunteers to conduct observations.
    - Results from this investigation will be used to inform decision-making around masking in K-12 school settings, report findings to evaluate messaging and education around mask use, and to identify locations on school campuses where mask adherence can be improved. Enrollment for the MasK-12 project will occur in early October. If you are interested in participating or would like to learn more, email eocevent335@cdc.gov.

Standing Updates

- CDC Partner Update – October 4 [Attachment]
    - Please see attached for the latest updates from CDC's State, Tribal, Local, and Territorial (STLT) Task Force.
- HHS COVID-19 Update – October 4 [Attachment]
    - Please see attached for the latest COVID-19 updates from the HHS Office of Intergovernmental and External Affairs. Updates typically include highlights from any recent COVID-19 Response Team briefings, as well as vaccine, testing, treatment and research updates, toolkits, and resources.
- Press Briefings: White House COVID-19 Response Team and Public Health Officials [Link]
    - The White House COVID-19 Response Team holds regular press briefings during the week, typically on **Mondays, Wednesdays,** and **Fridays** at **11:00 am EDT**. *Please note:* Briefings sometimes begin after 11:00 am. Visit www.whitehouse.gov/live for the latest schedule and broadcast links. All COVID briefings are publicly available on the White House YouTube channel; past briefings may appear in this playlist link.
- CSTE COVID-19 Response Resource Repository [Link]
    - The CSTE COVID-19 Response Resource Repository and related discussion forums are available via Basecamp to encourage jurisdictional sharing of information, resources, best practices, and challenges. To sign-up and access the Basecamp, please visit this link.
- Request Form for CSTE COVID-19 Call Topics [Link]
    - CSTE encourages members to suggest topics for future COVID-19 response-related calls with CSTE members, CDC, and/or partner organizations. To submit a request, please

visit this link.

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Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
preparedness.cste.org

From: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
Sent: Monday, October 04, 2021 3:30 PM EDT
To: CDC IMS 2019 NCOV Response STLT Partner Engagement <eocevent424@cdc.gov>
CC: Weakland, Aliki P. (CDC/DDID/NCEZID/DPEI) <agp4@cdc.gov>; Mizelle, Mike (CDC/DDNID/NCCDPHP/DCPC) <fkk9@cdc.gov>
Subject: COVID-19 Partner Updates: October 4, 2021

Good afternoon Partners,

Please see below recently updated and/or released COVID-19 resources and meetings. If you have any questions or if you would like additional information, please email CDC's STLT Policy and Public Health Partnerships at eocevent424@cdc.gov. Thank you for your partnership.

Best regards,
Shyonna Johnson, MPH (She/Her)
STLT Policy & Public Health Partnerships
State, Tribal, Local, and Territorial Support Task Force (STLT TF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS H21-5, Atlanta, GA 30349-4027
EOCevent424@cdc.gov

CDC 24/7
PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

October 4, 2021

CDC Resources

Community

- Recommendations for Tribal Ceremonies and Gatherings During the COVID-19 Outbreak: CDC offers the following recommendations to help tribal communities, elders, and leaders decide how best to keep their communities safe and prevent the spread of COVID-19. These considerations are meant to support—not replace—tribal laws, rules, and regulations aimed at protecting the health of tribal communities.

Science and Data

- COVID-19 Public Readiness and Emergency Preparedness (PREP) Act: HHS made a technical amendment to the current COVID-19 Public Readiness and Emergency Preparedness (PREP) Act declaration to supplement the references to the Advisory Committee on Immunization Practices (ACIP) with references to the Centers for Disease Control and Prevention (CDC). This change is being made to clarify that "ACIP recommendations" and "ACIP standard immunization schedules" are in fact recommendations and schedules made by CDC after consultation with ACIP. This clarification also applies to related guidance and opinions.
- COVID-19 Science Update Edition 107: The October 1, 2021 update includes information pertaining to detection, burden, impact, prevention, mitigation, and intervention strategies, and the social, behavioral, and communication science related to COVID-19.
- COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19: CDC recommends urgent action to increase Coronavirus Disease 2019 (COVID-19) vaccination among people who are pregnant, recently pregnant (including those who are lactating), who are trying to become pregnant now, or who might become pregnant in the future. CDC strongly recommends COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.
- FAQs About Medical Consent & Pfizer-BioNTech Booster Doses for Long-term Care Residents: A resource for providers participating in the CDC COVID-19 Vaccination Program, long-term care residents and their families.
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: CDC now recommends that people aged 65 years and older, residents in long-term care settings, and people aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 Vaccine at least 6 months after completing their Pfizer-BioNTech primary series. Other groups **may** receive a booster shot based on their individual risk and benefit. Learn more.

Work and School

Updated on September 29, 2021:

- Responding to COVID-19 Cases in K-12 Schools: Resources for School Administrators
- Overview of COVID-19 Quarantine for K-12 Schools

Upcoming Meetings

- **CDC Community of Practice Call:** On October 5th, 3:00 PM ET CDC will replay the Community of Practice on *The Role of Prevention Measures, Testing Strategies, and Vaccinations to Prevent the Spread of COVID-19 at Summer Youth Camps*. To watch the replay, please use your existing link or click here to register for the call series.
- **CDC Global COVID-19-Associated Orphanhood webinar**: On October 6th, 8:30-10:00 AM ET CDC will host a webinar on how increases in mortality of parents and other caregivers in the COVID-19 pandemic are accompanied by increases in extreme vulnerability from loss of livelihoods, schooling, health recovery and usual sources of service provision and support for children. To register for the webinar, please click here.

- **CDC All-State, Tribal, Local, and Territorial (STLT) Update Call:** The next call will be on Tuesday, October 12th, 2:00-2:45 PM ET. CDC hosts a weekly national call series to provide state, tribal, local, and territorial partners with the latest information on the COVID-19 outbreak and U.S. preparedness efforts. To register for the weekly call series, please click here.

Additional Resources

- FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting: On October 14th and 15th, the advisory committee will meet to discuss the use of booster doses of the Moderna COVID-19 Vaccine and the Janssen COVID-19 Vaccine.
- Find a COVID-19 vaccine near you: Vaccines.gov
  - Individuals in the U.S. can now utilize a text messaging service to locate vaccine locations, available in both English and Spanish. Individuals can text their ZIP code to 438829 (GETVAX) and 822862 (VACUNA) to find three locations nearby that have vaccines available.

References to non-CDC sites are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites. URL addresses listed were current as of the date of publication.

From: U.S. Food and Drug Administration <usfda@public.govdelivery.com>
Sent: Monday, October 04, 2021 5:19 PM EDT
To: Chaitram, Jasmine (CDC/DDPHSS/CSELS/DLS) <zoa6@cdc.gov>
Subject: FDA Authorizes COVID-19 Over-the-Counter Home Antigen Test

If your email program has trouble displaying this email, view as a webpage.

FDA - Center for Devices and Radiological Health

FDA Authorizes Additional COVID-19 Over-the-Counter Home Antigen Test

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for ACON Laboratories Flow*flex* COVID-19 Home Test, an over-the-counter COVID-19 antigen test.

- It can be used to test both symptomatic and asymptomatic individuals without the need for repeat testing over several days, known as serial testing.
- The authorization should significantly increase the availability of rapid, at-home tests for consumers and is expected to double rapid at-home testing capacity in the U.S. over the next several weeks. By years end, the manufacturer plans to produce more than 100 million tests per month, and this number will rise to 200 million per month by February 2022.

Learn More

Over-the-Counter and At-Home Tests Remain a High Priority

Since March 2020, the FDA has authorized over 400 COVID-19 tests and sample collection devices, including authorizations for rapid, OTC at-home tests. Today's action highlights the agency's continued commitment to increasing the availability of accurate and reliable at-home COVID-19 diagnostic tests, and to facilitating consumer access to these tests.

Questions?

If you have questions about this EUA announcement, contact the Division of Industry and Consumer Education

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From: HHS Intergovernmental and External Affairs <hhsiea@connect.hhs.gov>
Sent: Monday, October 04, 2021 8:07 PM EDT
To: mcone@cste.org <mcone@cste.org>
Subject: HHS COVID-19 Update - 10/4

To view this email as a web page, click here.

