Subject: [Records Center] General Records Request :: G000492-053020
Date: Tuesday, April 20, 2021 at 1:38:06 PM Pacific Daylight Time
From: King County Public Records
To: Sarah Wishingrad
CC: James.Apa@kingcounty.gov

EXTERNAL SENDER

--- Please respond above this line ---

April 20, 2021

Re: G000492-053020

Dear Ms. Sarah Wishingrad:

Thank you again for the public records request which the King County Executive Branch received from you on March 05, 2020. We understand you are seeking the following records:

"All email communications between (1) Public Health Director Patty Hayes and/or Health Officer Jeff Duchin, and (2) anyone communicating from an email address ending in cdc.gov, eop.gov, or hhs.gov."

An installment of records responsive to your request is available to you now in the King County Public Records Center. Click the link below to retrieve the records. Please note that the link works best with the Google Chrome browser, and any pop-up blockers need to be turned off.

General Records Request - G000492-053020

In addition, I have placed the new installment in your shared OneDrive folder.

Wishingrad OneDrive

We continue to gather and review responsive records, and we anticipate that we will be able to make another installment of responsive records, should they exist, available to you in approximately 4-6 weeks.

Please let me know if you have any questions.

Sincerely,

Jonathan Bibler
Public Records Officer
Public Health Seattle & King County

To monitor the progress or update this request please log into the

Powered by GovQA

From:	CSTE Emergency Response
Sent:	Monday, February 24, 2020 11:13 AM PST
To:	CSTE Emergency Response
CC:	CSTE Novel Coronavirus 2019; Erin Morton; mlipsitc@hsph.harvard.edu; rek160@mail.harvard.edu; Perz, Joseph (CDC/DDID/NCEZID/DHQP)
Subject:	CSTE COVID-19 Response | Ad Hoc Weekly All State Epi Call - TODAY at 4:00 pm EST
Attachments:	CSTE COVID-19 Response Ad Hoc Weekly All State Epi Call - Monday, February 24 at 400 pm EST.msg.eml

Sent to State Epidemiologists, CLUE and the CSTE Executive Board

CSTE's ad hoc weekly COVID-19 All State Epi call is **TODAY at 4:00 pm EST**. These calls provide an open forum for discussion of emerging issues and response-related needs**.** Please see the call information highlighted below and note this call is intended for State Epidemiologists, CLUE, and the CSTE Executive Board.

1. Welcome and Announcements, Sharon Watkins, CSTE President & Pennsylvania State Epidemiologist
2. Washington Liaison Update, Erin Morton, CRD Associates, LLC
3. Presentation on COVID-19 Community Transmission Modeling, Marc Lipsitch and Rebecca Kahn, Harvard T.H. Chan School of Public Health
4. CDC COVID-19 Infection Prevention and Control Updates and Discussion, Joseph Perz, Healthcare Infection Control Team Lead, MCCM Task Force
5. Next Ad Hoc Call, Monday, March 2, 2020, 4:00-5:00 pm EST

Council of State and Territorial Epidemiologists • 2635 Century Parkway NE, Ste 700 • Atlanta, Georgia 30345 T 770.458.3811 F 770.458.8516

Topic: CSTE COVID-19 Response | Ad Hoc Weekly All State Epi Call
Host: Matt Cone
Date: Every Monday, from Monday, February 24, 2020 to Monday, May 4, 2020
Time: 4:00 pm, Eastern Standard Time (New York, GMT-05:00)

Session number: 794 313 782
Session password: epi4321

Please click the link below to see more information, or to start the session.

To start the session
---
1. Go to https://cste.webex.com/cste/k2/j.php?MTID=tfebaa57e8bddcd420341120137d59a94
2. Log in to your account.
3. Click "Start Now".
4. Follow the instructions that appear on your screen.
To view in other time zones or languages, please click the link
https://cste.webex.com/cste/k2/j.php?MTID=tde7958b3ee30a95af0d6f666cb01aa2c

---
To join the session by phone only

To receive a call back, provide your phone number when you join the training session, or call the number below and enter the access code.
Call-in toll-free number (US/Canada):1-877-668-4490
Call-in toll number (US/Canada):1-408-792-6300
Show toll-free dialing restrictions: https://www.webex.com/pdf/tollfree_restrictions.pdf
Access code: 794 313 782

For assistance

You can contact Matt Cone at:
mcone@cste.org
1-(678)-258-9582

To add this session to your calendar program (for example Microsoft Outlook), click this link:
https://cste.webex.com/cste/k2/j.php?MTID=tcc9fb0b421fd49aec52a9401586cc521

https://www.webex.com

IMPORTANT NOTICE: This Webex service includes a feature that allows audio and any documents and other materials exchanged or viewed during the session to be recorded. By joining this session, you automatically consent to such recordings. If you do not consent to the recording, discuss your concerns with the meeting host prior to the start of the recording or do not join the session. Please note that any such recordings may be subject to discovery in the event of litigation.

--

CSTE
Council of State and Territorial Epidemiologists
Emergency Preparedness & Response Mailbox
Business Hours Line: 770.458.3811
After-Hours Line: 678.256.3945

From: Jeremy Arieh
Sent: Thursday, February 20, 2020 2:41 PM PST
To: Jeremy Arieh
Subject: CSTE COVID-19 Response | Ad Hoc Weekly All State Epi Call - Monday, February 24 at 4:00 pm EST

Sent to State Epidemiologists, CLUE and the CSTE Executive Board

The next CSTE ad hoc weekly COVID-19 All State Epi call is **TODAY at 4:00 pm EST**. These calls provide an open forum for discussion of emerging issues and response-related needs**.** Please see the call information below and note this call is intended for State Epidemiologists, City and Large Urban Area Epidemiologists (CLUE) and the CSTE Executive Board.

1. Welcome and Announcements, Sharon Watkins, CSTE President & Pennsylvania State Epidemiologist
2. Washington Liaison Update – Erin Morton, CRD Associates, LLC
3. Presentation on COVID-19 Community Transmission Modeling, Marc Lipsitch and Rebecca Kahn, Harvard T.H. Chan School of Public Health
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5. Next Ad Hoc Call, Monday, March 2, 2020, 4:00-5:00 pm EST

Council of State and Territorial Epidemiologists · 2635 Century Parkway NE, Ste 700 · Atlanta, Georgia 30345 T 770.458.3811 F 770.458.8516

Topic: CSTE COVID-19 Response | Ad Hoc Weekly All State Epi Call
Host: Matt Cone
Date: Every Monday, from Monday, February 24, 2020 to Monday, May 4, 2020
Time: 4:00 pm, Eastern Standard Time (New York, GMT-05:00)

Session number: 794 313 782
Session password: epi4321

Please click the link below to see more information, or to start the session.

To start the session
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3. Click "Start Now".

4. Follow the instructions that appear on your screen.
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https://cste.webex.com/cste/k2/j.php?MTID=tde7958b3ee30a95af0d6f666cb01aa2c

---
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To receive a call back, provide your phone number when you join the training session, or call the number below and enter the access code.
Call-in toll-free number (US/Canada):1-877-668-4490
Call-in toll number (US/Canada):1-408-792-6300
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For assistance

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https://www.webex.com

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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

From:	MIDRS
Sent:	Thursday, February 27, 2020 6:16 PM PST
To:	Duchin, Jeff; McKeirnan, Shelly; Gonzales, Elysia; fr1@miamidade.gov; ccalder@miamidade.gov; hector.pesquera@miamidade.gov; Kawakami, Vance; Benoliel, Eileen; Beth.Melius@DOH.WA.GOV; VSP@cdc.gov; frl3@cdc.gov; hvc4@cdc.gov; louisa.castrodale@alaska.gov; vsk9@cdc.gov; Michael.D.Boley@uscg.mil; wjf3@cdc.gov; Harold.P.Hurst@uscg.mil; fco9@cdc.gov; sad1@cdc.gov; kdr6@cdc.gov; ept3@cdc.gov; xhn6@cdc.gov; hrp6@cdc.gov; enh8@cdc.gov; pzp2@cdc.gov; bzv2@cdc.gov; ilz7@cdc.gov; fpn2@cdc.gov; tig8@cdc.gov; QS-Miami@cdc.gov; QS-SanJuan@cdc.gov; QS-Houston@cdc.gov; QS-Atlanta@cdc.gov; maritimeadmin@cdc.gov; ncc@uscg.mil; QS-ElPaso@cdc.gov; QS-SanDiego@cdc.gov; qs-anchorage@cdc.gov; Hatley, Noel; dhh0@cdc.gov; ixy3@cdc.gov; vts9@cdc.gov; viy7@cdc.gov
Subject:	3% Outbreak Feb 27, 2020 Ship: Caribbean Princess Next Port: PEV Pax: 224/3039 (7.37%) Crew: 17/1162 (1.46%)

[EXTERNAL Email Notice!] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

ATTENTION: The percentages of cases of gastrointestinal illness among passengers and crew has reached or exceeded 3%.
The VSP staff will be notified.

The Center for Disease Control and Prevention (CDC), Vessel Sanitation Program (VSP) will respond to this notification and follow up with the appropriate public health support. If you have additional questions, contact VSP's 24-hour answering service at 1-800-323-2132. If you do not need immediate attention, VSP will contact you on the next business day; however, if you need immediate attention ask for the officer on duty. The information in this notice is confidential and intended for the recipient only. Redistribution of this information without approval of the VSP will result in your removal from the distribution list. This notification is intended for planning purposes only.
Confirmation No.: 20200227211610470

Ship Name: Caribbean Princess

Voyage Number: CB2006

Report Type: 24HR

Emergency Contact Name: James Leonard

Emergency Contact Number: 661.753.2355

Embarkation Port Code: PEV

Embarkation Date: Feb 16, 2020

Next U.S. Arrival Port Code: PEV

Next U.S. Arrival Port Date Time: Feb 29 2020 7:00AM

Disembarkation Port Code: PEV

Disembarkation Date: Feb 29, 2020

Total Crew: 1162

Crew Gastroenteritis Case(s): 17

Percentage of Crew Gastroenteritis Cases (%): 1.46

Total Passengers: 3039

Passenger Gastroenteritis Case(s): 224

Percentage of Passenger Gastroenteritis Cases (%): 7.37

From:	MIDRS
Sent:	Friday, February 28, 2020 7:28 PM PST
To:	Duchin, Jeff; McKeirnan, Shelly; Gonzales, Elysia; fr1@miamidade.gov; ccalder@miamidade.gov; hector.pesquera@miamidade.gov; Kawakami, Vance; Benoliel, Eileen; Beth.Melius@DOH.WA.GOV; VSP@cdc.gov; frl3@cdc.gov; hvc4@cdc.gov; louisa.castrodale@alaska.gov; vsk9@cdc.gov; Michael.D.Boley@uscg.mil; wjf3@cdc.gov; Harold.P.Hurst@uscg.mil; fco9@cdc.gov; sad1@cdc.gov; kdr6@cdc.gov; ept3@cdc.gov; xhn6@cdc.gov; hrp6@cdc.gov; enh8@cdc.gov; pzp2@cdc.gov; bzv2@cdc.gov; ilz7@cdc.gov; fpn2@cdc.gov; tig8@cdc.gov; QS-Miami@cdc.gov; QS-SanJuan@cdc.gov; QS-Houston@cdc.gov; QS-Atlanta@cdc.gov; maritimeadmin@cdc.gov; ncc@uscg.mil; QS-ElPaso@cdc.gov; QS-SanDiego@cdc.gov; qs-anchorage@cdc.gov; Hatley, Noel; dhh0@cdc.gov; ixy3@cdc.gov; vts9@cdc.gov; viy7@cdc.gov
Subject:	3% Outbreak Feb 28, 2020 Ship: Caribbean Princess Next Port: PEV Pax: 230/3039 (7.57%) Crew: 17/1162 (1.46%)

[EXTERNAL Email Notice!] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

ATTENTION: The percentages of cases of gastrointestinal illness among passengers and crew has reached or exceeded 3%.
The VSP staff will be notified.

The Center for Disease Control and Prevention (CDC), Vessel Sanitation Program (VSP) will respond to this notification and follow up with the appropriate public health support. If you have additional questions, contact VSP's 24-hour answering service at 1-800-323-2132. If you do not need immediate attention, VSP will contact you on the next business day; however, if you need immediate attention ask for the officer on duty. The information in this notice is confidential and intended for the recipient only. Redistribution of this information without approval of the VSP will result in your removal from the distribution list. This notification is intended for planning purposes only.
Confirmation No.: 20200228222844957

Ship Name: Caribbean Princess

Voyage Number: CB2006

Report Type: 4HR

Emergency Contact Name: James Leonard

Emergency Contact Number: 661.753.2355

Embarkation Port Code: PEV

Embarkation Date: Feb 16, 2020

Next U.S. Arrival Port Code: PEV

Next U.S. Arrival Port Date Time: Feb 29 2020 7:00AM

Disembarkation Port Code: PEV

Disembarkation Date: Feb 29, 2020

Total Crew: 1162

Crew Gastroenteritis Case(s): 17

Percentage of Crew Gastroenteritis Cases (%): 1.46

Total Passengers: 3039

Passenger Gastroenteritis Case(s): 230

Percentage of Passenger Gastroenteritis Cases (%): 7.57

From: State and Local Readiness (CDC)
Sent: Sunday, February 23, 2020 1:31 PM PST
To: State and Local Readiness (CDC)
Subject: CDC's Social Vulnerability Index

Dear Colleagues:

Please use the link embedded to view the Social Vulnerability index of your jurisdiction. Social vulnerability refers to the resilience of communities when confronted by external stresses on human health, stresses such as natural or human-caused disasters, or disease outbreaks. Reducing social vulnerability can decrease both human suffering and economic loss. CDC's Social Vulnerability Index uses 15 U.S. census variables at tract level to help local officials identify communities that may need support in preparing for hazards; or recovering from disaster.

https://svi.cdc.gov/

Thank you,
State Coordination Task Force

Sent by BCC to PHEP Directors, SHOS, State Epis, Non-governmental Partners, STLTs, and BCHC

From:
Sent: Friday, February 21, 2020 6:09 PM PST
To: Bresee Joseph; Gayle E. Fischer (fez7@cdc.gov)
Subject: Seattle Fly Stuydy

Jeffrey S. Duchin, MD (he/him)
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section

Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

From:	Duchin, Jeff
Sent:	Friday, February 21, 2020 8:09 PM PST
To:	Langley, Gayle E. (CDC/DDID/NCIRD/DVD)
Subject:	Re: talk about sentinel surveillance in seattle

From: Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Sent: Friday, February 21, 2020 11:19 AM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/OD) <wdk1@cdc.gov>
Subject: Canceled: talk about sentinel surveillance in seattle
When: Friday, February 21, 2020 1:00 PM-1:30 PM.
Where: Skype Meeting

Join Skype Meeting

Trouble Joining? Try Skype Web App

Join by phone

(404) 553-8912,,29296727# (Atlanta Dial-in Conference Region)	English (United States)
(855) 348-8390,,29296727# (Atlanta Dial-in Conference Region)	English (United States)

Find a local number

Conference ID: 29296727

Forgot your dial-in PIN? | Help

From: Bresee, Joseph (CDC/DDID/NCIRD/ID)
Sent: Friday, February 21, 2020 9:18 AM PST
To: Duchin, Jeff; Langley, Gayle E. (CDC/DDID/NCIRD/DVD)
Subject: RE: Quick Call

Does for me

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Friday, February 21, 2020 12:17 PM
To: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Re: Quick Call

did not connect yet - does 4PM Eastern work?

Jeffrey S. Duchin, MD (he/him)
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
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From: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>
Sent: Friday, February 21, 2020 9:09 AM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: RE: Quick Call

Jusst back. Did you connect. Happy to talk. We can overcome the nasal swab issue.

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Thursday, February 20, 2020 8:39 PM
To: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Re: Quick Call

I can chat now or 11:30 EASTRN TOMORROW...

_____ Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

From: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>
Sent: Thursday, February 20, 2020 5:34:34 PM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Re: Quick Call

Will defer to your schedules.

Get Outlook for iOS

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Thursday, February 20, 2020 8:16:58 PM
To: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Quick Call

Joe, Gail, would you have time for a call tonight or tomorrow to discuss the Seattle flu study?

_____ Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
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Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
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From: Langley, Gayle E. (CDC/DDID/NCIRD/DVD)
Sent: Friday, February 21, 2020 9:18 AM PST
To: Bresee, Joseph (CDC/DDID/NCIRD/ID); Duchin, Jeff
Subject: RE: Quick Call

Me too. I can an invite. --gayle

From: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>
Sent: Friday, February 21, 2020 12:18 PM
To: Duchin, Jeff (CDC kingcounty.gov) <jeff.duchin@kingcounty.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: RE: Quick Call

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Subject: Re: Quick Call

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Sent: Friday, February 21, 2020 9:09 AM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
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From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Thursday, February 20, 2020 8:39 PM
To: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
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Sent: Thursday, February 20, 2020 5:34:34 PM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Re: Quick Call

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Sent: Thursday, February 20, 2020 8:16:58 PM
To: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Quick Call

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Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
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Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

From: Epix Helpdesk (CDC)
Sent: Friday, February 28, 2020 1:18 PM PST
To: Duchin, Jeff; Epix Helpdesk (CDC)
CC: EPIX Editor (CDC)
Subject: RE: Can youpelase send me this update? I'm locked out of SAMS

I'm not sure if you noticed or not but we have been including the public URL in the summary of the immediate email notification when the information that is being disseminated via Epi-X is available online. We hope that this addition to our business rules is beneficial to our users who are unable to access Epi-X.

I'll add your issue to my To Do list and reach out to you next week and, if you have time, we can resolve your login dilemma.

V/R,
Amanda

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Friday, February 28, 2020 4:06 PM
To: Epix Helpdesk (CDC) <epixhelp@cdc.gov>
Subject: RE: Can youpelase send me this update? I'm locked out of SAMS

Changing the OPW is not the issue, it always changes successfullu and I can log in afterwards ONE TIM ONLY AND THEN ENCVER AGAIN. No one has been able to helps ovlve the problem. And the corums should nto be secrer

_____
Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

From: Evanson, Amanda (CDC/DDPHSIS/CPR/DEO) <afe0@cdc.gov> **On Behalf Of** Epix Helpdesk (CDC)
Sent: Friday, February 28, 2020 1:02 PM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Subject: RE: Can youpelase send me this update? I'm locked out of SAMS

I totally understand your hesitation; thank goodness I can use my CDC PIV card to log into SAMS. When/if you are ready to change your password we will walk you through to make sure that it goes through the password change process as smoothly as possible.

Amanda

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Friday, February 28, 2020 3:54 PM
To: Epix Helpdesk (CDC) <epixhelp@cdc.gov>
Subject: Re: Can youpelase send me this update? I'm locked out of SAMS

I've changed it multiple times without success so I hope you can understand why I'm not prioritizing changing it again.

_____ Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
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Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

From: Evanson, Amanda (CDC/DDPHSIS/CPR/DEO) <afe0@cdc.gov> on behalf of Epix Helpdesk (CDC) <epixhelp@cdc.gov>
Sent: Friday, February 28, 2020 12:52:38 PM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Subject: RE: Can youpelase send me this update? I'm locked out of SAMS

My pleasure. Please know that we are here for you when you are available to walk us through changing your SAMS password.

Best,
Amanda

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Friday, February 28, 2020 3:47 PM
To: Epix Helpdesk (CDC) <epixhelp@cdc.gov>
Subject: RE: Can youpelase send me this update? I'm locked out of SAMS

Than kyio

_____
Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section

Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
401 5th Ave, Suite 1250, Seattle, WA 98104
Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

From: Evanson, Amanda (CDC/DDPHSIS/CPR/DEO) <afe0@cdc.gov> **On Behalf Of** Epix Helpdesk (CDC)
Sent: Friday, February 28, 2020 12:46 PM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Subject: RE: Can youpelase send me this update? I'm locked out of SAMS

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HI Dr. Duchin,

Do you want this HAN update? If so, here it is ☺

Best,
Amanda

Amanda F. Evanson
Health Communication Specialist/*Epi-X* Editor
Epi-X, Epidemic Information Exchange
Situational Awareness (SA)
Division of Emergency Operations (DEO)
Center for Preparedness and Response (CPR)
Centers For Disease Control and Prevention (CDC)
Phone: 404-660-7815 aevanson@cdc.gov

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Friday, February 28, 2020 3:41 PM
To: Epix Helpdesk (CDC) <epixhelp@cdc.gov>
Subject: Can youpelase send me this update? I'm locked out of SAMS

Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
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E-mail: jeff.duchin@kingcounty.gov

From: Chiller, Tom (CDC/DDID/NCEZID/DFWED)
Sent: Saturday, February 22, 2020 3:59 PM PST
To: Duchin, Jeff; Beer, Karlyn D. (CDC/DDID/NCEZID/DFWED); Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED)
Subject: Re: Health officer demands Seattle Children's release mold-related documents | king5.com

Thanks Jeff. As you know. This was released via FOIA end of last week I think.
Tom

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Friday, February 21, 2020 10:16:57 PM
To: Beer, Karlyn D. (CDC/DDID/NCEZID/DFWED) <ydh7@cdc.gov>; Jackson, Brendan R. (CDC/DDID/NCEZID/DFWED) <iyn0@cdc.gov>; Chiller, Tom (CDC/DDID/NCEZID/DFWED) <tnc3@cdc.gov>
Subject: Health officer demands Seattle Children's release mold-related documents | king5.com

FYI
https://www.king5.com/article/news/investigations/health-officer-demands-seattle-childrens-release-mold-related-documents/281-969ee48e-4f87-4ada-97da-feba7236633b

_____ Jeffrey S. Duchin, MD
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E-mail: jeff.duchin@kingcounty.gov

From: Kuhnert-Tallman, Wendi (CDC/DDID/OD)
Sent: Thursday, February 27, 2020 8:13 PM PST
To: Duchin, Jeff
Subject: Connecting

Hi Jeff, thanks for the call this evening! I have not yet received an email so I am sending one to you just to make a connection. We will make time to talk tmrw am. Just let us know what works. I will update our epi colleagues as well.
Thanks and have a good evening.
Wendi.
Get Outlook for iOS

From:	Thomas, Stephanie B. (CDC/DDID/NCIRD/OD)
Sent:	Monday, February 24, 2020 12:24 PM PST
To:	Duchin, Jeff
Subject:	FW: Background Materials, Meeting Presentations and Written Public Comments

This was sent on the 14th. ACIP is happening!

Stephanie Thomas
ACIP

From: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <aji8@cdc.gov>
Sent: Friday, February 14, 2020 9:05 AM
To: Advisory Committee on Immunization Practices (CDC) <acip@cdc.gov>
Subject: Background Materials, Meeting Presentations and Written Public Comments

Dear ACIP members, ex-officio and liaison representatives, and Steering Committee members,

Please use this link to access the background materials and draft presentation slides for the February ACIP meeting: https://centersfordiseasecontrol.sharefile.com/d-s574d68e09cf4de69. Please note that these background materials and draft slides can be shared within your organization in preparation for the upcoming meeting, but we do ask that they not be shared too broadly or be made public. We will continue to add materials to ShareFile as we receive them in advance of the meeting.

In addition, we are using regulations.gov to collect written public comment for this meeting. You can review the written public comment using this link: https://www.regulations.gov/docket?D=CDC-2020-0002. Comments received through February 28, 2020 will be posted and available for your review.

Please let Stephanie or me know if you have any questions, or difficulty accessing the materials.

Thank you,
Jessica

Jessica MacNeil, MPH
Epidemiologist
Deputy Executive Secretary, Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30329-4027
Phone: (404) 639-1194
Email: jmacneil@cdc.gov

From: Pillai, Satish K. (CDC/DDID/NCEZID/DPEI)
Sent: Monday, February 24, 2020 11:46 AM PST
To: Duchin, Jeff
Subject: thanks for the question

I've reached epi colleagues and leadership to close this loop asap.

From:	MIDRS
Sent:	Friday, February 28, 2020 9:30 PM PST
To:	Duchin, Jeff; McKeirnan, Shelly; Gonzales, Elysia; fr1@miamidade.gov; ccalder@miamidade.gov; hector.pesquera@miamidade.gov; Kawakami, Vance; Benoliel, Eileen; Beth.Melius@DOH.WA.GOV; VSP@cdc.gov; frl3@cdc.gov; hvc4@cdc.gov; louisa.castrodale@alaska.gov; vsk9@cdc.gov; Michael.D.Boley@uscg.mil; wjf3@cdc.gov; Harold.P.Hurst@uscg.mil; fco9@cdc.gov; sad1@cdc.gov; kdr6@cdc.gov; ept3@cdc.gov; xhn6@cdc.gov; hrp6@cdc.gov; enh8@cdc.gov; pzp2@cdc.gov; bzv2@cdc.gov; ilz7@cdc.gov; fpn2@cdc.gov; tig8@cdc.gov; QS-Miami@cdc.gov; QS-SanJuan@cdc.gov; QS-Houston@cdc.gov; QS-Atlanta@cdc.gov; maritimeadmin@cdc.gov; ncc@uscg.mil; QS-ElPaso@cdc.gov; QS-SanDiego@cdc.gov; qs-anchorage@cdc.gov; Hatley, Noel; dhh0@cdc.gov; ixy3@cdc.gov; vts9@cdc.gov; viy7@cdc.gov
Subject:	3% Outbreak Feb 29, 2020 Ship: Caribbean Princess Next Port: PEV Pax: 230/3039 (7.57%) Crew: 18/1162 (1.55%)

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ATTENTION: The percentages of cases of gastrointestinal illness among passengers and crew has reached or exceeded 3%.
The VSP staff will be notified.