HHS IEA logo

HHS Office of Intergovernmental and External Affairs COVID-19 Update for October 4, 2021

CASE UPDATE

New Cases (based on 7-day rolling average)

- **43,605,623** US cases
- **10.4% decrease** in new cases (7-day average), as of October 1st; (was 18.6% decrease last week)

Testing

- **582,771,630** tests completed (10/4)
- **6.5% positive** test rate as of the week of 9/24 – 9/30 (was 7.1% last week)

Hospitalizations

- **3,069,152** total COVID hospital admissions
- The 7-day average (9/25– 10/1) number of new confirmed COVID-19 admissions **decreased from 8,906 to 7,600** admissions per day

Deaths

- **700,176** total US deaths
- The 7-day average (9/25 – 10/1) number of reported deaths **decreased from 1,595 to 1,501** deaths per day

Vaccines

- **396,919,564** vaccine doses **administered** (10/4)
- **64.9%** (215.5 million people) of the population has received **1 or more doses** and **56%** (185.8 million people) of the population have been **fully vaccinated**
- **77.7%** of adults 18 and older have received **at least 1 dose** and **67.3%** have been **fully vaccinated**

STATEMENT BY PRESIDENT BIDEN (10/2) ON 700,000 AMERICAN DEATHS FROM COVID-19

Read the full statement here.

“To heal we must remember, and as our nation mourns the painful milestone of 700,000 American deaths due to COVID-19, we must not become numb to the sorrow. On this day, and every day, we remember all those we have lost to this pandemic and we pray for their loved ones left behind who are missing a piece of their soul.

As we do, the astonishing death toll is yet another reminder of just how important it is to get vaccinated. The vaccines are safe, free, and easy—and we have made extraordinary progress in our fight against COVID-19 over the last eight months because of the vaccines. More than three-quarters of all Americans age 12 and up have now received at least one vaccine dose—including nearly 94 percent of all seniors. Hundreds of thousands of families have been spared the unbearable loss that too many Americans have already endured during this pandemic.

If you haven’t already, please get vaccinated. It can save your life and the lives of those you love. It will help us beat COVID-19 and move forward, together, as one nation.”

HIGHLIGHTS FROM FRIDAY'S (10/1) WHITE HOUSE COVID-19 RESPONSE TEAM BRIEFING

Read the full briefing here.

Dr. Walensky

- **Vaccine Effectiveness:** Dr. Walensky outlined that there are still places in the country where far too many people remain unvacated, and many states where vaccination rates are less than 50 percent. Dr. Walenksy emphasized that COVID-19 vaccines are highly effective in preventing serious disease, hospitalizations, and deaths due to COVID-19. She also stated that "high vaccination coverage in your community translates into fewer cases, less of a burden on your local healthcare system, lower disease rates in your classrooms, and better health for those around you, including protecting children less than 12 years old who are not yet eligible for vaccination."
- **Vaccination in Pregnant Women:** Dr. Walensky commented that this week, CDC released ahealth alert highlighting the incredibly low rates of vaccination in pregnant people and those who may become pregnant, a group of people who are at high risk for severe complications from COVID-19. Overall, only 31 percent of pregnant people are fully vaccinated, and only 15 percent of Black pregnant people are vaccinated. Dr. Walenksy reinforced that these vaccines are safe and effective, including during pregnancy. She urged, "The benefits of vaccination far outweigh any risk to both mom and to baby."

Dr. Fauci

- **Vaccine Effectiveness:** Similar to Dr. Walensky, Dr. Fauci highlighted the effectiveness of the COVID-19 vaccines. Dr. Fauci pointed to a study in Seattle and King County which found that "p eople who are not fully vaccinated are eight times more likely to test positive, 41 times more likely to be hospitalized, and 57 times more likely to die compared to people who are vaccinated."
- **Booster Shots**: Dr. Fauci stated that booster shots provide further protection against SARS-CoV-2 infection and symptomatic COVID-19 disease for people who are at increased risk of severe COVID-19 disease. Dr. Fauci commented, "Twelve days or more after the booster dose, the rate of confirmed infection was lower in the booster group than in the non-booster group by a factor of 11.3 and the rate of severe illness lower by a factor of 19.5."
- **Vaccinating Children:** Dr. Fauci reiterated that a few days ago, Pfizer and BioNTech submitted their data to the FDA from their Phase 2/3 trials of the vaccine in children 5 to 11. He stated, "the FDA will make a regulatory determination, and the CDC with their ACIP will make a recommendation."

Jeff Zients

- **Vaccination Requirements:** Mr. Zients stated that the President's vaccination requirements will apply to about 100 million workers, which is two-thirds of all workers across the country. Mr. Zients reiterated that all employers should act now to protect their workforce and communities by enacting vaccination requirements. Mr. Zients emphasized, "When organizations implement vaccine requirements, vaccination rates soar to 90 percent or greater."
- **Booster Shots:** Mr. Zients commented that as we vaccinate the unvaccinated, the Administration is also focused on enhancing protection for vaccinated Americans through booster shots. Mr. Zients stated, "We estimate that by day's end, almost 2 million Americans will have rolled up their sleeves and gotten a booster shot — nearly 2 million booster shots in the first week. That's a very strong start."

Dr. Murthy

- **Process of Getting Children the Vaccine:** Dr. Murthy outlined the process towards vaccinating children for COVID-19. He stated that the Administration is following a guiding principle of safety, which warrants conducting separate clinical trials for children. He commented that once there is sufficient data from those clinical trials, the vaccine developers submit their data and a formal request to the FDA, which then conducts a thorough independent evaluation; if the FDA grants the vaccine an emergency use authorization, or EUA, then the vaccine can be administered. Dr. Murthy continued, "If the FDA grants the authorization, the CDC's Advisory Committee on Immunization Practices then meets to conduct their own review on specific clinical recommendations for healthcare providers."
- **Pfizer Vaccine Process for Children:** Dr. Murthy stated that the FDA has released a statement saying that, once they receive a formal request for authorization from Pfizer, they are prepared to complete a thorough independent review as quickly as possible, likely in a matter of weeks rather than months. Dr. Murthy emphasized, "The COVID-19 vaccines are FDA's top priority, and they know the urgency with which our children need a vaccine. They will be guided by science and safety as they evaluate vaccine data for children."
- **Get Vaccinated:** Dr. Murthy emphasized that up until children 5-11 years old can get vaccinated, it is important to follow masking policy, social distance outside/ in places with good ventilation, and get vaccinated. He stated, "Even though our youngest kids can't get vaccinated yet, the rest of us can. And when we are vaccinated, we act as barriers between our kids and the virus. So, if you are eligible to get vaccinated, please do so — if not for your own safety, then for the safety of unvaccinated children in your community."

VACCINE UPDATES

Mandatory COVID-19 Vaccination of DoD Civilian Employees: The Secretary of Defense directed the mandatory vaccination of Service members against the coronavirus disease 2019 (COVID-19) by signing the memorandum, "Mandatory Corona virus Disease 2019 Vaccination of Department of Defense Service Members ," on August 24, 2021. On September 9, 2021, the President of the United States directed Executive Branch agencies to implement a COVID-19 vaccination requirement for Federal employees to ensure the health and safety of the Federal workforce and members of the public with whom they interact by signing Executive Order 14043, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees." All DoD civilian employees must be fully vaccinated by November 22, 2021, subject to exemptions as required by law. Employees are considered fully vaccinated 2 weeks after completing the second dose of a two-dose COVID-19 vaccine or 2 weeks after receiving a single dose of a one-dose COVID-19 vaccine. New DoD civilian employees must be fully vaccinated by their entry on duty (start) date, or November 22, 2021, whichever is later.

FDA to Hold Advisory Committee Meetings to Discuss EUA for Booster Doses and COVID-19 Vaccines for Younger Children: On Friday, the U.S. Food and Drug Administration announced two upcoming meetings of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss newly available data for the currently available COVID-19 vaccines. On October 14 and 15, the advisory committee will meet to discuss the use of booster doses of the Moderna COVID-19 Vaccine and the Janssen COVID-19 Vaccine. Both vaccines are currently authorized for emergency use to prevent COVID-19 in individuals 18 years of age and older. The committee will also hear presentations and discuss the available data on the use of a booster of a different vaccine than the one used for the primary series of an authorized or approved COVID-19 vaccine (heterologous or “mix and match” booster).