The Center for Disease Control and Prevention (CDC), Vessel Sanitation Program (VSP) will respond to this notification and follow up with the appropriate public health support. If you have additional questions, contact VSP's 24-hour answering service at 1-800-323-2132. If you do not need immediate attention, VSP will contact you on the next business day; however, if you need immediate attention ask for the officer on duty. The information in this notice is confidential and intended for the recipient only. Redistribution of this information without approval of the VSP will result in your removal from the distribution list. This notification is intended for planning purposes only.
Confirmation No.: 20200229003033723

Ship Name: Caribbean Princess

Voyage Number: CB2006

Report Type: 4HR

Emergency Contact Name: James Leonard

Emergency Contact Number: 661.753.2355

Embarkation Port Code: PEV

Embarkation Date: Feb 16, 2020

Next U.S. Arrival Port Code: PEV

Next U.S. Arrival Port Date Time: Feb 29 2020 7:00AM

Disembarkation Port Code: PEV

Disembarkation Date: Feb 29, 2020

Total Crew: 1162

Crew Gastroenteritis Case(s): 18

Percentage of Crew Gastroenteritis Cases (%): 1.55

Total Passengers: 3039

Passenger Gastroenteritis Case(s): 230

Percentage of Passenger Gastroenteritis Cases (%): 7.57

From: Bresee, Joseph (CDC/DDID/NCIRD/ID)
Sent: Friday, February 21, 2020 9:09 AM PST
To: Duchin, Jeff; Langley, Gayle E. (CDC/DDID/NCIRD/DVD)
Subject: RE: Quick Call

Jusst back. Did you connect. Happy to talk. We can overcome the nasal swab issue.

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Thursday, February 20, 2020 8:39 PM
To: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Re: Quick Call

I can chat now or 11:30 EASTRN TOMORROW...

_____ Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
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Tel: (206) 296-4774; Direct: (206) 263-8171; Fax: (206) 296-4803
E-mail: jeff.duchin@kingcounty.gov

From: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>
Sent: Thursday, February 20, 2020 5:34:34 PM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Re: Quick Call

Will defer to your schedules.

Get Outlook for iOS

From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Thursday, February 20, 2020 8:16:58 PM
To: Bresee, Joseph (CDC/DDID/NCIRD/ID) <jsb6@cdc.gov>; Langley, Gayle E. (CDC/DDID/NCIRD/DVD) <fez7@cdc.gov>
Subject: Quick Call

Joe, Gail, would you have time for a call tonight or tomorrow to discuss the Seattle flu study?

_____ Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
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E-mail: jeff.duchin@kingcounty.gov

From: Pillai, Satish K. (CDC/DDID/NCEZID/DPEI)
Sent: Monday, February 24, 2020 4:46 PM PST
To: Duchin, Jeff
Subject: Re: thanks for the question

Jeff - wanted to loop back, and let you know I spoke with epi tf and IM leadership - very quick conversations and don't have too much detail, but the adjusted pui definition is nearly ready for clearance. There will be socialization with partners (epi tf is doing that) and hopefully posting as soon as tomorrow night (I am always a bit circumspect of the "as early/soon as" framing, but am hopeful that this will be the case here).
Get Outlook for iOS
From: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Sent: Monday, February 24, 2020 2:51:46 PM
To: Pillai, Satish K. (CDC/DDID/NCEZID/DPEI) <vig8@cdc.gov>
Subject: RE: thanks for the question

And THANK YOU!

Jeffrey S. Duchin, MD
Health Officer and Chief, Communicable Disease Epidemiology & Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Infectious Diseases, University of Washington
Adjunct Professor, School of Public Health
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E-mail: jeff.duchin@kingcounty.gov

From: Pillai, Satish K. (CDC/DDID/NCEZID/DPEI) <vig8@cdc.gov>
Sent: Monday, February 24, 2020 11:47 AM
To: Duchin, Jeff <Jeff.Duchin@kingcounty.gov>
Subject: thanks for the question

I've reached epi colleagues and leadership to close this loop asap.

From: State and Local Readiness (CDC)
Sent: Friday, February 28, 2020 11:56 AM PST
To: State and Local Readiness (CDC)
Subject: CDC Text Illness Monitoring (T.I.M) System Update
Attachments: T.I.M. FAQ_forPH_02.27.2020.pdf

Dear Colleagues,

The Text Illness Monitoring (T.I.M.) system has recently been modified to allow county-level campaigns to be added under state campaigns. This allows for local use of T.I.M. for COVID-19 symptom monitoring.

If a state would like to add county-level users in T.I.M., they should provide the names of the counties that should be activated. Once the T.I.M. support team activates these counties, states may then add county-level users as appropriate.

Local jurisdictions will be assigned at the county level and will have access to the data for that county only, and states will have access to all data within the state.

Local jurisdictions should coordinate with their state for access. States may send the list of counties they wish to activate in T.I.M. to eocevent340@cdc.gov.

Thank you,
State Coordination Task Force

Sent by BCC to PHEP Directors, SHOS, State Epis, Non-governmental Partners, STLTs, and BCHC

From:	Dooling, Kathleen L. (CDC/DDID/NCIRD/DVD)
Sent:	Friday, February 21, 2020 9:40 AM PST
To:	Adam Welch; Al Benson; Duchin, Jeff; Edward Belongia; Fishman, Jay A; Cohen, Jeffrey (NIH/NIAID) [E]; Jeff Curtis; Duchin, Jeff; Jeffrey Curtis; drkellymoore (drkellymoore@yahoo.com); william.schaffner@vumc.org; Ken Schmader; Lee, Grace M; Lisa Prosser; Lynn Bahta; Mary Pat Friedlander; Cieslak, Paul (CDC state.or.us); Agger, Paula (FDA/CBER); Robin Avery; Sandra Fryhofer; Steve Pergam; Vicki Morrison
CC:	Cohn, Amanda (CDC/DDID/NCIRD/OD); Guo, Angela (CDC/DDID/NCIRD/DVD) (CTR); Courtney Jones; Ortega-Sanchez, Ismael (CDC/DDID/NCIRD/DVD); St. Pierre, Jeanette (CDC/DDID/NCIRD/DVD); Kathy Parham; Kroger, Andrew (CDC/DDID/NCIRD/ISD); Patel, Manisha M. (CDC/DDID/NCIRD/DVD); Pallansch, Mark A. (CDC/DDID/NCIRD/DVD); Marin, Mona (CDC/DDID/NCIRD/DVD); Harpaz, Rafael (CDC/DDID/NCIRD/DVD); Rafael Harpaz; Schmid, Scott (CDC/DDID/NCIRD/DVD); Shainoor Ismail; Susan A Bartlett; Harrington, Theresa (CDC/DDID/NCEZID/DHQP); Coleman.Rotstein@uhn.ca; Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Su, John (CDC/DDID/NCEZID/DHQP); MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Wallace, Megan (CDC/DDID/NCIRD/DVD); Dr. Coleman Rotstein; Anderson, Tara C. (CDC/DDPHSS/CSELS/DHIS)
Subject:	HZWG meeting 02/24: slides
Attachments:	FEB 24 Herpes Zoster Work Group POST APPROVAL COMMITMENT UPDATE from GSK_FINAL.pdf

Hello HZWG,

During our meeting on Monday Feb 24, GSK will provide an update on their post-approval research commitments, with a highlight on safety studies. Slides for the presentation are attached.

We look forward to hearing from you on Monday.

Dial in: (855) 348-8390; Conference ID: 85389017

Sincerely,
Kathleen Dooling
Kathleen Dooling, MD MPH
Medical Officer, Measles, Mumps, Rubella, Herpesvirus and Domestic Polio Team
VVPDB/ DVD / NCIRD
Bldg 24 / Room 5211
Vic9@cdc.gov

Text Illness Monitoring (T.I.M.)

Frequently Asked Questions

About T.I.M.

What is T.I.M.?

Text Illness Monitoring (T.I.M.) is a mobile texting tool that facilitates symptom monitoring during an infectious disease outbreak. Monitoring conducted by public health officials has traditionally been conducted via telephone calls, which can be a time-consuming process requiring staff resources. CDC has developed T.I.M., a nationally-centralized option utilizing two-way Short Message Service (SMS)/text messaging to aid in the process. Text messaging is an efficient method to elicit, manage, and act on any coronavirus disease 2019 (COVID-19) symptoms among those who are exposed or potentially exposed to the virus. The T.I.M. system was utilized to monitor for influenza symptoms in Michigan[1] with success.

How is T.I.M. being used for the coronavirus disease 2019 response?

Use of T.I.M. is voluntary for health departments. Consenting persons in participating jurisdictions will receive 2-5 text messages a day for up to14 days asking if they have symptoms consistent with COVID-19. Health departments will immediately be alerted to any person in their jurisdiction that responds that they are experiencing symptoms and to any persons who fail to respond to two consecutive messages. Health departments would then follow up with individuals who are reporting symptoms or those that have been unresponsive.

Health Department Access

How do I get access to T.I.M.?

State and local public health departments may request access by sending an email to eocevent340@cdc.gov. Please provide a primary and secondary point of contact to act as an administrator in T.I.M. Instructions for adding users and assigning them to a campaign to receive notifications can be found in the "T.I.M. Adding a User and Alert Setup" guide available in the Resources section of T.I.M.

After registration, the public health administrators will receive an email with information on how to log in and access the system.

Can local public health jurisdictions use T.I.M.?

Yes, T.I.M. has recently been modified to allow county-level campaigns to be added under state campaigns. This allows for local use of T.I.M. for COVID-19 symptom monitoring. If a state would like to add county-level users in T.I.M., they should provide the names of the counties that should be activated. Once the T.I.M. support team activates these counties, states may then add county-level users as appropriate. Local jurisdictions will be assigned at the county level and will have access to the data for that county only. Local jurisdictions should coordinate with their state for access.

Who will be able to access the information in T.I.M.?

There are three levels of access to T.I.M.: CDC, state, and county. Public health administrators at the state level will have access to all data within their jurisdiction, including county level data. Local jurisdictions assigned at the county level

1 Stewart RJ, Rossow J, Eckel S, et al. Text-Based Illness Monitoring for Detection of Novel Influenza A Virus Infections During an Influenza A (H3N2)v Virus Outbreak in Michigan, 2016: Surveillance and Survey. JMIR Public Health Surveill. 2019;5(2):e10842. Published 2019 Apr 26. doi:10.2196/10842 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6658270/

will only have access to the data for the county to which they are assigned. CDC will have access to the deidentified aggregate data for monitoring campaigns.

Can I add other people in my jurisdiction as users?

State users with the administrator role may add both state and county-level users for their state. County level users can add users to their assigned county only.

Dashboard and Notifications

Is there a dashboard and what information can be seen?

The T.I.M. system includes a dashboard with summary information on number of persons being monitored, and information related to the alerts/notifications that public health needs to take action on (i.e., those that reply YES to a text indicating symptoms, those that have not responded to two consecutive texts). Jurisdictions can view the mobile phone number of participating individuals being monitored through the T.I.M. system and the messages they sent.

How will I know if someone responds that they have symptoms?

If someone in your jurisdiction replies YES to a text message indicating symptoms you will receive an email notification. An email notification will also be sent if a person does not respond to two consecutive texts sent. You can also view a list of all users that responded they have symptoms on the dashboard and in reports.

What data is stored in T.I.M. for individuals being monitored?

Data stored in T.I.M. includes mobile phone number, any text message response provided by that mobile phone, and the date and time it was sent.

Are there any reports available in T.I.M.?

Yes. There are two reports in T.I.M. One report lists all of the text responses received from the previous day, with each response tied to a phone number. The other report lists all of the text responses received for the entire campaign, also tied to phone numbers. Both reports can be exported as a .csv or Excel file or can be reviewed and filtered using HTML.

How are families or head of household tracked in the system?

Each mobile phone enrolled in T.I.M. represents one household or family unit. A text reply of 'YES' or 'SYM' indicates that at least one person in the household/family has developed symptoms. A text reply of 'NO' indicates that no one in the household/family has developed symptoms.

Enrollment and Messaging

What messages will individuals enrolled in T.I.M. receive?

A diagram of the 14-day text message workflow is below. Individuals will immediately receive a welcome message notifying them they have been enrolled in the text symptom monitoring program after the jurisdiction adds their mobile phone number to T.I.M. Individuals will receive a daily message to reply 'Yes' or 'No' to symptoms of COVID-19. At the end of the 14-day monitoring period, individuals will receive a final message informing them that they have completed monitoring and will be unenrolled from T.I.M.

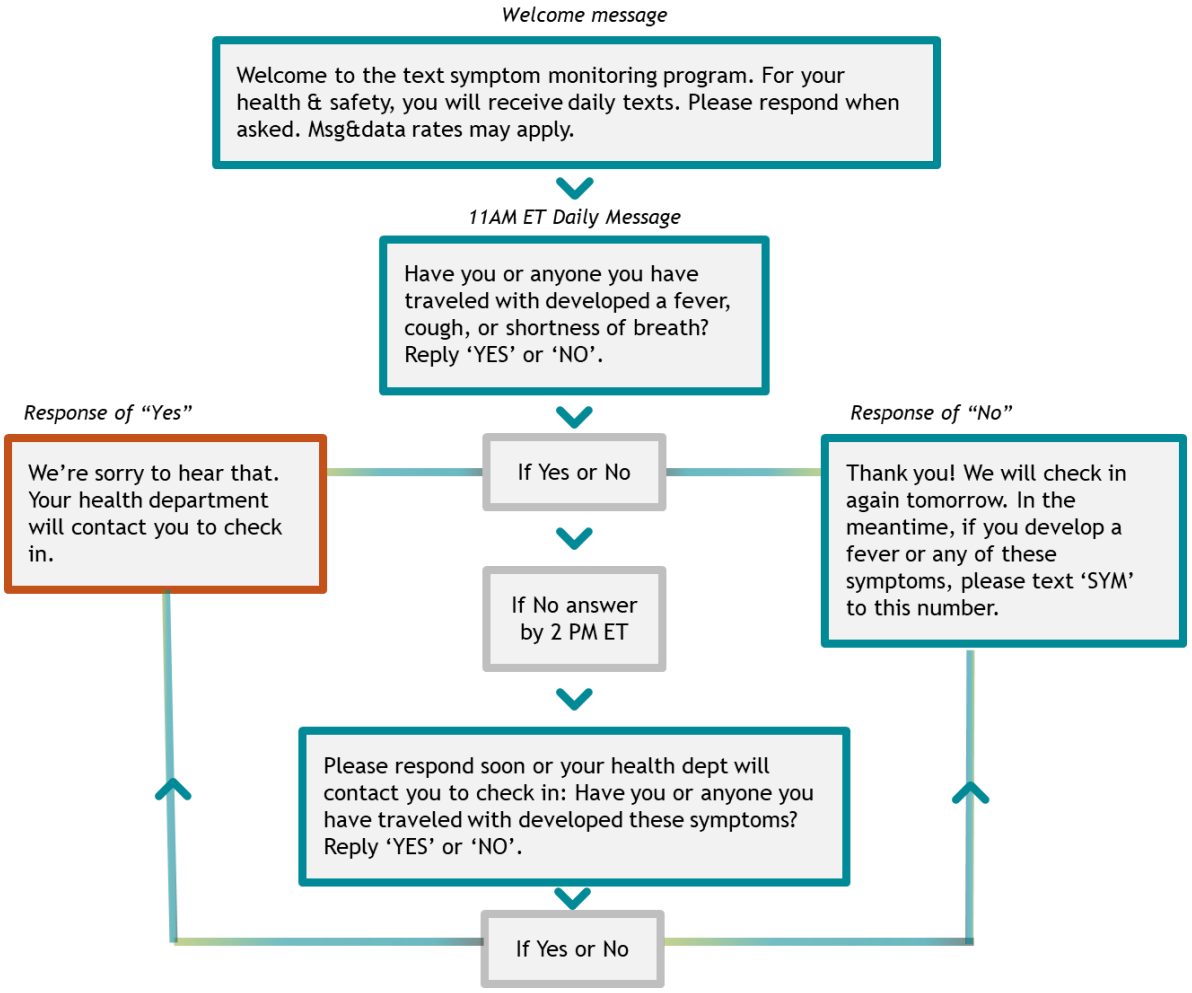


Figure 1. T.I.M. message flow

What information is needed to enroll individuals in T.I.M. for monitoring?

The only information needed to enroll an individual in T.I.M. is a U.S. mobile phone number. This mobile phone number is the only identifiable piece of information entered into T.I.M. Other personal information linked to the patient phone number should be maintained by the jurisdiction to cross-reference with the phone numbers in T.I.M. for any required follow up.

Infrastructure

Is there a cost to jurisdictions to implement T.I.M.?

T.I.M. is a web-based system that does not require additional hardware or software. The system is available at no cost to jurisdictions.

How is the data in T.I.M. secured?

T.I.M. is a secure, scalable, applications in alignment with HIPAA and HITECH compliance requirements. Please see Compliant Campaign's infrastructure security and compliance document for additional details:

What are the terms and conditions for using T.I.M.?

Terms and conditions are available here: https://www.tim-health.com/terms/.

Other

Is there flexibility to change the duration of monitoring?

Monitoring for COVID-19 is for 14 days. If an individual does not want or need to be monitored for the full 14 days, they can text 'STOP' and they will no longer receive text messages from the system.

Can we remove or edit phone numbers entered into T.I.M.?

If a number is enrolled in T.I.M. and needs to be edited or an incorrect number needs to be removed, please contact timsupport@compliantcampaign.com.

Update: Shingrix

FDA Post-Approval Commitments

February 24, 2020

RZV Post-Marketing Commitments Subject To Reporting Requirements (October 2017)

- Study Zoster-049: long-term efficacy, immunogenicity, and safety of SHINGRIX in adults ≥50 years of age
- Study Zoster-062: safety, reactogenicity, and immunogenicity of SHINGRIX in adults ≥50 years of age with a prior episode of Herpes Zoster
- Targeted safety study, EPI-Zoster-030 VS: evaluate the safety of SHINGRIX in adults ≥50 years of age in the United States

RZV: recombinant zoster vaccine

Zoster-049 ZOE-LTFU (Long-Term Follow-Up)

Title	Phase IIIb, open-label, multi-country, long-term follow-up study (ZOE-LTFU) for ZOE 50 + ZOE 70 to assess prophylactic efficacy, safety, and immunogenicity persistence of GSK Biologicals' Herpes Zoster subunit (HZ/su) vaccine and assessment of 1 or 2 additional doses on a 0 or 0, 2-month schedule
Purpose	Assess 1) long-term efficacy of HZ/su vaccine for prevention of HZ in subjects ≥50 years of age 2) immunogenicity responses of 1 or 2 additional doses of Shingrix in 2 subgroups who previously received 2 doses of HZ/su in ZOE studies
Population	N=7,534 subjects currently participating in Zoster-049 Revaccination Subgroup: N=61 subjects received 1 additional dose N=60 subjects received 2 additional doses
Timeline/ Output	• Zoster-049 year 2 efficacy readout (or year 6 efficacy from ZOE studies) anticipated to be available for sharing with HZ Work Group Q3 2020 • End-of-study 10-year efficacy from ZOE studies Post Approval Commitment (PAC) 25 May 2024

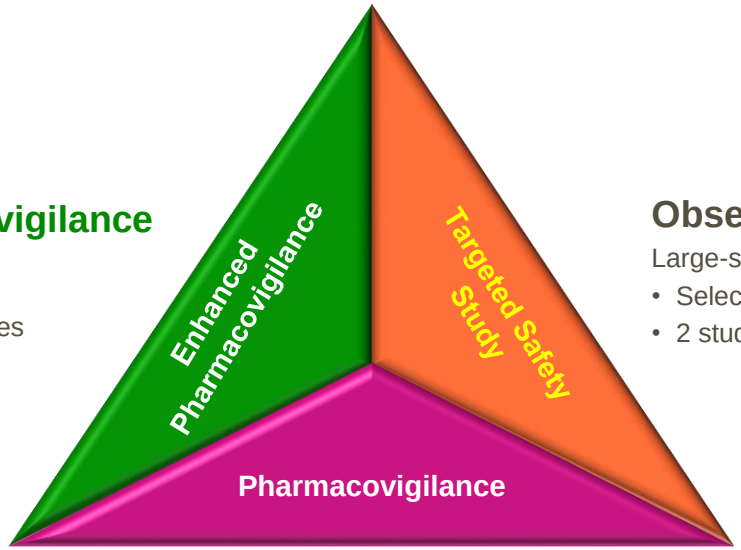
Zoster-062 History of Prior HZ

Title	Phase IIIb immunogenicity and safety study of HZ/su in adults ≥50 years of age with a prior episode of Herpes Zoster Initial Study 033
Purpose	Assess rate of HZ recurrence as well as reactogenicity, safety, and immunogenicity of Shingrix in a population with a history of HZ
Population	1,426 eligible subjects aged 50 years and above with a previous HZ episode (>6 months prior to enrollment) are enrolled in the study The study is being conducted in the European Union (EU) and non-EU regions (outside of North America)
Timeline/ Output	Enrollment initiated Sept 2019 Post Approval Commitment: 30 Nov 2021

Pharmacovigilance Plan

Enhanced Pharmacovigilance

- Background rates (predefined and ad hoc)
- Observed vs expected analyses
- Targeted follow-up procedure



Observational Studies

Large-scale databases (HMO/EMR)

- Selected outcomes of interest
- 2 studies – 2 data sources

Data Sources

- Spontaneous reports
- Vaccine exposure
- Nonclinical/clinical data

Methods

- Weekly individual case review
- Monthly aggregate reviews
- Monthly literature review

Post-Approval Safety Study—Epidemiology

Presented Feb 2018

- Prospective observational cohort study in the United States
- Data sources currently under feasibility assessment (eg, with PRISM)
- At least 60,000 subjects ≥50 years vaccinated with RZV; at least one unexposed group

Endpoints:

- Gout, polymyalgia rheumatica, temporal arteritis within 12 months after vaccination with RZV
- Serious adverse events (SAEs) within 12 months after vaccination with RZV
- 10 other predefined AEs of special interest or pIMDs within 12 months after vaccination with RZV
- Medically attended adverse events (MAEs) within 60 days after vaccination with RZV

Current proposal to CBER/EMA–Dec 2019

- Retrospective observational studies
- Data sources – Sentinel distributed database (Epi-Zoster-030) and CMS Medicare data (Epi-Zoster-032)
- Feasibility assessment informed the following:
  - Study design, exposure, and outcome definitions
  - Estimated sample sizes and estimated data accrual period

Endpoints:

- Discussion with collaborators, clinical experts; and CBER consultation
- Endpoints narrowed down to most clinically important to assess
- Risk windows for various outcomes vary, and are based on clinical cause of outcome of interest, biological plausibility and what is known about the vaccine; and statistical signal from VSD RCA

Post-Approval Safety Study—Epidemiology

Presented Feb 2018

Primary objective

– To assess the risk of gout, polymyalgia rheumatica, and temporal arteritis (giant cell arteritis) in vaccinated subjects within 12 months after vaccination with RZV

Secondary objectives

– To estimate the incidence of MAEs in vaccinated and unvaccinated subjects within 60 days after vaccination with RZV

– To estimate the incidence of SAEs in vaccinated and unvaccinated subjects within 12 months after vaccination with RZV

– To estimate the incidence of 10 pre-defined adverse events of special interest or pIMDs in vaccinated and unvaccinated subjects within 12 months after vaccination with RZV:
  – Psoriasis, rheumatoid arthritis (RA), inflammatory bowel diseases (IBD), autoimmune thyroiditis, idiopathic thrombocytopenia, optic neuritis, leukocytoclastic vasculitis, multiple sclerosis (MS), Guillain Barré syndrome, Still disease (adult onset)

Current proposal to CBER/EMA–Dec 2019

Primary objectives

– To assess the following in the identified risk windows post vaccination:
  – Gout within 30 days
  – GBS with 42 days
  – PMR with 183 days
  – GCA with 183 days