Janssen COVID-19 Vaccine: On September 29, the FDA authorized an emergency use authorization (EUA) for one additional batch of the Janssen COVID-19 vaccine manufactured at the Emergent facility. To date, a total of nine batches of Janssen COVID-19 vaccine that were manufactured at the Emergent facility have been authorized. The FDA conducted a thorough review of facility records and quality testing performed by the manufacturer. Based on this review and considering the current COVID-19 public health emergency, the FDA has concluded that these batches are suitable for use. While the FDA is not yet ready to include the Emergent BioSolutions plant in the Janssen EUA as an authorized manufacturing facility, the agency continues to work through issues on this matter with Janssen and Emergent BioSolutions management.

Janssen COVID-19 Vaccine Booster Shots: CDC updated their webpage on the Janssen COVID-19 vaccine to include information on the booster shot. At this time, people who got the J&J/Janssen vaccine are not eligible for a booster shot. More data on the effectiveness and safety of J&J/Janssen booster shots are expected soon. With those data in hand, CDC will keep the public informed with a timely plan for J&J/Janssen booster shots.

COVID-19 Booster Shots: On September 24, Janet Woodcock, M.D., Acting FDA Commissioner and Peter Marks, M.D., Ph.D, director of the FDA’s Center for Biologics Evaluation and Research, discussed the FDA’s authorization of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for certain populations with stakeholders.

TESTING AND TREATMENT

DLA Supports White House Initiative with $2.78 Billion in Testing Supplies: The Defense Logistics Agency (DLA) awarded six contracts with a combined maximum value of just over $2.78 billion for up to 150 million at-home and 400 million point-of-care COVID-19 test kits in support of White House initiatives to defeat COVID-19. The combination of test types was requested by HHS to support the White House initiative announced Sept. 9, 2021. Kits will be sent on a recurring basis to federally qualified health centers, nursing homes, colleges and universities and other vulnerable populations over the one-year period of the respective contracts.

Contact Tracing: CDC updated their information on contact tracing , which is the key to slowing the spread of COVID-19 and helps protect you, your family, and your community. Specifically, CDC added in what to do if you come into close contact with someone diagnosed with COVID-19 (and are vaccinated, unvaccinated, or recovered from COVID), if you think you may have COVID-19 and are waiting for the test results, if you have symptoms of COVID-19, or if you are diagnosed with COVID-19.

FDA Testing Update: As of Friday, 412 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs) . These include 289 molecular tests and sample collection devices, 88 antibody and other immune response tests and 35 antigen tests. There are 65 molecular authorizations and one antibody authorization that can be used with home-collected samples. There is one molecular prescription at-home test, three antigen prescription at-home tests, seven antigen over-the-counter (OTC) at-home tests and two molecular OTC at-home tests. The FDA has authorized 16 antigen tests and eight molecular tests for serial screening programs. The FDA has also authorized 641 revisions to EUA authorizations.

INFORMATION FOR SPECIFIC POPULATIONS

CDC Completes Sixty-Day Assessment of Order under 42 U.S.C. 265: Following a review of the latest information regarding the status of the COVID-19 pandemic and associated public health risks, the CDC is expanding the requirement for a negative COVID-19 test to all air passengers entering the United States . After examining the current impact of the COVID-19 pandemic throughout the United States and at the U.S. borders, the ongoing risks of transmission and spread of COVID-19 in the congregate settings of facilities at the ports of entry and U.S. Border Patrol stations, the continued threat from the Delta variant, and the availability of testing, vaccination, and other mitigation measures, CDC has determined that the Order continues to be necessary at this time. CDC will continue to reassess the Order.

Medical Conditions: CDC updated their information for people who have medical conditions. Specifically, CDC added information on receiving a booster shot. People aged 18–49 years with underlying medical conditions may get a booster shot of Pfizer-BioNTech vaccine based on their individual benefits and risks. Bring your vaccination card, which you received at your first vaccination appointment, to your booster dose vaccination appointment.

Patient Tips for Healthcare Provider Appointments for Post-COVID Conditions: CDC updated their information for patients on preparing for their healthcare provider appointments for post-COVID conditions. Specifically, CDC uploaded a Healthcare Appointment Checklist for Post-COVID Conditions in Spanish to review before your next appointment.

Emergency Rental Assistance Program: Administration for Community Living (ACL) released a webinar on the Emergency Rental Assistance Program (ERAP), and tools to assist the people you serve.

RESEARCH

Multicomponent Strategies to Prevent SARS-CoV-2 Transmission: CDC released an *MMWR* on the multicomponent strategies to prevent SARS-CoV-2 transmission at nine overnight youth summer camps from June – August 2021. Previous studies have demonstrated the importance of prevention strategies to reduce SARS-CoV-2 transmission in overnight camps. During June–August 2021, a total of 7,173 campers and staff members attended nine U.S. overnight camps that implemented multiple prevention strategies including high vaccination coverage (>93% among eligible persons aged ≥12 years); prearrival and frequent screening testing (38,059 tests); and additional concomitant prevention measures. Nine laboratory-confirmed COVID-19 cases and no secondary infections were detected. Implementation of high vaccination coverage coupled with multiple prevention strategies is critical to averting COVID-19 outbreaks in congregate settings, including overnight camps. These findings highlight important guiding principles for school and youth-based COVID-19 prevention protocols.

COVID-19 Outbreaks at Youth Summer Camps: CDC released an *MMWR* on COVID-19 outbreaks at youth summer camps in Louisiana from June – July 2021. According to sequencing data reported by CDC, the highly transmissible B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, has been the predominant lineage circulating in Louisiana since the week of June 20, 2021. In Louisiana, the increased spread of the Delta variant corresponded with the start of the state's fourth and largest increase in average daily COVID-19 incidence to date. This report describes COVID-19 outbreaks in Louisiana youth summer camps as the Delta variant became the predominant lineage during June–July 2021. This activity was reviewed by the Louisiana Department of Health (LDH) and was conducted consistent with applicable state law and LDH policy.

NCI Study Highlights the Pandemic's Disproportionate Impact on Black, American Indian/ Alaska Native, and Latino Adults: The National Cancer Society (NCI), part of NIH, found that the global COVID-19 pandemic has taken a disproportionate toll on Black, American Indian/Alaska Native, and Latino individuals in the United States, causing more deaths by population size, both directly and indirectly, in these groups compared with white or Asian individuals. Roughly 2.9 million people died in the United States between March 1, 2020, and December 31, 2020. Compared with the same period in 2019, there were 477,200 excess deaths, with 74% of them due to COVID-19. The scientists found that, after adjusting for age, the number of excess deaths by population size among Black, American Indian/Alaska Native, and Latino men and women were more than double those in white and Asian men and women.

Science Update: On Friday, CDC released their weekly COVID-19 Science Update. This week's research includes research on COVID-19 in the phase 3 trial of MRNA-1273 during the Delta-variant surge, the social and economic inequality in COVID-19 vaccination coverage across Illinois counties, and more.

COVID Data Tracker Weekly Review: On Friday, CDC released their weekly review from the COVID Data Tracker . Last week the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for a single booster shot of the Pfizer-BioNTech COVID-19 vaccine. Certain populations are now eligible to receive a booster shot of the Pfizer-BioNTech vaccine at least 6 months after receiving their second Pfizer-BioNTech shot. These populations include people ages 65 years and older, people ages 18 years and older who have underlying medical conditions, and people ages 18 years and older who live or work in high-risk settings.