Secondary objectives

– To assess the risk of :
  – SVT (within 30 days) and ION (within 183 days) post-vaccination

Next steps

– Protocol is under review by CBER/EMA

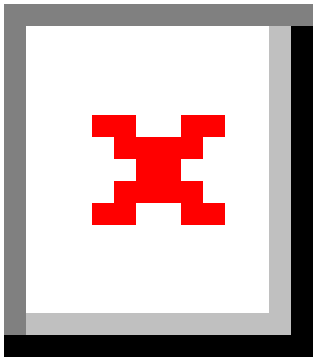
– Finalized after feedback received

– More details on the study design will then be made available

Next Steps

- Follow up with the HZ Work Group to share details of the finalized targeted safety study protocols in Quarter 3 2020
- Anticipate update on 049 2-year efficacy readout (6 year efficacy from ZOE studies) Quarter 4 2020

From:	YYang@acponline.org
Sent:	Friday, February 21, 2020 7:22 PM PST
To:	jdscott@uw.edu; Duchin, Jeff; golden@u.washington.edu; golden@uw.edu; mhninburg@hepeducation.org; xdg9@cdc.gov; irm6@cdc.gov; Lauren@nvhr.org; Fagalde, Meaghan; snglick@uw.edu; Barash, Elizabeth; Armstrong, Hilary; kris.kowdley@wsu.edu; mmessers@gmail.com; Pallavi.M.Patel@kp.org; Meaghan.Munn@kingcounty.gov
CC:	michael.bretthauer@medisin.uio.no; KCwirko@acponline.org
Subject:	Decision from Annals of Internal Medicine
Attachments:	Comments.html, M20-0069-manuscript.pdf



February 21, 2020

John Scott MD, MSc
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REF: M20-0069

Dear Dr. Scott:

Thank you for submitting your manuscript, "A Population-based Intervention to Improve Care

Cascades of Patients with Hepatitis C Virus Infection" to *Annals of Internal Medicine.*

A Senior Editor, an Associate Editor and 3 external reviewers read your paper. In addition, your paper was discussed by our entire editorial team at one of our weekly manuscript conferences. I am sorry to write with the news that we have decided not to accept it for publication. Our decision was influenced in part by the reviewers' questions and comments, which you can review by clicking the link at the bottom of this page. A line-numbered version of your manuscript was sent to our reviewers to help them point to specific locations within your paper when providing their comments. A copy of this line-numbered version of your manuscript is attached here. Not all reviewers choose to refer to line-numbers in this manner. While some of the reviewers' comments were positive, reviews are only one of the factors that we take into consideration in our editorial decisions.

We read with interest your manuscript about improving hepatitis C care through engaging primary care practices and providers. However, we had a number of major concerns. While there were significant increases in hepatitis C screening and treatment activities during the project period, the editors were concerned that there was no preplanned rigorous evaluation of the intervention effect. As such, it is difficult to know the true impact/effectiveness of the various facets of the program based on these results, especially since the program period likely coincided with changes in underlying hepatitis C testing and treatment trends resulting from adoption of new hepatitis C practice guidance and the expansion of DAA therapy options and access. In addition, there was no formal methodology employed in the identification of the key barriers or in the overall design of the elaborate multifaceted intervention. Furthermore, there was no systematic and preplanned formative evaluation of the program or information on the cost of the program to establish its reach, feasibility, sustainability and scalability. Based on these considerations, we thought that the findings had limited ability to change clinical practice or influence policy. In the end, the manuscript had a lower priority than the many other papers we are considering at this time.

Space constraints allow us to publish only a small fraction of the many excellent submissions that we receive. We hope that you find the reviewers' comments helpful and while we are unable to publish this manuscript, we do hope that we'll have future opportunities to consider your work.

Sincerely,

Yu-Xiao Yang, MD, MSCE

Deputy Editor

A Population-based Intervention to Improve Care Cascades of Patients with Hepatitis C Virus Infection

Manuscript# - M20-0069

Conflicts

Are you aware that any of the authors' academic institutions or employers has any financial interest in or a financial conflict with the subject matter or materials discussed in this manuscript? - No

Employment - No

Did all authors have full access to all study data, take full responsibility for the accuracy of the data analysis, and have authority over manuscript preparation and decisions to submit the manuscript for publication? - Yes

Consulting - No

Honoraria for advice or public speaking - No

Stock ownership or options (other than mutual funds) - No

Expert testimony - No

Grants Received / Pending - Yes: The University of Washington received funds for clinical trials sponsored by Tacere Therapeutics and Tibotec, for which JS was the principal investigator

Advisory board - Yes: JS served on expert advice committees to Bristol Myers-Squibb in 2014 and Gilead in 2013-14.

Medical Education - No

Patents Received / Pending - No

Royalties - No

Other - No

Is this manuscript currently under consideration elsewhere (e.g., at another journal or the Cochrane Library), or has a similar version of this manuscript been published elsewhere (e.g., in another journal or the Cochrane Library)? - No

Payment for involvement in the preparation of this manuscript - No

Company Service - No

Are there any concurrently submitted or previously published papers containing content that is found in this manuscript? - Yes: The assembly of a hepatitis C data system that integrated clinical data from EHRs, laboratory reports and case investigations into a unified data management system that facilitated public health investigations and monitoring of patients through the hepatitis C care cascade is described in this accepted publication: Baer A, Munn M, Drake C, Sohlberg E, Barash E, Glick S, et al. Design of an Enhanced Public Health Surveillance System for Hepatitis C Elimination in King County, Washington. Public Health Rep (in press).

Manuscript: M20-0069 Preprint Questions

Prior posting of a study at a preprint server does not preclude its evaluation at *Annals of Internal Medicine.*

Have you posted a report of this work on a preprint server?

No

A Population-based Intervention to Improve Care Cascades of Patients with Hepatitis C Virus Infection

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IRB Statement: The State of Washington Human Research Review Section determined that the program does not require review by the Washington State Institutional Review Board (WSIRB)

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Abstract

Background: Hepatitis C virus (HCV) infection is common in the US, leading to significant morbidity and mortality. Simplified screening recommendations and highly effective antivirals present an opportunity to eliminate HCV.

Objective: To increase testing, linkage to care, treatment and cure of HCV.

Design: Observational, prospective, population-based intervention program between September, 2014-September, 2018.

Setting: Three community health centers, three large multi-clinic health care systems, and an HCV patient education and advocacy group in King County, WA.

Patients: Patients with documented hepatitis C-related diagnosis code, positive HCV lab test, or prescription of hepatitis C medication and who were seen at least once at a participating clinical site in prior year were included.

Interventions: Electronic health record (EHR) prompts and reports were created. Case management linked patients to care. Primary care providers received training through classroom didactics, an online curriculum, specialty clinic shadowing and a telemedicine program.

Measurements: HCV antibody and RNA levels, hepatitis C medications, HCV genotype and fibrosis testing.

Results: The proportion of baby boomer (population born from 1945-1965) patients with documentation of HCV testing increased from 18% to 54% during the project period. Of 77577 baby boomer patients screened at 87 partner clinics, 2401 (3%) were newly identified HCV antibody positive. The number of patients staged for treatment (either by genotype or a fibrosis test) increased by 391% and treated increased by 1263%. Among the 79% of patients tested after treatment, 95% achieved sustained virologic response.

Limitations: Incomplete data on treatment outcome.

Conclusion: A combination of EHR-based healthcare system interventions, active linkage-to-care, and clinician training contributed to a tripling in the number of patients screened and more than tenfold increase of those treated. The interventions are scalable and foundational to the goal of HCV elimination.

Introduction:

An estimated 2.4 million Americans (1%) were chronically infected with hepatitis C virus (HCV) in 2013-2016 (1) and approximately 17,000-80,000 persons with hepatitis C die annually (2–4). New HCV infections increased nearly 3-fold from 2010 and 2015; during 2012-2013, the annual number of hepatitis C-related deaths exceeded the total number of deaths reported to the Centers for Disease Control and Prevention associated with the 60 other nationally notifiable infectious diseases combined (5). The economic costs of chronic hepatitis C in the US are in the billions of dollars each year (6). Despite this cost, there is a gap in the literature of reports of population-level interventions in the United States to identify and treat cases in order to achieve national targets for hepatitis C elimination (7).

Data from the US National Health and Nutrition Examination Survey found that among those born between 1945-1965 ("baby boomers"), 2.6% tested positive for the HCV antibody and 85% of those tested positive for HCV RNA (8). Although the prevalence of HCV infection is highest among baby boomers, there has been an increasing trend in new HCV infections among younger patients and in rural areas as a result of the opioid crisis and increase use of injection drugs (9,10). Indeed, the incidence of acute hepatitis C has increased dramatically in the past decade (11,12).

Highly effective direct acting antiviral (DAA) therapy and simplified Centers for Disease Control and Prevention (CDC) and US Preventive Services Taskforce hepatitis C screening guidelines recommending testing of all baby boomers provided new opportunities for persons with chronic HCV infection to be identified and treated (13). Sustained virologic response (SVR) for all genotypes using all-oral, single tablet DAA regimens to treat chronic HCV infections now exceed 95%, including populations once considered to be difficult to treat, such as patients who are HIV/HCV co-infected, have cirrhosis, have severe renal impairment or had failed prior therapy (14–19). Importantly, patients who achieve SVR have decreases in all-cause mortality and development of hepatocellular carcinoma (20,21). Because of the availability of highly effective treatments for hepatitis C, expanded screening recommendations, and increased access to health care services, the National Academies of Science, Engineering and Medicine (NASEM) and the US Department of Health and Human Services National Viral Hepatitis Action Plan have called for the elimination of hepatitis C as a public health problem in the US (7,22).

Despite these advances, significant challenges to hepatitis C elimination remain, including diagnosing at-risk vulnerable populations, linking diagnosed patients to care, and initiating curative antiviral treatment (22). Collectively, these steps are referred to as the "care cascade." This framework, which has been used extensively by public health agencies responding to the HIV epidemic (23,24), can be used to highlight gaps in care and prioritize intervention to improve clinical outcomes (25). Numerous US studies have examined the hepatitis C care cascade in the pre-DAA era (26). A review by the CDC, described these deficits at each step: as few as 50% of HCV-infected patients are aware of their diagnosis; once diagnosed, a minority of patients (32-38%) are referred to care, 7-11% of cases are treated, and 5-6% are cured (27).

As a step towards realizing the goal of elimination of hepatitis C as a public health problem, we developed a population-based public health and healthcare collaboration, the HCV Test and Cure Coalition (HCV-TAC). The report the results of the project, which employed enhancements to provider education, public health surveillance, healthcare system electronic medical records and data reporting capacity, and case management in order to increase the testing, linkage to care, treatment, and cure of persons with HCV infection in King County, the most populated county in Washington State.

Methods:

From September, 2014-September, 2018 Public Health - Seattle & King County (Public Health) developed the HCV-TAC Coalition, a collaboration with three community health centers, three large multi-clinic healthcare systems (private, public and capitated), and a hepatitis C patient education and advocacy group. Collectively, these health systems provide care for patients across a broad spectrum of racial and socioeconomic groups in King County. The HCV-TAC Coalition engaged partners on a quarterly basis, including experts in information technology, primary care clinicians, hepatology specialists, nurses, case managers, and project champions to review progress towards project milestones.

Our strategy included the following key components: identification and hepatitis C testing of eligible patients in accordance with CDC guidelines; developing a data system to integrate laboratory and clinical data into public health surveillance records; monitoring patients along the care cascade and providing case management to promote linkage to medical care and curative therapy when indicated; and enhancing hepatitis C treatment capacity among primary care providers.

HCV-TAC partners used several interventions to increase hepatitis C screening in the outpatient primary care setting. Several sites modified their EHR to flag patients needing hepatitis C testing under health maintenance activities. Other sites put up CDC-produced posters in clinic waiting rooms to inform patients about hepatitis C screening for baby boomers, mailed screening reminders to baby boomer patients, and had reception staff give reminder cards at clinic check-in for baby boomers to ask their provider about hepatitis C testing.

To train primary care providers (PCP) to evaluate and care for patients with chronic hepatitis C, the HCV-TAC program employed 5 different strategies: case-based telemedicine, an online tutorial, didactics, clinic tutorials and a hybrid tutorial/teleconference model. Project ECHO (Extension for Community Health Outcomes) was developed at the University of New Mexico to safely and effectively treat common, complex chronic diseases and monitor outcomes in rural and underserved areas (28,29). First used for the treatment of hepatitis C in New Mexico, Project ECHO was adopted by the University of Washington for regularly-scheduled telehealth clinics that function as “knowledge networks,” bringing together interdisciplinary specialists from academic medical centers and community-based PCP.

An online tutorial, HCV Online (www.hepatitisc.uw.edu), was adapted during the project period for use in King County. The publicly available website consists of an interactive online course covering 26 core competencies, with learning objectives and practice goals. A 40-question multiple choice, “boards

style" examination is required for those seeking continuing medical education credits, and a certificate of completion is issued if 80% of the answers are correct. A progress tracker allows a supervisor to see multiple clinicians in a group and areas of knowledge deficits.

Hepatology and infectious disease specialists gave presentations to PCPs on hepatitis C evaluation and treatment, and offered PCPs opportunities to shadow specialists seeing patients with HCV infection. One healthcare system pioneered a clinic tutorial/teleconference model in which PCPs were trained on hepatitis C evaluation and treatment and presented their cases to hepatitis C specialists in a regular teleconference and through an internal "eReferral" system. During the project, there were 252 PCPs working at 6 clinics who were trained on hepatitis C evaluation and treatment.

Public Health and a patient advocacy organization, the Hepatitis Education Project, worked with clinicians to provide case management designed to ensure patient linkage to care, progress through the HCV care cascade, and to provide point of care testing, information, and medical and financial navigation services.

Public Health promoted public awareness of HCV infection and the importance of screening through a dedicated webpage, a blog, media releases and in-depth stories in the local press and radio. Targeted outreach included communities of color and the Seattle syringe exchange. Educational information distributed to the public included materials from CDC's *Know More Hepatitis* campaign.

In order to improve the quality of public health hepatitis C monitoring, we developed a hepatitis C data system that integrated clinical data from EHRs, laboratory reports and case investigations into a unified data management system that facilitated public health investigations and monitoring of patients through the hepatitis C care cascade (30).

Analytic methods:

Data were available for a baseline period (9/30/2013 – 9/29/2014), and the project period, beginning with year 1 (9/30/2014 – 9/29/2015) through the end of year 4 (9/30/2017 – 9/29/2018). To be included in the study analysis, patients had to reside in King County and have at least one visit to a participating primary care or liver specialty clinic during the project period.

Data collection methods have been described previously (30). Briefly, HCV-TAC partners extracted laboratory and clinical data from EHRs by identifying three subsets of patients who: (A) had a hepatitis C-related diagnosis code, positive hepatitis C lab test, or prescription of hepatitis C medication; (B) were born between 1945-1965 and tested negative for HCV antibody; and (C) were born between 1945-1965 (baby boomer cohort) and had no record of hepatitis C testing.

Epidemiologists assessed baby boomer screening rates by project year for each partner site by identifying unique baby boomer patients with at least one visit to a partner clinic during that project year, and calculating the percentage of those patients who had been screened for HCV antibody before or during the year. If HCV antibody test results were available, test dates were used to determine when the screening occurred; if no laboratory data were available, the subset assigned by partners was used

to determine screening status (i.e., HCV positive, HCV negative, never screened). Among baby boomer patients who tested HCV antibody positive during the project period, we assessed the percentage of patients who: 1) were not tested for HCV RNA; 2) had the same specimen immediately tested for HCV RNA (reflex RNA testing); and 3) were tested for HCV RNA at a later date.

To be included in the analysis of the hepatitis C care cascade, patients were required to have a positive HCV RNA test. An HCV positive patient was considered staged for treatment if either: 1) they had laboratory test results allowing computation of an AST:platelet ratio (APRI) and HCV genotype testing; or 2) had a liver fibrosis staging test (e.g., Fibrosure, liver biopsy, Fibroscan, etc.). Patients with a prescription for hepatitis C DAA medication but no information on staging were considered to have missing staging data. Patients with a prescription for a hepatitis C DAA medication in the EHR were considered prescribed treatment. Treatment start and end dates were obtained from prescription information from EHRs. All patients with hepatitis C prescriptions had at least one treatment date, and treatment completion was calculated for those without a treatment end date using 12-week treatment duration. Patients more than 12 weeks post-treatment completion were eligible for SVR testing to determine cure. Patients with detectable HCV RNA at SVR testing were considered treatment failures, and those with undetectable HCV RNA at SVR testing were considered cured. Progress over the project period in screening, uptake of reflex HCV RNA testing, and milestones on the care cascade were analyzed by comparing baseline to year 4 using Chi-square tests and p-values with $\alpha=0.05$ significance. Data management activities and analyses were performed using SAS 9.4.

Results:

HCV-TAC partners identified 232,214 patients residing in King County with at least one visit to a partner primary care or liver specialty clinic during the baseline or project period. Because the focus of the study was on baby boomers, nearly all of the patients included in the analysis were born between 1945-65 (n=225,363). A diagram of patients and their testing outcomes is shown in Figure 1, and patient demographics are described in Table 1.

HCV antibody test results were available for 80,204 baby boomers patients, including 2,627 patients screened before the project period. Of the 77,577 baby boomers screened for HCV antibody during the project period, 2,401 were antibody positive (3%). The proportion testing positive declined from 8% at baseline to 2.5% by Year 4. After accounting for patients who were seen at multiple partner sites, there were 2,250 unique baby boomer patients who screened HCV antibody positive during the project period. Some HCV antibody positive baby boomers were screened more than once during the project period, resulting in 2,613 positive antibody tests eligible for reflex RNA testing.

Of the 2,250 unique baby boomer patients who tested HCV antibody positive during the project period, 73% (N=1,635) were HCV RNA positive and included in the care cascade analysis, 561 patients were HCV RNA negative, and 54 had not received HCV RNA testing.

Among the 2,627 baby boomer patients screened before the project period, 211 (8%) were antibody positive; after accounting for patients who were seen at multiple partner sites, there were 192 unique persons who were HCV antibody positive. Of these 192 baby boomer patients, 156 (81%) were HCV RNA positive and included in the care cascade analysis, 26 tested HCV RNA negative, and 10 had not received confirmatory HCV RNA testing.

There were 6,418 baby boomer patients identified as having HCV by medical history, but for whom HCV antibody test results were not available. After accounting for patients who were seen at multiple partner sites, there were 5,540 unique persons identified in this group, including 3,887 who were HCV RNA positive and included in the care cascade analysis, 503 who tested HCV RNA negative, and 1,150 patients with no laboratory record of any positive HCV antibody or RNA test.

Partners also identified 6,851 persons diagnosed with hepatitis C who were not baby boomers. After accounting for patients seen at multiple partner sites, there were 6,038 unique persons identified; 2592 were found to be HCV RNA positive and were included in the care cascade analysis, 650 tested RNA negative, and 2,796 had no laboratory record of positive HCV antibody or RNA testing.

Hepatitis C screening of baby boomer patients increased significantly, from 18% of baby boomer patients to 54% of baby boomer patients from baseline to year 4 (Figure 2). The percentage of antibody positive tests reflexed for HCV RNA increased significantly during the project period from 46% (212 of 462) at baseline to 81% (427 of 529) in Year 4 ($p<0.0001$).

In total, 8,270 HCV infected patients with a detectable HCV RNA test who resided in King County were included in the hepatitis C care cascade analysis. Characteristics of these patients are described in Table 2. The majority were non-Hispanic white (59%, n=4854), male (66%, n=5421), insured by Medicaid at some time (53%, n=4387), and seen at only one partner site (67%, n=5539). Thirteen percent of patients (n=1082) had advanced fibrosis (stage F3 or F4); 7% of patients were HIV positive (n=607); 29% were diagnosed with opioid use disorder (n=2403). Seventy-nine percent (n=6,531) of HCV infected patients were staged for treatment, and 53% (n=4,347) were prescribed hepatitis C treatment. Among these patients, 79% (n=3,413) received RNA testing 12 weeks after treatment end to determine SVR. Of those tested for SVR, 95% (n=3,243) achieved SVR, while 5% (n=170) had detectable HCV RNA (Figure 3).

The percentage of patients who were diagnosed with HCV infection and were staged ($p<0.0001$), treated ($p<0.0001$), and cured ($p<0.0001$) increased significantly from the baseline period to Year 4 (Figure 4). The number of patients diagnosed increased by 76%, those staged for treatment (either by genotype or a fibrosis test) increased by 3.9 fold, those treated increased by 12.6 fold, and those achieving SVR increased by 14.4 fold.

Discussion:

Over a period of 4 years, hepatitis C testing, linkage to care, treatment and cure increased significantly for patients monitored by the HCV Test and Cure program. The proportion of baby boomers who were screened increased from 18% at baseline to 54% at the end of the project period. This rate is higher than recent reports documenting an increased testing rate of baby boomers from 12.3% to 17.3% nationally (31).The percentage of baby boomers who received reflex HCV RNA testing after screening antibody positive increased from 46% at baseline to 81% in year 4, ensuring timely diagnosis. There was a 3.9-fold increase in the number of patients staged for treatment, and a 12.6-fold increase in the number of patients who started antiviral therapy, relative to the baseline period. Treatment failure among those assessed for SVR was low (5%), although a significant proportion of patients who completed treatment did not receive SVR assessment (21%).

Several factors contributed to the success of the HCV-TAC program. First, there was a strong collaboration between healthcare systems, patient advocacy organizations, and the public health department, which allowed for a coordinated and integrated approach to expanding screening of at-risk patients, sharing of clinical best practices, and promotion of healthcare system improvements such as EHR modifications and reflex HCV RNA testing. Second, enhancements to clinical EHR and associated data systems increased the availability and utility of clinical data for public health population-level surveillance and program evaluation. A key element of our project was monitoring hepatitis C testing and treatment using a care cascade framework analogous to that used successfully by public health systems to monitor HIV control. Third, we provided clinicians with high-quality hepatitis C training including a wide variety of educational opportunities that provided the skills and resources for them to successfully treat hepatitis C. Finally, an important extrinsic factor influencing our success was the lifting of Washington State Medicaid restrictions for hepatitis C treatment based on fibrosis level after legal challenges in 2016. This watershed court ruling brought Washington State's Medicaid policy in line with the AASLD/IDSA HCV guidelines (32) and opened up treatment options for an estimated >50% of early stage patients known to be infected with hepatitis C who were previously ineligible for treatment (33).

Successful collaboration and data sharing between the health department and coalition partners led to significant improvements in hepatitis C surveillance. To assess baby boomer screening and uptake of reflex HCV RNA testing, we used a combination of laboratory test results and partner-identified classification of patient HCV infection status (never screened, HCV negative, and HCV positive). This methodology allowed us to determine the hepatitis C screening status for all baby boomer patients at each clinic visit. Accordingly, we were able to track and report individual- and clinic-level progress toward screening goals over the course of the project period.

De-duplication and merging clinic EHR data with the public health surveillance database provided access to historical data for each patient diagnosed with hepatitis C, regardless of clinical provider and track patients diagnosed with hepatitis C across healthcare systems. We found that a third of patients (n=2731) included in the hepatitis C care cascade were seen at more than one partner site during the baseline and project periods.

Of the non-baby boomer patients identified as having HCV infection, a significant proportion did not have HCV laboratory results available for analysis (46%, n=2796 of 6038 non-baby boomer patients). EHRs identified these patients as having hepatitis C based on documentation of a hepatitis C diagnosis or DAA treatment, but without laboratory testing information it is not possible to verify HCV infection status. The high proportion of non-baby boomer patients without hepatitis C laboratory testing could reflect a history of past hepatitis C testing elsewhere and not reflected in the EHR, or that partners were not properly extracting all available hepatitis C laboratory data from their EHR systems.

Our findings have several important limitations. First, due to the movement of patients across healthcare systems, it is possible that partner EHRs could not identify all patients previously screened for hepatitis C in another healthcare system. Second, as previously described (30), inaccurate calculations of treatment start and end dates based on prescription order dates in the EHR may have resulted in some patients being incorrectly categorized as never tested for SVR, or failing treatment. We found 21% of patients who completed treatment did not have HCV RNA testing at least 12 weeks after stopping therapy. However, based on other studies from the Veterans Affairs and at specialty clinics outside of the registration clinical trials, it is likely that >90-95% of those treated achieved cure (34,35). Third, cooperative agreement funding provided resources for database development, EHR enhancements and clinician training, which may not be easily replicated in other settings without comparable investments. Fourth, our study population may not be generalizable to other communities. For example, other parts of the United States have a greater proportion of African-American and Latino patients. We attempted to address this limitation by recruiting health systems across demographic and socioeconomic strata. Additionally, there may be fewer PWID compared with the total population of HCV-infected persons since the focus of this study was the baby boomer cohort. Therefore, these results may not be generalizable to populations with different demographic characteristics or risk behaviors. Finally, the specific partners and interventions necessary to optimize population level identification and treatment of persons with chronic HCV infection will reflect the local environment with respect to the epidemiology of chronic HCV infection, healthcare delivery and public health systems.