Marvin Figueroa

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200 Independence Avenue, S.W., Washington, DC, 20201 US

Emergency Preparedness & Response

Coronavirus Disease (COVID-19)

From: Centers for Disease Control and Prevention <no-reply@emailupdates.cdc.gov>
Sent: Monday, October 04, 2021 4:20 PM EDT
To: commandcenter@cste.org <commandcenter@cste.org>
Subject: Lab Alert: Ellume Issues Voluntary Recall of Specific Lots of Ellume COVID-19 Home Tests

Audience: Clinical Laboratory Professionals
Level: Laboratory Alert

On October 1, 2021, the digital diagnostics company Ellume announced a voluntary recall on specific lots of the Ellume COVID-19 Home Test, the company's rapid, self-administered COVID-19 antigen test, because there is an increased chance that tests from the affected lot numbers may give a false positive result.

Ellume advises consumers to visit their website to check whether their product is part of the affected lots and, if affected, to receive further instructions.

The voluntary recall is being taken after specific product lots reported false positive test result rates higher than was observed in clinical testing. Ellume has investigated the issue, identified the root cause, implemented additional controls, and is working on resolving the issue that led to this recall. Information relating to the action to be taken by distributors and retailers for the affected lots is also provided on the company's website.

Please share this message with your networks and invite them to opt in to LOCS to receive future updates.

Online resources:

- Information for Laboratories about Coronavirus (COVID-19)
- Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories
- CDC Coronavirus (COVID-19) Website
- CDC Laboratory Outreach Communication System (LOCS)
- Clinical Laboratory COVID-19 Response Calls

Questions?

- If you are a clinical or public health laboratory professional, contact LOCS.
- For media inquiries, contact the CDC Newsroom.
- For all other questions, contact CDC-INFO.

Thank you,
The Laboratory Outreach Communication System

Laboratory Outreach Communication System (LOCS) | Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Centers for Disease Control and Prevention (CDC)
LOCS@cdc.gov
www.cdc.gov/csels/dls/locs

MasK-12

Mask Adherence Surveillance in K-12 Settings Project

What is it? MasK-12 is a mask observation project to measure the proportion of students, teachers, and staff wearing masks, and wearing them correctly, in school.

How does it work?

School-based trained observers visit various areas within the school to note the proportion of students, teachers, and staff who are wearing masks correctly. School districts will identify the observers, which may include high school students, staff, or other volunteers.

How do I get involved?

School districts interested in participating should partner with their state health department to submit a project enrollment survey and letter of interest to the Centers for Disease Control and Prevention (CDC). **Both schools with and without mask mandates can participate.**

What are the benefits?

Data collected will be regularly reported to schools throughout the project to allow for regular feedback and monitoring at each school site. **High school student observers gain valuable hands-on public health experience.**

Please direct questions and comments to eocevent335@cdc.gov.

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Morbidity and Mortality Weekly Report
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National and State Trends in Anxiety and Depression Severity Scores Among Adults During the COVID-19 Pandemic — United States, 2020–2021

Haomiao Jia, PhD[1]; Rebecca J. Guerin, PhD[2]; John P. Barile, PhD[3]; Andrea H. Okun, DrPH[2]; Lela McKnight-Eily, PhD[4]; Stephen J. Blumberg, PhD[5]; Rashid Njai, PhD[6,7]; William W. Thompson, PhD[7,8]

Recent studies indicate an increase in the percentage of adults who reported clinically relevant symptoms of anxiety and depression during the COVID-19 pandemic (*1*–*3*). For example, based on U.S. Census Bureau Household Pulse Survey (HPS) data, CDC reported significant increases in symptoms of anxiety and depressive disorders among adults aged ≥18 years during August 19, 2020–February 1, 2021, with the largest increases among adults aged 18–29 years and among those with less than a high school education (*1*). To assess more recent national trends, as well as state-specific trends, CDC used HPS data (*4*) to assess trends in reported anxiety and depression among U.S. adults in all 50 states and the District of Columbia (DC) during August 19, 2020–June 7, 2021 (*1*). Nationally, the average anxiety severity score increased 13% from August 19–31, 2020, to December 9–21, 2020 (average percent change [APC] per survey wave = 1.5%) and then decreased 26.8% from December 9–21, 2020, to May 26–June 7, 2021 (APC = –3.1%). The average depression severity score increased 14.8% from August 19–31, 2020, to December 9–21, 2020 (APC = 1.7%) and then decreased 24.8% from December 9–21, 2020, to May 26–June 7, 2021 (APC = –2.8%). State-specific trends were generally similar to national trends, with both anxiety and depression scores for most states peaking during the December 9–21, 2020, or January 6–18, 2021, survey waves. Across the entire study period, the frequency of anxiety and depression symptoms was positively correlated with the average number of daily COVID-19 cases. Mental health services and resources, including telehealth behavioral services, are critical during the COVID-19 pandemic.

Data were obtained from HPS (*4*), a biweekly, online survey. The survey, developed with assistance from CDC and other federal agencies to assess the social and economic impacts of the COVID-19 pandemic on U.S. households, began on April 23, 2020. Samples for HPS are drawn from an extract of the U.S. Census Bureau's master address file that includes email and mobile telephone numbers of approximately 117 million U.S. housing units. Survey data include sample weights to be used in analyses to generate results representative of U.S. adults aged ≥18 years based on age, sex, race/ethnicity, and educational attainment; the data from this experimental product were designed to produce estimates at state and national levels.* This analysis examined data for adults aged ≥18 years collected from the 19 biweekly surveys (waves) conducted during August 19, 2020–June 7, 2021 (waves 13–31), with breaks during December 22, 2020–January 5, 2021, because of expected decreases in survey response rates during holiday seasons, and during March 30–April 13, 2021, when HPS transitioned to a new survey cycle (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/110122). The total sample size was 1,526,154 for all 19 waves, ranging from 58,729 (wave 18) to 110,019 (wave 14). Overall survey response rates ranged from 5.3% to 10.3% among the 19 waves examined.

Frequency of experiencing anxiety and depressive symptoms was assessed using the four-item Patient Health Questionnaire (PHQ-4),† which includes the two-item Generalized Anxiety Disorder (GAD-2) scale and the two-item PHQ-2, which assesses symptoms of depression (*5*). For each survey response,

* U.S. Census Bureau experimental data products are statistical products created using new data sources or previously untested methodologies.

† HPS includes a modified version of the validated PHQ-4 measure for depression and anxiety with a 1-week (versus a 2-week) recall period to reflect the weekly administration of the questions. The two anxiety questions asked about 1) feeling nervous, anxious, or on edge and 2) not being able to stop or control worrying. The two depression questions asked about 1) having little interest or pleasure in doing things and 2) feeling down, depressed, or hopeless.

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answers were assigned a numerical value: not at all = 0, several days = 1, more than one half of the days = 2, and nearly every day = 3. The anxiety severity score was calculated by summing the two GAD-2 responses, and the depression severity score was calculated by summing the two PHQ-2 responses. The sum of both severity scores could range from 0 to 6.

Weighted mean anxiety and depression severity scores for the United States were calculated for each wave. For state estimates, weighted age-standardized mean scores were calculated using direct standardization. State-specific trends were modeled using linear mixed models with cubic splines for sampling waves (*6*) to obtain smoothed age-adjusted estimates for each wave. The age-standardized state-level average anxiety and depression severity scores for the 50 states and DC are presented for the first two waves (August 19–September 24, 2020), the peak period in anxiety and depression severity scores nationally (December 9, 2020–January 18, 2021), and the last two waves (May 12–June 7, 2021). APCs for anxiety and depression severity scores per wave were calculated, and bootstrapping was used to obtain 95% confidence intervals (CIs) for APCs[§] (*7*). A change in the mean severity score indicates a change in the frequency of symptoms. To allow relative comparisons of HPS estimates with those from a nonpandemic period, weighted means and CIs were calculated for anxiety and depression severity scores using data from the 2019 National Health Interview Survey (NHIS), with data from 31,997 adults aged ≥18 years.[¶] Daily numbers of COVID-19 cases were obtained from the CDC COVID Data Tracker and were averaged across the same periods that the HPS anxiety and depression symptom data were collected. Average counts of daily cases were compared with the symptom data using Pearson correlations. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[**]

Nationally, the average anxiety severity scores increased from 2.0 during August 19–31, 2020, to 2.3 during December 9–21, 2020 (APC = 1.5% per wave), reflecting a 13.0% increase in symptoms (Figure) (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/110123). During this same period, the average depression severity score increased from 1.6 to 2.0, reflecting a 14.8% increase. From December 9–21, 2020, to May 26–June 7, 2021, the average anxiety severity score decreased to 1.7 (APC = –3.1% per wave), reflecting a 26.8% decrease; during this same period, the average depression severity score decreased to 1.4 (APC = –2.8% per wave), reflecting a 24.8% decrease.