The NASEM has concluded that the elimination of HCV transmission and chronic infection as a public health problem is feasible in the United States (22). Among the barriers to achieving elimination identified by NASEM are inadequate surveillance systems, failure to identify infected persons, limited access to treatment medications due to high cost, and difficulty retaining high-risk persons in care. Our study has shown that with appropriate resources and a multi-faceted strategy, major improvements in addressing barriers to hepatitis C elimination are possible.

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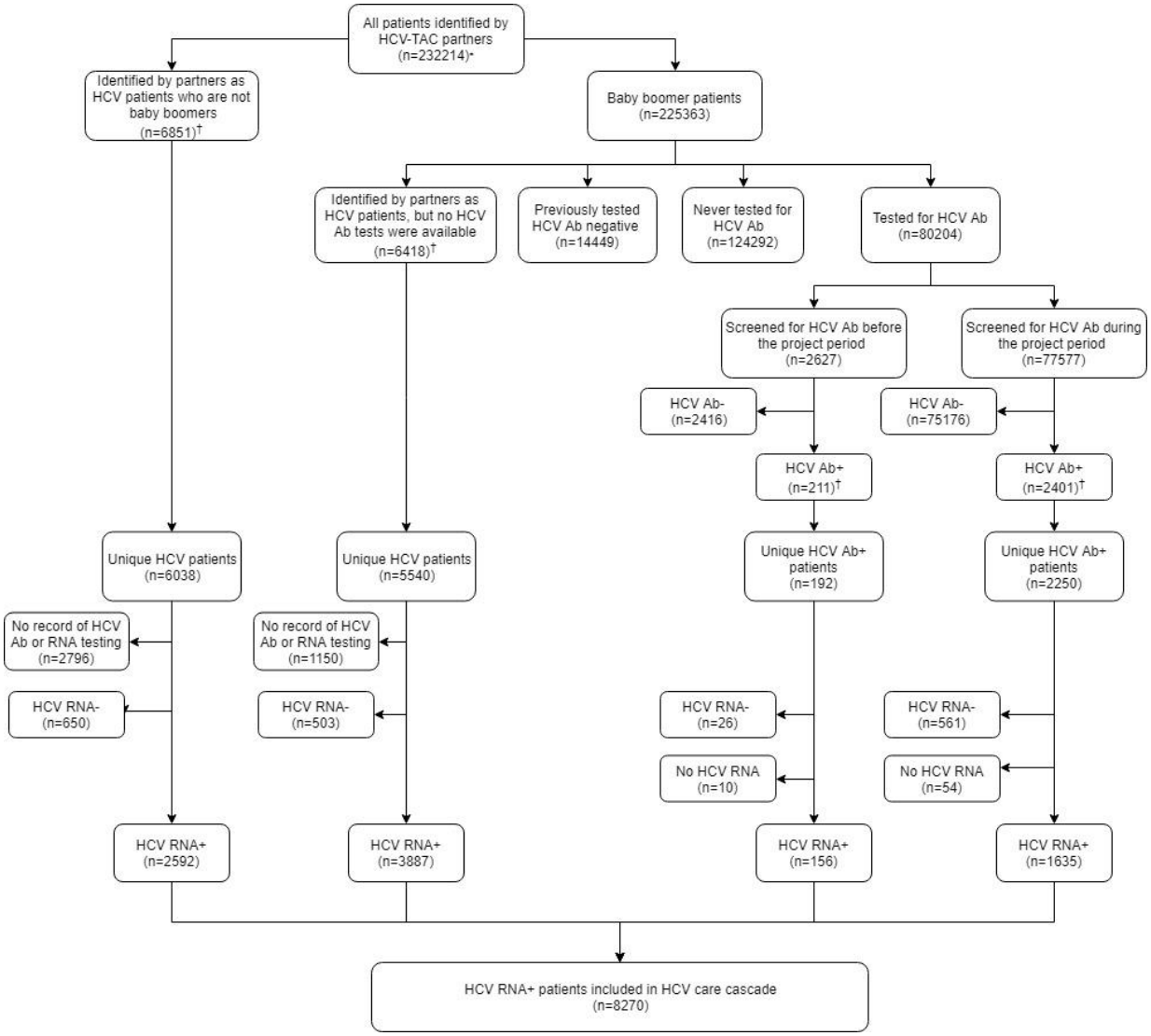
Figure 1. Flow and classification of patients residing in King County identified by Hepatitis C – Test and Cure (HCV-TAC) partner organizations from 9/30/2013 – 9/29/2018



* Includes all patients identified by each HCV-TAC partner organization; individuals seen at more than one healthcare system are counted more than once in the total number. Records for hepatitis C patients were de-duplicated in the public health surveillance database.

† Numbers may not match the next step because of lack of PHI, de-duplication, and exclusion of persons not residing in King County

Figure 2. Percent of baby boomer patients residing in King County with visits to Hepatitis C – Test & Cure partner clinics who have been screened for hepatitis C virus (HCV) antibody, by project year (9/30/13 – 9/29/18)

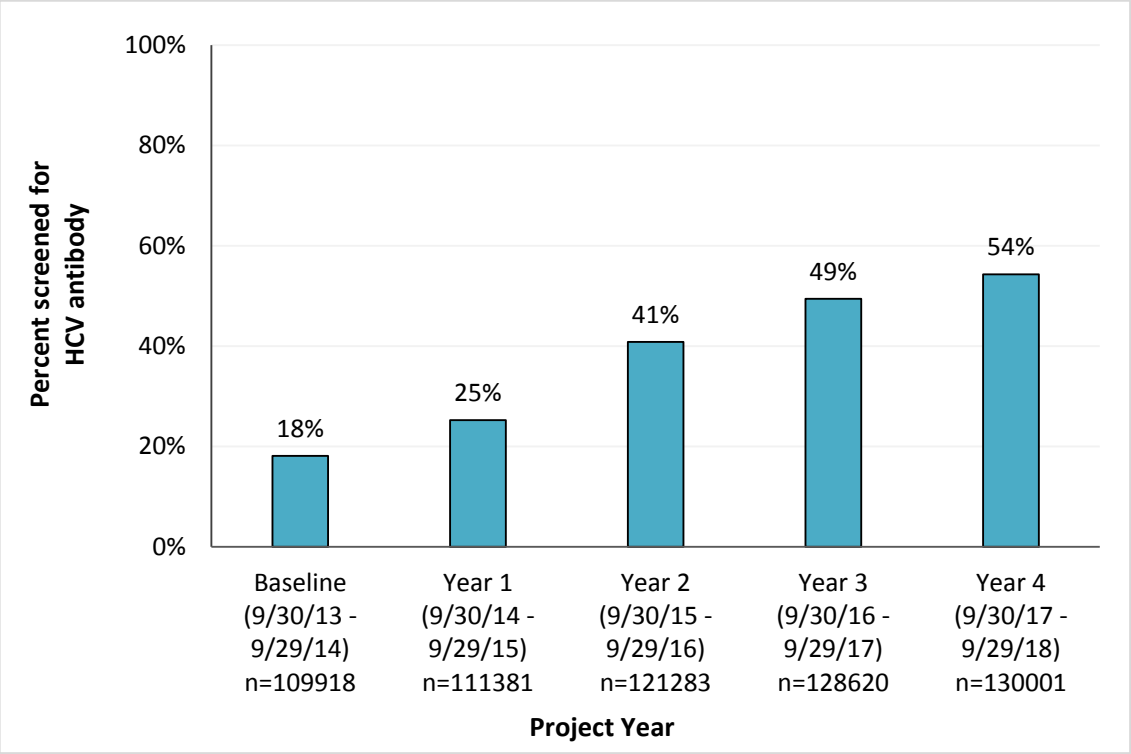
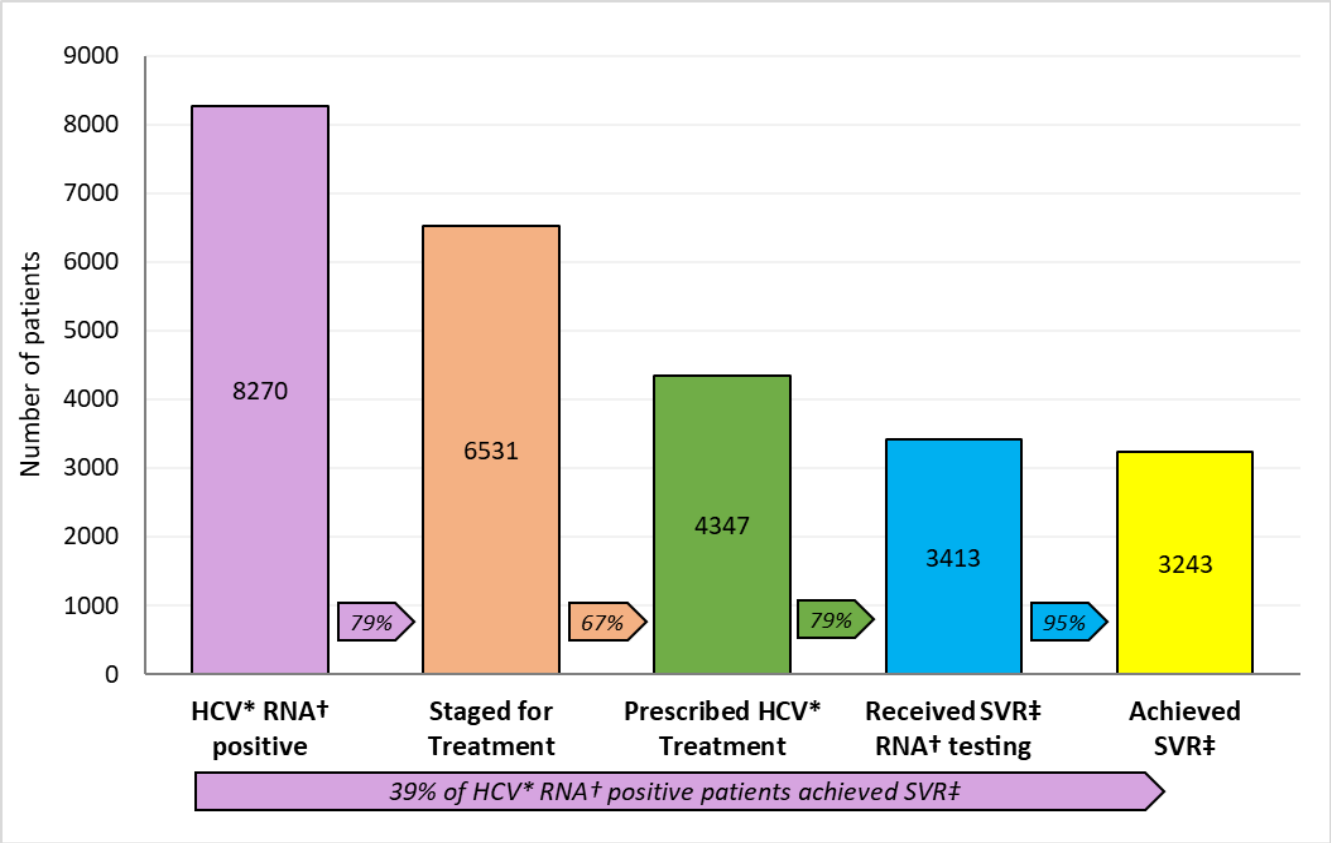


Figure 3. Hepatitis C care cascade for patients with HCV* RNA† positive results residing in King County and seen at partner clinics during the project period (N=8270), 9/30/2013 – 9/29/2018

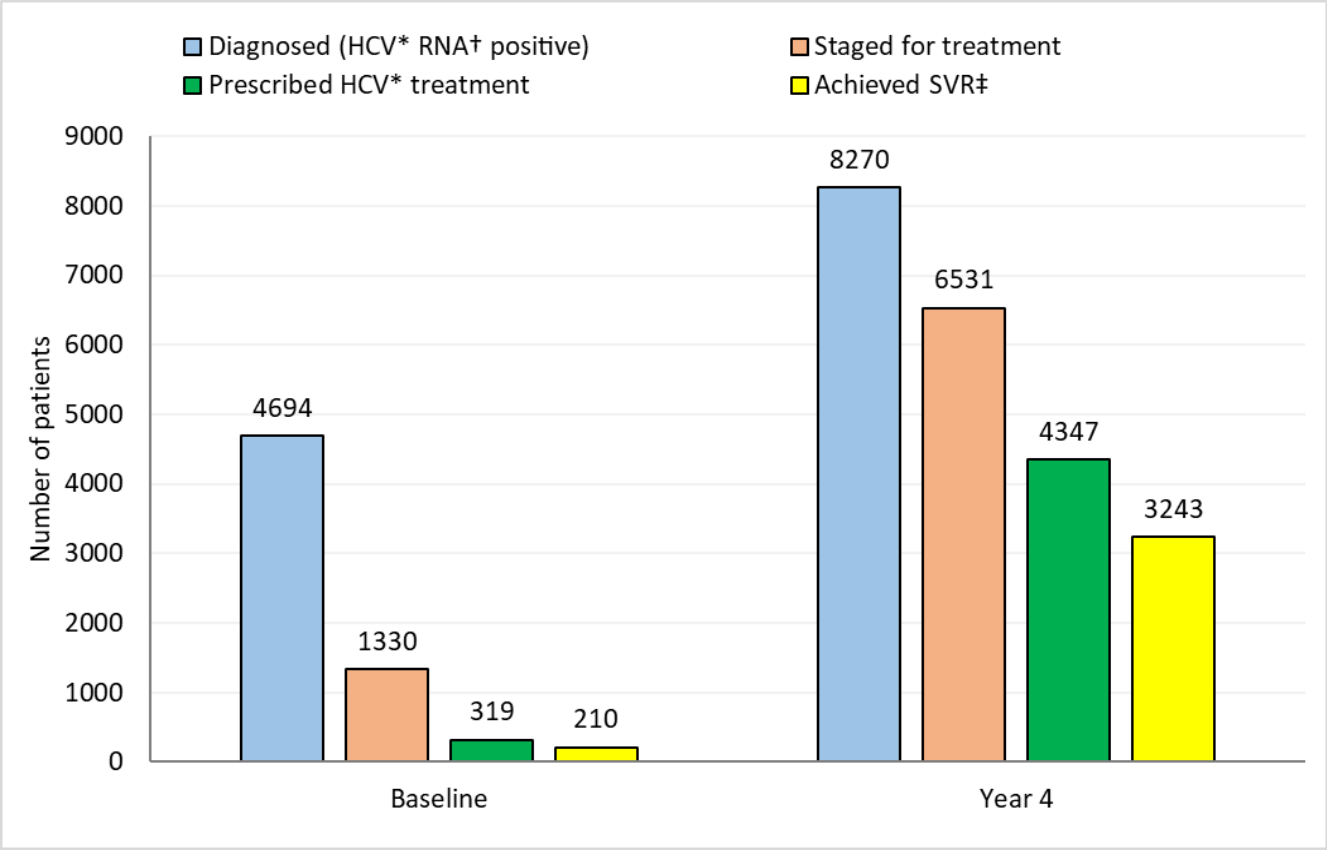


*HCV = hepatitis C virus

†RNA = ribonucleic acid

‡SVR = sustained viral response

Figure 4. Comparison of hepatitis C care cascade at end of baseline year (9/30/2013 – 9/29/2014) and end of year 4 (9/30/2017 – 9/29/2018)



*HCV = hepatitis C virus

†RNA = ribonucleic acid

‡SVR = sustained viral response

Table 1: Characteristics of all Hepatitis C – Test & Cure partner patients residing in King County and seen at partner clinics from 9/30/13 – 9/29/18

	Total (N = 232214)			Baby boomers (born from 1945-1965) (N = 225363)			Non-baby boomers (not born from 1945-1965) (N = 6851)	
Characteristic	Number	Percent (%)		Number	Percent (%)		Number	Percent (%)
Gender								
Female	122791	52.9%		119816	53.2%		2975	43.4%
Male	109368	47.1%		105496	46.8%		3872	56.5%
Unknown	55	0.02%		51	0.02%		4	0.06%
Race/ethnicity								
Non-Hispanic White	140915	60.7%		137493	61.0%		3422	50.0%
Non-Hispanic Black	26058	11.2%		24878	11.0%		1180	17.2%
Non-Hispanic Asian	31458	13.6%		30530	13.6%		928	13.6%
Non-Hispanic AIAN*	2464	1.1%		2309	1.0%		155	2.3%
Non-Hispanic Other or Multiracial	4326	1.9%		4124	1.8%		202	3.0%
Hispanic	15449	6.7%		14714	6.5%		735	10.7%
Unknown	11544	5.0%		11315	5.0%		229	3.3%
Uninsured at any time	37238	16.0%		35075	15.6%		2163	31.6%

*AIAN = American Indian Alaska Native

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458 Table 2. Characteristics of patients with detectable hepatitis C virus (HCV) ribonucleic acid (RNA) results residing in King County and seen at
459 partner clinics from 9/30/13 – 9/29/18 that were included in hepatitis C care cascade analysis

Characteristic	Number	Percent (%)
Total HCV RNA positive patients	8270	100%
Born from 1945-1965	5678	68.7%
Gender		
Female	2849	34.5%
Male	5421	65.6%
Race/ethnicity		
Non-Hispanic White	4854	58.7%
Non-Hispanic Black	1894	22.9%
Non-Hispanic Asian	508	6.1%
Non-Hispanic AIAN*	191	2.3%
Non-Hispanic Other or Multiracial	177	2.1%
Hispanic	521	6.3%
Unknown	125	1.5%
Homeless at any time	1162	14.1%
Insurance Status		
Medicaid	3829	46.3%
Private Insurance	2202	26.6%
Medicare	2084	25.2%
Self-pay or other insurance	136140	1.7%
Unknown	15	0.2%

Uninsured at any time	1472	17.8%
On Medicaid at any time	4387	53.1%
HIV positive	607	7.3%
Cirrhosis	2396	29.0%
Liver transplant	68	0.8%
Chronic kidney disease	629	7.6%
Diabetes	1706	20.6%
Opioid use disorder	2403	29.1%
HBV co-infection	665	8.0%
History of injection drug use	1886	22.9%
History of alcohol use disorder	624	7.6%
Genotype (GT)		
GT 1	4208	50.9%
GT 2	642	7.8%
GT 3	729	8.8%
GT 4	86	1.0%
GT 5	6	0.1%
GT 6	117	1.4%
No record of genotype test	2482	30.0%
Tested for APRI[†] at any time	8120	98.2%
Most recent fibrosis stage		
F0	820	9.9%
F1	472	5.7%
F2	938	11.3%
F3	483	5.8%

F4	599	7.2%
No record of fibrosis staging	4958	60.0%
Number of partner sites patient was seen at:		
1	5539	67.0%
2	2315	28.0%
3	387	4.7%
4	29	0.4%

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461 *AIAN = American Indian Alaska Native

462 †APRI = Alanine Aminotransferase to Platelet Ratio Index

Comments for Manuscript "A Population-based Intervention to Improve Care Cascades of Patients with Hepatitis C Virus Infection."

Reviewer Comments
Reviewer Number:1 Comments for the Authors: This is a well written important study. The strengths of the manuscript are as follows: -Highlights nicely the current HCV epidemic that lead to the design of this study -Highlights nicely the importance of HCV diagnosis and management -The aim of the study and the study group are clear and easily identified -Highlights nicely the successful collaboration of the members of the coalition which included IT specialists, PCP, hepatologists, infectious disease doctors, nurses, case managers and project champions, patient advocacy organizations and the public health department. -The interventions provided by the coalition are detailed and stated clearly -Limitations of the study are included and addressed appropriately Addressing the following may help to validate and strengthen your conclusions: -More than 200000 patients were identified by the coalition, however more than half were not screened for HCV. Did the authors identify reasons for this significant discrepancy? **Reviewer Number:2** This study is both an impressive community health intervention and research study. The manuscript is well written and clear and can be a model for PCPs and HCV experts how to partner to work on these issues in other cities. **Reviewer Number:3** This manuscript was reviewed by a Lay Reviewer. The goal of the study was to increase Hepatitis C virus (HCV) testing in patients, care for the disease and eliminate the virus from the United States population, because HCV is a public health problem. The study used a collaborative method with infectious diseases professionals, community healthcare clinics; trained physicians to handle care, electronic healthcare records (EHR), primary care providers plus HCV baby boomer patients born between 1945 and 1965 to achieve study goals. Between 2013 – 2016, research results showed that HCV testing increased from 18% to 54% during study period and of the 77,577 patients screened at collaborating clinics, 2,401 were HCV antibody positive. Study interventions such as EHR and linking more patients to care, caused more patients to be screened and treated, even though the study data on entire treatment outcome is not complete. Study Strengths 1. The study setting is appropriate because it included a variety of care settings from small groups to large entities. 2. The HCV Test and Cure Coalition (HCV-TAC) is a qualitative strength because the program was the medium through which researchers were able to increase testing, and linked patients to care and treatment. The program facilitated medical professionals training, interventions to increase screening in private care settings and met every three months to review study goals. 3. The research material was clear and easy to understand. The “care cascade” also made it

possible to understand the scope of the study and see the plan of treatment.
Weaknesses included:
1. One limitation of the study was the incomplete data on treatment outcome. The study did not tell the reason why the data was incomplete on treatment outcome and what measurement the study used to determine how much data would have been collected to determine a successful treatment outcome. That information would have been important because it would help us to know if all the study goals were met.
2. The study sample was a weakness because it did not extended research to other counties within Washington. That would be encouraging. The study would have a bigger sample to research and there would be the possibility of bringing skewness to the research limitation, for example the data might not have been incomplete.
3. It was difficult to determine which sample of the American population was focused on in the research. That was a weakness because that was not established in the introduction. The study needs to include that baby boomers are the focus early in the introduction.
4. The study did not involve a method for follow up treatment and this appears to be a weakness. It would have been beneficial to establish a method of follow up care after patients were linked to care. That would encourage HCV patients to stay in the care program for treatment, even after the study ended if necessary.

The topic of study design fits the interest of the community. This study is bringing Hepatitis C Infection awareness among individuals. The study indicated that HCV is a public health problem which means that the Center of Disease Control and Prevention (CDC) and US Preventative Services Taskforce will hopefully continue to be active agents to assist with community screening, testing and treating the infection.
It is difficult to know who specifically may benefit from the study and interventions. However, patients and caregivers might, due to medical situations. HCV campaigns and other interventions activities could be useful to other age groups.
Patients, caregivers and people in the community would want to know more about current Hepatitis C campaigns, where they are held and how they can get screening. People in the community would want to know which agencies or Center of Diseases Control and Prevention dedicated website they could log onto for initial screening with the intention of people being linked to a patient care or health care provider in their area for personal follow up. The community wants to know the cost for HCV drugs and if they are discounted and what treatments are covered by insurance.
There is a lack of diversity in the sample size. For example, Table 1 shows 4326 Non-Hispanic AIAN Other or Multiracial subjects were involved in the study. That number is a very small proportion of subjects when compared to whites and Non-Hispanic Asians. It would have been notable to have a bigger sample of Non-Hispanic AIAN to support ethnic diversity.
The author demonstrated some understanding of the social and environment setting in which people live because the study made sure study participants could access healthcare through clinicians. There was access to testing. Private care providers were trained specially to evaluate and treat the Hepatitis Infection to handle patients. Therefore, the author understood the social setting requirements for the study.

The study can influence individuals who have HCV and those who do not have the infection nor is getting treatment for it. Life expectancy is shortened for patients with the infection. With that in mind, this study will let individuals know that they can get continuous care through private care providers to manage or cure the infection. Drug abusers and younger people will be impacted by this study. The study highlighted that an increase in the use of injection drugs caused Hepatitis C to increase tremendously. This study would discourage drug abuse with the use of injections. People who do not have the infection will do regular screening. This study wants to care for the infection and eliminate it from the population. To get that accomplished, the study will encourage individuals to get screening. Patients will want to treat their Hepatitis C Infection while people in the community wants to guard their health from picking up the infection to live longer. This study will impact the Center for Disease Control (CDC) and Prevention. CDC will give public health guidance and assist medical professionals to monitor, control and treat the spread for the HCV infection. Due to that, this study has some societal impacts.

Two sections of the manuscript pose questions as follows:

- Line 307, the fourth limitation. Why was the study not generalized to other communities with more African American and Latino subjects?
- Are the minority percentages represented in the study reflective of the county and/or the percentage of minority patients that have HCV?