Analyses of 2019 NHIS data indicate that the weighted average anxiety and depression severity scores among adults aged ≥18 years were 0.63 and 0.51, respectively. Quarterly weighted average anxiety and depression severity scores ranged from 0.61 to 0.65 and from 0.50 to 0.52, respectively; variation in these quarterly scores was substantially less than that in HPS during similar months.

In most states, the average anxiety and depression severity scores increased from August–September 2020 to December 2020–January 2021 (Table 1) (Supplementary Figure, https://stacks.cdc.gov/view/cdc/110121). By May–June 2021, anxiety and depression severity scores were similar to or lower than those during August–September 2020. During August–December 2020 and January–June 2021, state-level trends in anxiety and depression severity scores were similar to national trends, with scores for most states peaking during December 9–21, 2020, or January 6–18, 2021. States with larger increases in severity scores during August–December 2020 also tended to have larger decreases during January–June 2021 (Table 2). Mississippi, Oklahoma, and South Carolina had the largest percentage increases in anxiety scores during August–December 2020, whereas Minnesota, Mississippi, and South Carolina had the largest percentage increases in depression scores; Florida and New York had the smallest percentage increases in depression and anxiety scores, respectively. During January–June 2021, Minnesota, Rhode Island, and Utah had the largest percentage decreases in anxiety scores; Idaho, Michigan, and Wisconsin had the largest percentage decreases for depression severity scores, whereas New York had the smallest decrease in both anxiety and depression scores.

For the same periods that HPS was administered, an association was found between numbers of COVID-19 cases and the frequency of anxiety and depression symptoms. The average number of daily COVID-19 cases was highly positively correlated with anxiety (rho = 0.79) and depression (rho = 0.81) severity scores (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/110123).

[§] Percent change (PC) from wave i to i+1 is defined as $PC_{t+1} = \left(\frac{\mu_{i+1} - \mu_i}{\mu_i} - 1\right) \times 100$. APC was calculated for a period of n+1 waves' data from wave i to wave i+n as $APC = \left\{exp\left[\frac{\sum_{t=i+1}^{i+n} ln(PC_t + 1)}{n}\right] - 1\right\} \times 100$.

[¶] Data for the 2019 survey year were obtained from NHIS, a survey conducted continuously throughout the year by CDC's National Center for Health Statistics. NHIS is a nationally representative cross-sectional survey of the U.S. civilian noninstitutionalized population. NHIS uses geographically clustered sampling to select each household; one adult per household is randomly selected to be interviewed. Interviews are generally conducted in respondents' homes; follow-up interviews to complete surveys might occur by telephone when necessary. Methodological details, protocols, and Ethics Review Board approvals are described elsewhere (https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm). Weighted means for the anxiety and depression severity scores were estimated, accounting for the complex sampling design. Means and CIs for adults aged ≥18 years were estimated using the SAS SurveyMeans procedure.

[**] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect.241(d); 5 U.S.C.0 Sect.552a; 44 U.S.C. Sect. 3501 et seq.

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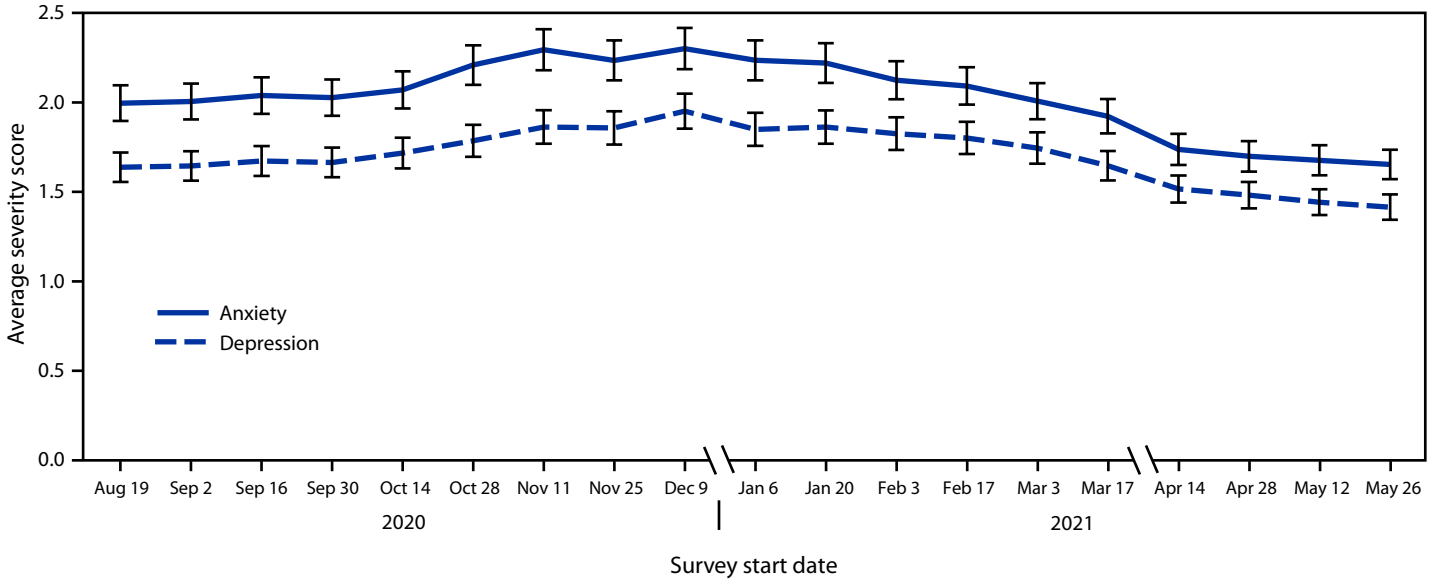
FIGURE. Trends in average anxiety and depression severity scores* among adults, by survey start date — Household Pulse Survey, United States, August 19, 2020–June 7, 2021†



* 95% confidence intervals indicated by error bars.
† Data for adults aged ≥18 years were collected from 19 biweekly surveys (waves) conducted during August 19, 2020–June 7, 2021 (waves 13–31), with breaks during December 22, 2020–January 5, 2021, and March 30–April 13, 2021.

Discussion

The frequency of anxiety and depression symptoms experienced among U.S. adults increased after August 2020 and peaked during December 2020–January 2021. The frequency of symptoms subsequently decreased but in June 2021 remained elevated compared with estimates from the 2019 NHIS. The relative increases and decreases in frequency of reported symptoms of anxiety and depression at both the national and state levels mirrored the national weekly number of new COVID-19 cases during the same period.

An international group of clinicians and mental health experts recommends that during pandemics, delivery systems for mental health care be adapted to mitigate disparities in the provision of health care (*8*). Predicting and planning for fluctuations in demand for behavioral health services is often difficult; however, real-time monitoring of mental health symptoms can provide important information for responding to surges in the demand for mental health services during national emergencies. The observed differences in severity score magnitude and peaks across states in this study indicate that these efforts are important at both the national and state levels.

The findings in this report are subject to at least six limitations. First, modified GAD-2 and PHQ-2 items were administered using a 1-week time frame rather than a 2-week time frame, which might have reduced comparability between HPS and NHIS. Second, short forms were used for GAD and PHQ; restricted ranges of scores might have decreased the likelihood of detecting differences in symptoms nationally or by state. Third, the HPS response rate was <10%, which might have introduced bias; however, trends are less likely than point estimates to be affected, and sample weights somewhat mitigate this bias (*9*). Fourth, peak periods in mental health symptoms overlapped with a break in survey data collection during the holiday season; reported symptoms during that period might have been underestimates if the peak occurred during the break. Fifth, the decrease in the frequency of symptoms observed through June 2021 occurred before the recent surge in COVID-19 cases involving the B.1.617.2 (Delta) variant; that decreasing trend might have slowed or reversed since June. Finally, these data are based on self-report and are subject to recall and social desirability biases.

The increased frequency of reported symptoms of anxiety and depression in this study indicates that mental health services and resources, including telehealth behavioral services, are critical during the COVID-19 pandemic, particularly among populations disproportionately affected by COVID-19. National COVID-19 trends demonstrate that certain populations have been disproportionately affected by high COVID-19 incidence, which also suggests that these populations might be more vulnerable to the psychological consequences of COVID-19. The mental health impact of COVID-19 also might have community-specific effects when morbidity and mortality rates are increasing as a result of COVID-19. Fluctuations in symptoms of anxiety and depression during the

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TABLE 1. Average anxiety and depression severity scores, by state/area — Household Pulse Survey, United States, August–September 2020, December 2020–January 2021, and May–June 2021

State/Area	Mean severity score (95% CI)					
	Anxiety			Depression		
	Aug 19–Sep 14, 2020	Dec 9, 2020–Jan 18, 2021	May 12–Jun 7, 2021	Aug 19–Sep 14, 2020	Dec 9, 2020–Jan 18, 2021	May 12–Jun 7, 2021
Alabama	2.02 (1.90–2.15)	2.38 (2.19–2.57)	1.75 (1.49–2.00)	1.73 (1.61–1.84)	1.99 (1.81–2.16)	1.48 (1.26–1.71)
Alaska	1.84 (1.73–1.95)	2.24 (2.11–2.36)	1.51 (1.32–1.70)	1.54 (1.43–1.64)	1.89 (1.77–2.02)	1.29 (1.12–1.46)
Arizona	2.05 (1.95–2.15)	2.16 (2.05–2.27)	1.82 (1.62–2.01)	1.77 (1.68–1.87)	1.92 (1.80–2.04)	1.50 (1.34–1.67)
Arkansas	2.06 (1.94–2.19)	2.35 (2.16–2.54)	1.73 (1.46–1.99)	1.74 (1.63–1.85)	1.92 (1.75–2.09)	1.51 (1.29–1.73)
California	2.12 (2.05–2.20)	2.45 (2.35–2.55)	1.73 (1.61–1.86)	1.80 (1.72–1.87)	2.06 (1.96–2.16)	1.51 (1.39–1.62)
Colorado	2.04 (1.94–2.14)	2.30 (2.18–2.42)	1.78 (1.59–1.97)	1.64 (1.56–1.72)	1.90 (1.78–2.01)	1.41 (1.24–1.58)
Connecticut	2.09 (1.97–2.20)	2.39 (2.24–2.55)	1.53 (1.31–1.74)	1.61 (1.51–1.71)	1.97 (1.83–2.11)	1.21 (1.02–1.40)
Delaware	1.84 (1.69–1.99)	2.26 (2.08–2.44)	1.74 (1.45–2.03)	1.58 (1.43–1.72)	1.90 (1.73–2.07)	1.43 (1.17–1.70)
District of Columbia	2.05 (1.85–2.24)	2.10 (1.91–2.28)	1.59 (1.38–1.79)	1.59 (1.40–1.78)	1.58 (1.42–1.74)	1.35 (1.15–1.54)
Florida	2.10 (2.01–2.20)	2.31 (2.17–2.45)	1.67 (1.48–1.85)	1.73 (1.64–1.81)	1.85 (1.72–1.97)	1.36 (1.19–1.52)
Georgia	1.96 (1.86–2.06)	2.32 (2.17–2.47)	1.78 (1.57–1.99)	1.63 (1.53–1.72)	1.93 (1.78–2.07)	1.50 (1.32–1.68)
Hawaii	2.17 (2.01–2.34)	2.02 (1.81–2.23)	1.81 (1.54–2.07)	1.80 (1.65–1.94)	1.66 (1.46–1.85)	1.47 (1.22–1.71)
Idaho	1.91 (1.80–2.02)	2.18 (2.04–2.33)	1.59 (1.33–1.84)	1.54 (1.44–1.64)	1.88 (1.74–2.02)	1.23 (1.04–1.43)
Illinois	2.04 (1.95–2.14)	2.27 (2.14–2.40)	1.64 (1.45–1.83)	1.62 (1.54–1.71)	1.79 (1.68–1.90)	1.43 (1.24–1.62)
Indiana	1.95 (1.85–2.05)	2.11 (1.98–2.24)	1.67 (1.50–1.85)	1.56 (1.47–1.65)	1.75 (1.62–1.87)	1.45 (1.28–1.62)
Iowa	1.82 (1.72–1.92)	2.14 (1.98–2.31)	1.57 (1.36–1.78)	1.50 (1.40–1.60)	1.87 (1.72–2.02)	1.38 (1.18–1.58)
Kansas	1.90 (1.81–2.00)	2.18 (2.04–2.32)	1.53 (1.37–1.70)	1.52 (1.43–1.61)	1.86 (1.71–2.01)	1.30 (1.15–1.45)
Kentucky	2.13 (2.01–2.25)	2.36 (2.18–2.54)	1.64 (1.39–1.90)	1.81 (1.69–1.92)	2.00 (1.84–2.16)	1.57 (1.33–1.81)
Louisiana	2.25 (2.10–2.39)	2.49 (2.28–2.71)	1.86 (1.61–2.11)	1.83 (1.70–1.96)	2.11 (1.91–2.31)	1.56 (1.33–1.79)
Maine	2.14 (2.00–2.28)	2.28 (2.06–2.49)	1.54 (1.28–1.80)	1.63 (1.50–1.76)	1.81 (1.62–2.00)	1.39 (1.15–1.62)
Maryland	1.92 (1.83–2.02)	2.21 (2.08–2.34)	1.56 (1.39–1.72)	1.56 (1.47–1.65)	1.84 (1.71–1.97)	1.25 (1.12–1.37)
Massachusetts	1.98 (1.88–2.07)	2.27 (2.14–2.40)	1.62 (1.47–1.77)	1.52 (1.44–1.60)	1.79 (1.67–1.91)	1.36 (1.22–1.50)
Michigan	2.01 (1.91–2.11)	2.42 (2.29–2.55)	1.49 (1.33–1.66)	1.62 (1.53–1.71)	2.07 (1.93–2.20)	1.34 (1.18–1.50)
Minnesota	1.79 (1.71–1.87)	2.04 (1.92–2.17)	1.51 (1.35–1.67)	1.38 (1.30–1.45)	1.69 (1.58–1.80)	1.29 (1.13–1.45)
Mississippi	1.98 (1.85–2.11)	2.47 (2.26–2.68)	1.96 (1.63–2.30)	1.71 (1.59–1.82)	2.20 (2.01–2.40)	1.74 (1.33–2.15)
Missouri	1.90 (1.80–2.00)	2.28 (2.13–2.43)	1.88 (1.65–2.12)	1.58 (1.48–1.68)	1.93 (1.76–2.10)	1.63 (1.42–1.85)
Montana	1.89 (1.75–2.02)	2.34 (2.16–2.52)	1.31 (1.08–1.55)	1.46 (1.34–1.58)	1.88 (1.71–2.05)	1.21 (0.97–1.45)
Nebraska	1.71 (1.61–1.81)	1.95 (1.81–2.09)	1.29 (1.12–1.47)	1.45 (1.36–1.55)	1.74 (1.60–1.88)	1.10 (0.93–1.27)
Nevada	2.15 (2.03–2.27)	2.40 (2.24–2.55)	1.88 (1.64–2.13)	1.78 (1.66–1.90)	2.10 (1.96–2.24)	1.66 (1.42–1.90)
New Hampshire	1.97 (1.84–2.09)	2.10 (1.93–2.27)	1.75 (1.50–2.00)	1.52 (1.40–1.65)	1.67 (1.49–1.85)	1.60 (1.37–1.84)
New Jersey	2.07 (1.96–2.17)	2.27 (2.13–2.41)	1.73 (1.53–1.93)	1.61 (1.52–1.70)	1.87 (1.74–2.01)	1.46 (1.23–1.69)
New Mexico	2.26 (2.13–2.39)	2.39 (2.23–2.55)	1.80 (1.57–2.04)	1.86 (1.74–1.99)	2.07 (1.92–2.23)	1.63 (1.40–1.86)
New York	2.07 (1.96–2.17)	2.22 (2.08–2.36)	1.63 (1.41–1.84)	1.65 (1.56–1.75)	1.82 (1.70–1.95)	1.49 (1.29–1.69)
North Carolina	1.94 (1.83–2.05)	2.27 (2.12–2.42)	1.79 (1.55–2.04)	1.52 (1.42–1.63)	1.87 (1.73–2.01)	1.56 (1.35–1.77)
North Dakota	1.55 (1.42–1.68)	1.94 (1.72–2.16)	1.46 (1.09–1.84)	1.21 (1.08–1.34)	1.56 (1.39–1.74)	1.37 (0.97–1.77)
Ohio	2.02 (1.91–2.14)	2.29 (2.12–2.46)	1.64 (1.43–1.84)	1.75 (1.63–1.86)	2.11 (1.95–2.27)	1.48 (1.27–1.69)
Oklahoma	2.10 (1.98–2.22)	2.49 (2.34–2.64)	1.76 (1.54–1.99)	1.72 (1.61–1.83)	2.09 (1.95–2.23)	1.56 (1.36–1.76)
Oregon	2.25 (2.17–2.34)	2.50 (2.39–2.61)	1.85 (1.69–2.00)	1.78 (1.70–1.87)	2.12 (2.01–2.23)	1.57 (1.43–1.72)
Pennsylvania	1.99 (1.89–2.08)	2.21 (2.07–2.34)	1.73 (1.57–1.90)	1.62 (1.53–1.71)	1.95 (1.82–2.09)	1.38 (1.22–1.53)
Rhode Island	1.99 (1.86–2.13)	2.32 (2.10–2.54)	1.62 (1.26–1.98)	1.59 (1.46–1.73)	1.85 (1.67–2.03)	1.40 (1.05–1.75)
South Carolina	1.75 (1.63–1.87)	2.23 (2.07–2.40)	1.72 (1.46–1.99)	1.44 (1.33–1.55)	1.83 (1.67–1.99)	1.50 (1.27–1.73)
South Dakota	1.57 (1.46–1.68)	1.90 (1.70–2.10)	1.51 (1.23–1.79)	1.30 (1.19–1.41)	1.60 (1.41–1.80)	1.42 (1.09–1.74)
Tennessee	1.99 (1.88–2.10)	2.25 (2.10–2.40)	1.61 (1.42–1.80)	1.67 (1.57–1.78)	1.95 (1.81–2.09)	1.38 (1.20–1.57)
Texas	1.97 (1.89–2.05)	2.25 (2.14–2.36)	1.79 (1.62–1.96)	1.67 (1.60–1.75)	1.92 (1.82–2.02)	1.54 (1.37–1.70)
Utah	1.82 (1.73–1.91)	2.14 (2.04–2.24)	1.53 (1.39–1.68)	1.48 (1.40–1.57)	1.80 (1.70–1.90)	1.31 (1.18–1.45)
Vermont	1.97 (1.82–2.12)	2.23 (2.03–2.44)	1.57 (1.27–1.87)	1.55 (1.41–1.69)	1.73 (1.55–1.91)	1.41 (1.06–1.76)
Virginia	1.94 (1.83–2.04)	2.26 (2.13–2.40)	1.67 (1.48–1.85)	1.60 (1.50–1.70)	1.88 (1.75–2.02)	1.49 (1.30–1.67)
Washington	2.02 (1.95–2.09)	2.34 (2.24–2.44)	1.78 (1.65–1.91)	1.60 (1.53–1.67)	1.97 (1.87–2.06)	1.54 (1.40–1.67)
West Virginia	2.02 (1.87–2.17)	2.58 (2.38–2.77)	1.77 (1.48–2.05)	1.67 (1.53–1.82)	2.33 (2.14–2.52)	1.51 (1.28–1.74)
Wisconsin	1.79 (1.69–1.89)	2.11 (1.97–2.25)	1.46 (1.26–1.65)	1.46 (1.36–1.55)	1.73 (1.60–1.86)	1.12 (0.96–1.28)
Wyoming	1.94 (1.80–2.07)	2.19 (1.94–2.45)	1.32 (1.04–1.60)	1.50 (1.37–1.63)	1.72 (1.51–1.92)	1.23 (1.01–1.44)

Abbreviation: CI = confidence interval.

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TABLE 2. National and state average percent change in anxiety and depression severity scores, by state/area — Household Pulse Survey, United States, August 2020–June 2021

State/Area	Anxiety severity score			Depression severity score		
	Average % change* (95% CI)		Peak survey wave	Average % change* (95% CI)		Peak survey wave
	Aug–Dec 2020	Jan–Jun 2021		Aug–Dec 2020	Jan–Jun 2021	
U.S. total	**1.5 (1.3 to 1.7)**	**–3.1 (–3.3 to –2.9)**	**21**	**1.7 (1.5 to 2.0)**	**–2.8 (–3.0 to –2.6)**	**22**
Alabama	1.7 (0.8 to 2.6)	–2.8 (–3.7 to –2.0)	22	1.7 (0.7 to 2.7)	–2.5 (–3.4 to –1.5)	22
Alaska	1.9 (1.4 to 2.5)	–3.3 (–3.9 to –2.7)	21	2.2 (1.6 to 2.8)	–3.0 (–3.7 to –2.3)	22
Arizona	1.2 (0.5 to 1.8)	–2.6 (–3.3 to –1.9)	20	1.1 (0.3 to 1.8)	–2.6 (–3.3 to –1.9)	22
Arkansas	1.8 (1.0 to 2.7)	–2.7 (–3.6 to –1.8)	21	1.7 (0.8 to 2.6)	–2.4 (–3.3 to –1.4)	22
California	1.5 (0.9 to 2.1)	–3.2 (–3.7 to –2.7)	21	1.5 (0.8 to 2.2)	–2.6 (–3.2 to –2.0)	22
Colorado	1.6 (0.9 to 2.2)	–3.0 (–3.6 to –2.3)	20	1.6 (0.9 to 2.3)	–2.6 (–3.3 to –1.8)	21
Connecticut	1.7 (1.0 to 2.4)	–3.3 (–4.0 to –2.6)	21	2.3 (1.4 to 3.1)	–3.3 (–4.0 to –2.5)	22
Delaware	1.8 (1.1 to 2.5)	–3.0 (–3.8 to –2.3)	20	2.0 (1.2 to 2.9)	–2.8 (–3.7 to –1.9)	21
District of Columbia	1.4 (0.6 to 2.3)	–2.9 (–3.6 to –2.2)	21	1.6 (0.5 to 2.6)	–2.5 (–3.3 to –1.6)	22
Florida	1.1 (0.3 to 1.8)	–2.8 (–3.6 to –2.1)	20	0.9 (0.1 to 1.7)	–2.5 (–3.3 to –1.6)	19
Georgia	1.9 (1.1 to 2.8)	–2.7 (–3.5 to –1.9)	21	2.3 (1.4 to 3.2)	–2.7 (–3.6 to –1.8)	22
Hawaii	0.9 (0.0 to 1.8)	–2.9 (–3.7 to –2.1)	20	1.0 (0.0 to 2.1)	–2.7 (–3.6 to –1.7)	20
Idaho	1.7 (1.0 to 2.4)	–3.3 (–4.0 to –2.6)	21	2.3 (1.5 to 3.1)	–3.4 (–4.2 to –2.7)	22
Illinois	1.3 (0.6 to 2.0)	–3.0 (–3.6 to –2.3)	21	1.8 (1.0 to 2.6)	–2.7 (–3.6 to –1.9)	22
Indiana	1.5 (0.8 to 2.2)	–3.0 (–3.7 to –2.2)	21	2.0 (1.2 to 2.8)	–2.8 (–3.5 to –2.0)	21
Iowa	1.9 (1.1 to 2.7)	–3.2 (–3.9 to –2.5)	21	2.2 (1.3 to 3.1)	–3.0 (–3.8 to –2.2)	22
Kansas	1.6 (0.9 to 2.3)	–3.4 (–4.1 to –2.7)	20	2.2 (1.4 to 3.0)	–3.2 (–4.0 to –2.4)	21
Kentucky	1.2 (0.4 to 2.1)	–3.0 (–3.8 to –2.2)	21	1.2 (0.3 to 2.1)	–2.5 (–3.4 to –1.7)	22
Louisiana	1.5 (0.6 to 2.3)	–2.9 (–3.8 to –1.9)	22	2.0 (1.0 to 3.0)	–2.7 (–3.7 to –1.7)	22
Maine	1.4 (0.6 to 2.1)	–3.4 (–4.1 to –2.7)	21	2.0 (1.1 to 2.9)	–3.2 (–4.1 to –2.4)	22
Maryland	1.8 (1.1 to 2.5)	–3.3 (–4.0 to –2.7)	21	2.1 (1.3 to 2.9)	–3.2 (–4.0 to –2.5)	22
Massachusetts	1.6 (0.9 to 2.3)	–3.1 (–3.7 to –2.6)	20	2.0 (1.3 to 2.8)	–2.9 (–3.6 to –2.2)	21
Michigan	1.7 (0.9 to 2.4)	–3.5 (–4.1 to –2.8)	22	2.3 (1.5 to 3.1)	–3.5 (–4.2 to –2.8)	22
Minnesota	2.0 (1.4 to 2.7)	–3.5 (–4.1 to –2.8)	20	2.6 (1.8 to 3.4)	–3.1 (–3.9 to –2.3)	21
Mississippi	2.2 (1.3 to 3.0)	–3.4 (–4.3 to –2.5)	22	2.5 (1.5 to 3.5)	–3.3 (–4.2 to –2.3)	22
Missouri	1.9 (1.1 to 2.7)	–2.8 (–3.5 to –2.0)	21	2.0 (1.1 to 3.0)	–2.7 (–3.5 to –1.8)	22
Montana	1.7 (0.9 to 2.4)	–3.5 (–4.3 to –2.6)	20	2.2 (1.3 to 3.0)	–3.2 (–4.1 to –2.4)	21
Nebraska	1.8 (1.1 to 2.5)	–3.4 (–4.0 to –2.7)	20	2.2 (1.4 to 3.0)	–3.3 (–4.0 to –2.5)	22
Nevada	1.7 (0.9 to 2.4)	–3.4 (–4.2 to –2.7)	20	2.0 (1.1 to 2.8)	–3.3 (–4.1 to –2.5)	21
New Hampshire	1.7 (1.0 to 2.3)	–3.1 (–3.8 to –2.3)	21	2.1 (1.2 to 2.9)	–2.5 (–3.4 to –1.7)	22
New Jersey	1.3 (0.6 to 2.0)	–3.0 (–3.7 to –2.3)	21	1.7 (0.9 to 2.6)	–2.6 (–3.4 to –1.8)	22
New Mexico	1.4 (0.7 to 2.1)	–3.1 (–3.8 to –2.5)	20	1.7 (0.9 to 2.5)	–2.9 (–3.6 to –2.2)	21
New York	0.8 (0.1 to 1.6)	–2.4 (–3.2 to –1.6)	22	1.1 (0.2 to 2.0)	–1.9 (–2.8 to –0.9)	23
North Carolina	2.0 (1.2 to 2.9)	–2.7 (–3.5 to –1.9)	22	2.3 (1.3 to 3.3)	–2.5 (–3.4 to –1.6)	22
North Dakota	1.9 (1.1 to 2.7)	–3.2 (–4.1 to –2.4)	21	2.2 (1.3 to 3.1)	–2.9 (–3.9 to –1.9)	22
Ohio	1.5 (0.7 to 2.4)	–3.3 (–4.1 to –2.5)	21	1.8 (0.8 to 2.8)	–2.8 (–3.7 to –1.9)	22
Oklahoma	2.2 (1.4 to 2.9)	–3.2 (–4.1 to –2.4)	21	2.3 (1.4 to 3.2)	–2.7 (–3.6 to –1.9)	22
Oregon	1.0 (0.5 to 1.6)	–3.0 (–3.5 to –2.5)	21	1.8 (1.1 to 2.4)	–3.0 (–3.6 to –2.4)	22
Pennsylvania	1.6 (0.8 to 2.3)	–2.8 (–3.4 to –2.1)	20	2.0 (1.1 to 2.8)	–3.0 (–3.8 to –2.2)	21
Rhode Island	1.8 (1.0 to 2.5)	–3.5 (–4.3 to –2.7)	21	2.2 (1.3 to 3.0)	–3.4 (–4.2 to –2.5)	22
South Carolina	2.2 (1.3 to 3.2)	–2.9 (–3.8 to –2.0)	20	2.6 (1.6 to 3.7)	–2.9 (–3.9 to –1.9)	21
South Dakota	2.0 (1.3 to 2.7)	–3.5 (–4.3 to –2.7)	21	2.3 (1.5 to 3.1)	–3.0 (–4.0 to –2.1)	21
Tennessee	1.8 (1.0 to 2.6)	–3.1 (–3.9 to –2.3)	22	2.0 (1.1 to 3.0)	–3.1 (–3.9 to –2.2)	22
Texas	2.1 (1.4 to 2.8)	–2.7 (–3.4 to –2.0)	20	2.0 (1.2 to 2.7)	–2.3 (–3.1 to –1.5)	20
Utah	2.0 (1.4 to 2.7)	–3.7 (–4.3 to –3.1)	21	2.2 (1.5 to 3.0)	–3.3 (–4.0 to –2.6)	22
Vermont	1.6 (1.0 to 2.3)	–3.1 (–3.9 to –2.4)	20	1.8 (1.0 to 2.5)	–2.7 (–3.5 to –1.8)	21
Virginia	1.7 (0.9 to 2.4)	–2.9 (–3.7 to –2.2)	21	1.4 (0.5 to 2.3)	–2.3 (–3.1 to –1.4)	22
Washington	1.7 (1.1 to 2.2)	–3.1 (–3.6 to –2.6)	21	2.1 (1.5 to 2.8)	–2.8 (–3.4 to –2.2)	22
West Virginia	1.8 (1.0 to 2.7)	–2.9 (–3.7 to –2.0)	21	2.2 (1.2 to 3.2)	–2.9 (–3.7 to –2.0)	22
Wisconsin	1.7 (0.9 to 2.5)	–3.4 (–4.2 to –2.6)	20	2.2 (1.3 to 3.1)	–3.5 (–4.3 to –2.7)	21
Wyoming	1.8 (1.1 to 2.4)	–3.3 (–4.2 to –2.5)	21	2.1 (1.4 to 2.9)	–3.1 (–4.0 to –2.2)	22

Abbreviation: CI = confidence interval.

* Percent change (PC) from wave *i* to *i*+1 is defined as $PC_{t+1} = \left(\frac{\mu_{i+1} - \mu_i}{\mu_i} - 1\right) \times 100$. Average percent change (APC) was calculated for a period of *n*+1 waves' data from wave *i* to wave *i*+*n* as $APC = \left\{exp\left[\frac{\sum_{t=i+1}^{i+n} ln(PC_t + 1)}{n}\right] - 1\right\} \times 100$. https://doi.org/10.1002/sim.3733

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Summary

What is already known about this topic?

U.S. Census Bureau Household Pulse Survey data indicate that the percentage of U.S. adults with symptoms of anxiety and depressive disorders increased nationwide from August 2020 to February 2021.

What is added by this report?

Nationwide, average anxiety severity scores increased 13% from August to December 2020 and then decreased 26.8% from December 2020 to June 2021. Similar increases and decreases occurred in depression severity scores.

What are the implications for public health practice?

Mental health services and resources, including telehealth behavioral services, are critical during the COVID-19 pandemic.

pandemic highlight the importance of real-time monitoring of mental health symptoms. Tracking these outcomes, including by demographic characteristics, can provide early indicators of potential increases in the demand for mental health services and for the health care providers needed to treat persons with clinically significant symptoms (*10*).

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